AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

FEDERAL REGISTER

Vol. 76 Wednesday,

No. 230 November 30, 2011

Pages 73993–74624

OFFICE OF THE FEDERAL REGISTER

The **FEDERAL REGISTER** (ISSN 0097–6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, Washington, DC 20408, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

The **FEDERAL REGISTER** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders, Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress, and other Federal agency documents of public interest.

Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless the issuing agency requests earlier filing. For a list of documents currently on file for public inspection, see *www.ofr.gov.*

The seal of the National Archives and Records Administration authenticates the Federal Register as the official serial publication established under the Federal Register Act. Under 44 U.S.C. 1507, the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and on 24x microfiche. It is also available online at no charge at *www.fdsys.gov*, a service of the U.S. Government Printing Office.

The online edition of the **Federal Register** is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6:00 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 59, 1 (January 2, 1994) forward. For more information, contact the GPO Customer Contact Center, U.S. Government Printing Office. Phone 202-512-1800 or 866-512-1800 (toll free). E-mail, *gpo@custhelp.com.*

The annual subscription price for the **Federal Register** paper edition is $749 plus postage, or $808, plus postage, for a combined **Federal Register, Federal Register** Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the **Federal Register** Index and LSA is $165, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily **Federal Register,** including postage, is based on the number of pages: $11 for an issue containing less than 200 pages; $22 for an issue containing 200 to 400 pages; and $33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for $3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: U.S. Government Printing Office—New Orders, P.O. Box 979050, St. Louis, MO 63197-9000; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, see *bookstore.gpo.gov.*

There are no restrictions on the republication of material appearing in the **Federal Register.**

How To Cite This Publication: Use the volume number and the page number. Example: 76 FR 12345.

Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Printing Office, Washington, DC 20402, along with the entire mailing label from the last issue received.

SUBSCRIPTIONS AND COPIES

PUBLIC	
Subscriptions:	
Paper or fiche	**202–512–1800**
Assistance with public subscriptions	**202–512–1806**
General online information	**202–512–1530; 1–888–293–6498**
Single copies/back copies:	
Paper or fiche	**202–512–1800**
Assistance with public single copies	**1–866–512–1800 (Toll-Free)**
FEDERAL AGENCIES	
Subscriptions:	
Paper or fiche	**202–741–6005**
Assistance with Federal agency subscriptions	**202–741–6005**

Printed on recycled paper.

Contents

Federal Register

Vol. 76, No. 230

Wednesday, November 30, 2011

Agriculture Department
See Food Safety and Inspection Service

Centers for Disease Control and Prevention
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 74064–74067

Centers for Medicare & Medicaid Services
RULES
Medicare and Medicaid Programs:
Hospital Outpatient Prospective Payment; Ambulatory Surgical Center Payment; Hospital Value-Based Purchasing Program; Physician Self-Referral; and Patient Notification Requirements in Provider Agreements, 74122–74584
NOTICES
Medicare Program:
New Application Deadline for Advance Payment Model, 74067–74068

Civil Rights Commission
NOTICES
Meetings:
Maine State Advisory Committee, 74040

Coast Guard
RULES
Drawbridge Operations:
Gulf Intracoastal Waterway (Algiers Alternate Route), Belle Chasse, LA, 73998–74000
Special Local Regulations:
Orange Bowl International Youth Regatta, Biscayne Bay, Miami, FL, 73996–73998
NOTICES
Meetings:
Guidance on Domestic Implementation of International Standards for Oceangoing Barges Carrying Noxious Liquid Substances, 74068–74069

Commerce Department
See Industry and Security Bureau
See International Trade Administration
See National Oceanic and Atmospheric Administration

Education Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 74048–74049

Employment and Training Administration
NOTICES
Random Assignment Study to Evaluate YouthBuild Program, 74076

Energy Department
See Energy Efficiency and Renewable Energy Office
NOTICES
National Coal Council; Renewal, 74049

Energy Efficiency and Renewable Energy Office
NOTICES
Measured Building Energy Performance Data Taxonomy, 74050–74051

Environmental Protection Agency
RULES
Approvals and Promulgations of Implementation Plans; Designation of Areas for Air Quality Planning:
Baton Rouge, LA Area; Redesignation to Attainment for the 1997 8-Hour Ozone Standard, 74000–74003
PROPOSED RULES
Approvals and Promulgations of Implementation Plans; Volatile Organic Compound Emission Control Measures:
Chicago and Metro-East St. Louis Ozone Nonattainment Areas, 74014–74017
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 74051–74053
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Protection of Stratospheric Ozone, 74055–74057
Reporting Requirements under Environmental Protection Agency's Climate Leaders Partnership; Renewal, 74053–74055
Clean Water Act Section 303(d); Availability of List Decisions, 74057–74058

Executive Office of the President
See Presidential Documents

Export-Import Bank
NOTICES
Meetings:
Advisory Committee, 74058

Federal Aviation Administration
PROPOSED RULES
Airworthiness Directives:
Boeing Co. Airplanes, 74012–74013
Learjet Inc. Model 60 Airplanes, 74010–74012

Federal Communications Commission
PROPOSED RULES
Consumer Information and Disclosure; Truth-in-Billing and Billing Format:
Empowering Consumers to Prevent and Detect Billing for Unauthorized Charges, 74017–74018
NOTICES
Suspensions and Initiations of Debarment Proceedings, 74058–74060

Federal Maritime Commission
NOTICES
Agreements Filed, 74060
Ocean Transportation Intermediary Licenses; Applicants, 74060–74061

Federal Railroad Administration
RULES
Railroad Workplace Safety:
Adjacent-Track On-Track Safety for Roadway Workers, 74586–74620

Fish and Wildlife Service
PROPOSED RULES
Endangered and Threatened Wildlife and Plants:
Designation of Critical Habitat for Southern Selkirk Mountains Population of Woodland Caribou (Rangifer tarandus caribou), 74018–74038
NOTICES
Endangered and Threatened Species; Permits, 74070–74072
Endangered and Threatened Wildlife and Plants; Incidental Take Permit Applications, etc:
Kaheawa Pastures Wind Energy Generation Facility, Maui County, HI, 74072–74073

Food and Drug Administration
NOTICES
Approaches to Reducing Sodium Consumption; Establishment of Dockets:
Request for Comments, Data, and Information; Extension of Comment Period, 74039–74040

Food Safety and Inspection Service
NOTICES
Approaches to Reducing Sodium Consumption; Establishment of Dockets:
Request for Comments, Data, and Information; Extension of Comment Period, 74039–74040

Health and Human Services Department
See Centers for Disease Control and Prevention
See Centers for Medicare & Medicaid Services
See Food and Drug Administration
NOTICES
Federal Financial Participation in State Assistance Expenditures; Federal Matching Shares for Medicaid, etc.:
October 1, 2012 through September 30, 2013, 74061–74063
Mandatory Guidelines for Federal Workplace Drug Testing Programs:
Approval of Entities that Certify Medical Review Officers, 74063–74064

Homeland Security Department
See Coast Guard

Industry and Security Bureau
NOTICES
Recruitment of Private-Sector Members:
Emerging Technology and Research Advisory Committee, 74040–74041

Interior Department
See Fish and Wildlife Service
See Land Management Bureau
See Reclamation Bureau
NOTICES
Environmental Assessments; Availability, etc.:
Central Utah Project Completion Act; Block Notice 1A Heber Sub-Area Agricultural Water to Municipal and Industrial Water Conversion, 74069

Internal Revenue Service
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 74116–74117
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Regulation Project, 74117–74119
Revenue Procedure 97–15, 74118

International Trade Administration
NOTICES
Antidumping Duty Administrative Reviews; Results, Amendments, Extensions, etc.:
Honey from Argentina, 74044–74045
Request for Revocation in Part, 74041–74044
Applications for Duty-Free Entry of Scientific Instruments, 74045–74046

Justice Department
NOTICES
Meetings:
Office on Violence Against Women, 74075–74076

Labor Department
See Employment and Training Administration

Land Management Bureau
NOTICES
Filings of Plats:
Colorado, 74073–74074

Millennium Challenge Corporation
NOTICES
Meetings; Sunshine Act, 74077

National Credit Union Administration
RULES
Golden Parachute and Indemnification Payments:
Technical Correction, 73994–73996
Remittance Transfers, 73993–73994

National Oceanic and Atmospheric Administration
RULES
Atlantic Highly Migratory Species:
Adjustments to the Atlantic Bluefin Tuna General and Harpoon Category, 74003–74009
Fisheries of Northeastern United States:
Bluefish Fishery; Quota Transfer, 74009
PROPOSED RULES
Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic:
Reef Fish Resources of the Gulf of Mexico, Commercial Reef Fish Fishery of the Gulf of Mexico; Control Date, 74038
NOTICES
Environmental Impact Statements; Availability, etc.:
Snapper–Grouper Fishery off Southern Atlantic States; Amendments 18A, 18B, 18C, 20A, and 20B, 74046–74048
Fishing Capacity Reduction Program:
Longline Catcher Processor Subsector of Bering Sea and Aleutian Islands Non Pollock Groundfish Fishery, 74048

National Science Foundation
NOTICES
Meetings; Sunshine Act, 74077

Nuclear Regulatory Commission
NOTICES
Meetings:
Advisory Committee on Medical Uses of Isotopes, 74077–74078

Postal Regulatory Commission
NOTICES
Standard Mail Market Tests, 74078

Postal Service
NOTICES
Meetings; Sunshine Act, 74078–74079

Presidential Documents
EXECUTIVE ORDERS
Committees; Establishment, Renewal, Termination, etc.:
Federal Advisory Committees; Continuance (EO 13591), 74621–74624

Reclamation Bureau
NOTICES
Environmental Impact Statements; Availability, etc.:
Windy Gap Firming Project, Colorado, 74074–74075

Securities and Exchange Commission
NOTICES
Self-Regulatory Organizations; Proposed Rule Changes:
BATS Exchange, Inc., 74079–74080, 74086–74088
BATS Y-Exchange, Inc., 74107–74108
C2 Options Exchange, Inc., 74097–74099
Chicago Board Options Exchange, Inc., 74111–74113
Chicago Stock Exchange, Inc., 74088–74090
EDGA Exchange, Inc., 74092–74093, 74101–74103
EDGX Exchange, Inc., 74090–74091, 74093–74095
Financial Industry Regulatory Authority, Inc., 74105–74107
International Securities Exchange, LLC, 74095–74097
NASDAQ OMX BX, Inc., 74109–74111
NASDAQ OMX PHLX LLC, 74113–74115
NASDAQ Stock Market LLC, 74084–74086
National Stock Exchange, Inc., 74103–74105
New York Stock Exchange LLC, 74080–74082
NYSE Amex LLC, 74082–74084
NYSE Arca, Inc., 74099–74101

Small Business Administration
NOTICES
Disaster Declarations:
Connecticut, 74115
Requests for Exemptions:
Emergence Capital Partners SBIC, L.P., 74115

Surface Transportation Board
NOTICES
Acquisition and Operation Exemptions:
Alabama and Florida Railway Co., Inc., etc. from Mississippi Tennessee Holdings, LLC and Mississippi Tennessee Railroad, LLC, 74116

Transportation Department
See Federal Aviation Administration
See Federal Railroad Administration
See Surface Transportation Board

Treasury Department
See Internal Revenue Service

Separate Parts In This Issue

Part II
Health and Human Services Department, Centers for Medicare & Medicaid Services, 74122–74584

Part III
Transportation Department, Federal Railroad Administration, 74586–74620

Part IV
Presidential Documents, 74621–74624

Reader Aids

Consult the Reader Aids section at the end of this page for phone numbers, online resources, finding aids, reminders, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents LISTSERV electronic mailing list, go to http://listserv.access.gpo.gov and select Online mailing list archives, FEDREGTOC-L, Join or leave the list (or change settings); then follow the instructions.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

3 CFR

Executive Orders:

13591.....74623

12 CFR

701.....73993
750.....73994

14 CFR

Proposed Rules:

39 (2 documents) 74010, 74012

33 CFR

100.....73996
117.....73998

40 CFR

52.....74000
81.....74000

Proposed Rules:

52.....74014

42 CFR

410.....74122
411.....74122
416.....74122
419.....74122
489.....74122
495.....74122

47 CFR

Proposed Rules:

64.....74017

49 CFR

214.....74586

50 CFR

635.....74003
648.....74009

Proposed Rules:

17.....74018
622.....74038

Rules and Regulations

Federal Register
Vol. 76, No. 230
Wednesday, November 30, 2011

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

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

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 701

RIN 3133–AD94

Remittance Transfers

AGENCY: National Credit Union Administration (NCUA).

ACTION: Final rule.

SUMMARY: NCUA is amending its rules to conform to amendments made to the Federal Credit Union Act (FCU Act) by the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act). The final rule adds remittance transfers, as now defined under the Electronic Fund Transfer Act (EFTA), as an example of money transfer instruments federal credit unions (FCUs) may provide to persons within their fields of membership.

DATES: Effective on November 30, 2011 NCUA is adopting the interim final rule published on July 27, 2011, 76 FR 44761, without change.

FOR FURTHER INFORMATION CONTACT: Chrisanthy Loizos, Staff Attorney, Office of General Counsel, at the above address or *telephone:* (703) 518–6540.

SUPPLEMENTARY INFORMATION:

I. Background
II. Summary of Public Comments
III. Final Rule
IV. Regulatory Procedures

I. Background [1]

Why is NCUA adopting this rule?

Since 2006, FCUs have had the authority to provide certain financial services to all persons within their fields of membership under the Financial Services Regulatory Relief Act of 2006 (Reg Relief Act), Public Law 109–351. Congress intended to allow FCUs ''to sell negotiable checks, money orders, and other similar transfer instruments, including international and domestic electronic fund transfers, to anyone eligible for membership, regardless of their membership status.'' S. Rpt. 109–256, p. 5; H. Rpt. 109–356 Part 1, p. 63. As a result, NCUA created a rule, § 701.30, to address an FCU's authority to provide financial services to persons within its field of membership. 71 FR 62875 (Oct. 27, 2006) (interim final rule); 72 FR 7927 (Feb. 22, 2007) (final rule).

Section 1073 of the Dodd-Frank Act added a new Section 919 to the EFTA, entitled ''Remittance Transfers.'' Public Law 111–203, § 1073, 124 Stat. 2066 (2010). The new Section 919 of the EFTA creates protections for consumers who, through remittance transfer providers, send money to designated recipients located in foreign countries. 15 U.S.C. 1693o–1. Paragraph (d) of Section 1073 of Dodd-Frank amended the FCU Act to specify that a remittance transfer, as defined by new Section 919 of the EFTA, is an example of a money transfer instrument that FCUs may sell to persons within their fields of membership. 12 U.S.C. 1757(12)(A).

Section 919(g)(2) of the EFTA, defines a remittance transfer as an electronic transfer of funds requested by a sender to a designated recipient that is initiated by a remittance transfer provider, regardless of whether the sender has an account with the remittance transfer provider or whether the transfer meets the statute's definition of an electronic funds transfer (EFT). 15 U.S.C. 1693o–1(g)(2). The law excludes small value transactions from the definition. Remittance transfers, typically consumer to consumer payments, may be executed through a variety of means, including international wire transfers, international automated clearing house transactions, other account-to-account or account-to-cash products, and reloadable prepaid cards. The law requires remittance transfer providers to give consumers certain disclosures, including a receipt that contains remittance transfer fees, the exchange rate to be used by the remittance transfer provider, the amount of currency to be received by the recipient and the estimated date of delivery. In addition, the law requires the sender to receive a statement that addresses error resolution rights.

The Board of Governors of the Federal Reserve proposed a remittance transfer rule, which addresses disclosure requirements and error resolution, and provides a detailed analysis of the services offered by remittance transfer providers. 99 FR 29902 (May 23, 2011). The Consumer Financial Protection Bureau assumed responsibility for issuing the final remittance transfer rule after the close of the comment period on July 22, 2011.

FCUs have had the authority to transfer funds at the request of consumers within their fields of membership to recipients internationally since the adoption of the Reg Relief Act. The amendment to the FCU Act's powers provision by the Dodd-Frank Act makes plain that FCUs may offer all variations of remittance transfers, as now defined by the EFTA, for the benefit of consumers within their fields of membership, subject to certain consumer protections. The addition of remittance transfers as an example of permissible money transfer instruments, in addition to the newly-enacted consumer disclosures and rights, demonstrate the clear intention of Congress to promote access to remittance transfers and ensure protections for consumers.

Finally, Section 1073(d) of the Dodd-Frank Act adjusted Section 107(12) of the FCU Act by removing the reference to the receipt of international and domestic EFTs from subparagraph (B). As explained below, this simply eliminates a redundancy and does not affect the ability of FCUs to offer EFT services.

What changes did the interim final rule make?

In the interim final rule, the NCUA Board (Board) amended § 701.30 to directly track the statutory provisions of Section 1073 of the Dodd-Frank Act. 76 FR 44761 (Jul. 27, 2011). The Board added remittance transfers as defined by Section 919 of the EFTA as an example of permissible money transfer instruments in paragraph (a). The Board also amended paragraph (b) to remove the language referring to an FCU's receipt of international and domestic EFTs.

[1] President Obama signed the Plain Writing Act of 2010 (Pub. L. 111–274) into law on October 13, 2010 ''to improve the effectiveness and accountability of federal agencies to the public by promoting clear Government communication that the public can understand and use.'' This preamble is written to meet plain writing objectives.

The Board notes the amendment to § 701.30(b) will have no effect on FCUs. The Board views the deletion of the phrase ''and receive international and domestic electronic fund transfers'' from the Section 107(12)(B) of the FCU Act as a housekeeping amendment. When Congress adopted the phrase in Section 107(12)(B) through the Reg Relief Act, it simply clarified the authority it granted to FCUs in Section 107(12)(A). 12 U.S.C. 1757(12). Section 903 of the EFTA defines ''electronic fund transfer'' as ''any transfer of funds * * * initiated through an electronic terminal, telephonic instrument, or computer or magnetic tape so as to order, instruct, or authorize a financial institution to debit or credit an account.'' 15 U.S.C. 1693a(6); see also 12 CFR 205.3(b). By allowing FCUs ''to sell'' international and domestic EFTs in Section 107(12)(A) of the FCU Act, Congress permitted FCUs to send or receive funds upon instruction because, by definition, EFTs are authorizations to debit or credit an account. To read the power ''to sell'' EFT services separately from the ability to ''receive'' EFTs would be wholly inconsistent with Congressional intent to provide EFT services to persons in the field of membership, particularly for those who may not have ready and affordable access to these services. It would also be unfeasible for an FCU to offer consumers the ability to initiate transfers from their accounts but not receive EFTs. As discussed above, Congress clearly intended to promote the availability of services to consumers under Section 1073 of the Dodd-Frank Act by explicitly referencing remittance transfers services. The amendment to FCU Act Section 107(12)(B) was not meant to restrict or otherwise limit an FCU's ability to effectively provide services to consumers.

II. Summary of Public Comments

In response to the Board's request for comments, NCUA received only one comment letter. The commenter, a credit union trade association, fully supported the interim rule and the Board's reading of Section 1073 of the Dodd-Frank Act. The commenter agreed the Dodd-Frank Act did not change FCUs' authorized business activities but simply added ''remittance transfers,'' as now defined by and regulated under the EFTA, as an example of a type of international electronic funds transfer service. The commenter also had the understanding that Congress's deletion from FCU Act Section 107(12) of the express authority for persons within the field of membership to receive electronic funds transfers was simply to remove redundant language and has no substantive effect.

III. Final Rule

As discussed above, the Board is adopting the interim final rule published on July 27, 2011, 76 FR 44761, without change.

IV. Regulatory Procedures

Regulatory Flexibility Act

NCUA must prepare an analysis to describe any significant economic impact a proposed rule may have on a substantial number of small entities (primarily those under ten million dollars in assets) the Regulatory Flexibility Act. This proposed rule reduces compliance burden and extends regulatory relief while maintaining existing safety and soundness standards. NCUA has determined this rule will not have a significant economic impact on a substantial number of small credit unions, so NCUA is not required to conduct a regulatory flexibility analysis.

Paperwork Reduction Act

NCUA has determined that this rule will not increase paperwork requirements under the Paperwork Reduction Act of 1995 and regulations of the Office of Management and Budget.

Executive Order 13132

Executive Order 13132 encourages independent regulatory agencies to consider the impact of their actions on state and local interests. NCUA, an independent regulatory agency as defined in 44 U.S.C. 3502(5), voluntarily complies with the executive order to adhere to fundamental federalism principles. This 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. NCUA has determined that this rule does not constitute a policy that has federalism implications for purposes of the executive order.

The Treasury and General Government Appropriations Act, 1999—Assessment of Federal Regulations and Policies on Families

NCUA has determined that this rule will not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act, 1999, Public Law 105–277, 112 Stat. 2681 (1998).

Small Business Regulatory Enforcement Fairness Act

When NCUA issues a final rule, as defined in the Section 551 of the Administrative Procedure Act, it triggers a reporting requirement for congressional review of agency rules, under the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121 (SBREFA). The Office of Management and Budget has determined that this rule is not a major rule for purposes of SBREFA.

List of Subjects in 12 CFR Part 701

Credit unions.

By the National Credit Union Administration Board on November 17, 2011.

Mary Rupp,

Secretary of the Board.

PART 701—ORGANIZATION AND OPERATION OF FEDERAL CREDIT UNIONS

Accordingly, the interim final amending 12 CFR part 701 which was published at 76 FR 44761 on July 27, 2011, is adopted as a final rule without change.

[FR Doc. 2011–30365 Filed 11–29–11; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 750

RIN 3133–AD73

Golden Parachute and Indemnification Payments; Technical Correction

AGENCY: National Credit Union Administration (NCUA).

ACTION: Final rule.

SUMMARY: NCUA is finalizing an interim rule to make a technical correction to its rule restricting a federally insured credit union (FICU) from making golden parachute and indemnification payments to an institution-affiliated party (IAP). The amendment corrects an exception to the definition of golden parachute payment pertaining to plans offered under section 457 of the Internal Revenue Code. The interim final rule became effective on June 27, 2011. This rulemaking finalizes the interim rule without change.

DATES: Effective on November 30, 2011 NCUA is adopting the interim final rule published on June 24, 2011, 76 FR 36979, without change.

FOR FURTHER INFORMATION CONTACT: Pamela Yu, Staff Attorney, Office of

General Counsel, at 1775 Duke Street, Alexandria, Virginia 22314–3428, or *telephone:* (703) 518–6540.

SUPPLEMENTARY INFORMATION:

I. Background
II. Summary of Public Comments
III. Final Rule
IV. Regulatory Procedures

I. Background [1]

A. Why is NCUA adopting this rule?

On June 24, 2011, NCUA published an interim final rule to correct new part 750, which restricts a FICU from making certain golden parachute and indemnification payments to an IAP. 76 FR 36979. The interim rule became effective June 27, 2011 to correspond with the effective date of the new part 750. Public comments were accepted, however, until July 24, 2011. NCUA is issuing this rulemaking to finalize the interim rule without change.

B. What changes did the interim final rule make?

The interim final rule corrected an exception to the definition of golden parachute payment in § 750.1(e)(2) pertaining to plans offered under § 457 of the Internal Revenue Code of 1986, as amended (IRC). The technical amendment was necessary to conform the regulatory text with the rule's intent, as described in the preamble to the final rule. 76 FR 30510 (May 26, 2011).

II. Summary of Public Comments

NCUA received two comments on the interim final rule: one from a trade organization and one from a state credit union league. One comment was supportive of the interim final rule, noting that the correction is consistent with the intent of the rule to permit post-employment payments that have reasonable business purposes. The other commenter, however, expressed concern about the amendment and suggested alternative language for the golden parachute exception at § 750.1(e)(2). NCUA has reviewed and analyzed both comment letters and, as discussed in more detail below, has determined to finalize the interim rule without change.

III. Final Rule

Part 750 establishes a comprehensive framework for golden parachute and indemnification payments made by a FICU to an IAP. The intent of the rule is to prevent the wrongful or improper disposition of FICU assets and inhibit unwarranted rewards to IAPs that can contribute to a FICU's troubled condition. The purpose of the rule is not, however, to prohibit post-employment payments having reasonable business purposes. Accordingly, the rule excludes from the definition of ''golden parachute payment'' certain qualified retirement plans such as those permitted under § 401 of the IRC. As discussed in the preamble to the final rule, in response to comments on the proposed rule, the NCUA Board (Board) intended to provide similar treatment to retirement plans that are permissible under § 457 of the IRC, which are frequently used by credit unions and other tax exempt organizations.

Plans qualifying as eligible deferred compensation plans under § 457(b) of the IRC exhibit characteristics that are similar to the more common § 401(k) deferred compensation plans that many employers make available to their employees. For example, the amount of income that may be deferred under such a plan is equivalent to that which may be deferred under § 401, which for 2011 is $16,500. As with § 401 plans, moreover, manipulation of the timing and amount of the payout are also closely circumscribed by law. For example, these plans may not typically provide for an in-service distribution prior to retirement. Accordingly, the Board intended for § 457(b) plans to be treated like § 401 plans and excluded from the definition of golden parachute payment.

Although the preamble to the final rule made reference to plans under subsection (b) and (f) of § 457, it did not provide any substantive discussion concerning the differences between them. In fact, however, § 457 plans that are permissible under subsection (f) are significantly broader and are accorded much greater flexibility in terms of structure, coverage, eligibility, participation, vesting, *etc.* Section 457(f) plans are sometimes referred to as ''golden handcuffs'' because the contribution rules are generous but there is a risk of forfeiture if the individual leaves prior to retirement. These plans are highly customizable, and can be designed in a broad variety of ways. As such, the intent of the rule has always been that § 457(f) plans must meet the ''bona fide'' criteria outlined in § 750.1(c) to qualify as exceptions to the otherwise applicable golden parachute restrictions. Because of the limits inherent in § 457(b) and the constraints governing plans offered under that subsection, the Board intended to specify that only § 457(b) plans are excluded by definition from the term ''golden parachute payment''.

Accordingly, the interim final rule amended § 750.1(e) to clarify that plans offered by FICUs under § 457(b) of the IRC are specifically excluded from the definition of a prohibited golden parachute payment. Although not specifically excluded under § 750.1(e), certain plans offered under § 457(f) may also be permissible if the plan meets the ''bona fide'' exemption criteria outlined in § 750.1(c). In other words, all § 457(b) are excluded under the rule; however, § 457(f) plans must meet the ''bona fide'' criteria outlined in § 750.1(c) to qualify as exceptions to the golden parachute payment definition.

One commenter expressed concern about the amendment and suggested that the provision should specifically exclude § 457(b) plans and any § 457(f) plans that meet the criteria of the ''bona fide deferred compensation'' definition. This commenter also suggested alternative language for the exception at § 750.1(e)(2), to exclude any payment made pursuant to a deferred compensation plan under § 457(b) ''or under section 457(f) * * * if such payment is a ''bona fide deferred compensation'' plan under § 750.1(c).''

The Board has determined not to adopt this commenter's proposed language because the technical correction made by the interim rule results in the same effect but in a more clear and concise manner. Because § 457(f) plans have the potential for broader flexibility than § 457(b) plans, FICUs could exploit this flexibility to make abusive arrangements for their senior staff. By contrast, § 457(b) plans are, by statutory definition, sufficiently narrow such that additional controls are not necessary. Accordingly, the Board permanently adopts the technical amendment to the golden parachute exception at § 750.1(e) without alteration. The Board emphasizes that § 457(f) plans are not prohibited outright under the rule. Rather, to be permissible such plans must be ''bona fide.''

IV. Regulatory Procedures

Regulatory Flexibility Act

The Regulatory Flexibility Act requires NCUA to prepare an analysis to describe any significant economic impact any proposed regulation may have on a substantial number of small entities (those under $10 million in assets). This final rule provides clarification regarding the applicability of one of the exceptions to otherwise applicable regulatory restrictions. Accordingly, it will not have a

[1] President Obama signed the Plain Writing Act of 2010 (Pub. L. 111–274) into law on October 13, 2010 ''to improve the effectiveness and accountability of federal agencies to the public by promoting clear Government communication that the public can understand and use.'' This preamble is written to meet plain writing objectives.

significant economic impact on a substantial number of small credit unions, and therefore, no regulatory flexibility analysis is required.

The Treasury and General Government Appropriations Act, 1999—Assessment of Federal Regulations and Policies on Families

NCUA has determined that this rule will not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act, 1999, Public Law 105–277, 112 Stat. 2681 (1998).

Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) (SBREFA) provides generally for congressional review of agency rules. A reporting requirement is triggered in instances where NCUA issues a final rule as defined by Section 551 of the APA. 5 U.S.C. 551. NCUA does not believe this final rule is a ''major rule'' within the meaning of the relevant sections of SBREFA. NCUA has submitted the rule to the Office of Management and Budget for its determination in that regard.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) applies to rulemakings in which an agency by rule creates a new paperwork burden on regulated entities or modifies an existing burden. 44 U.S.C. 3507(d); 5 CFR part 1320. For purposes of the PRA, a paperwork burden may take the form of either a reporting or a recordkeeping requirement, both referred to as information collections. These technical corrections do not impose any new paperwork burden.

List of Subjects in 12 CFR Part 750

Credit unions, Golden parachute payments, Indemnity payments.

By the National Credit Union Administration Board, this 17th day of November, 2011.

Mary F. Rupp,

Secretary of the Board.

For the reasons discussed above, the National Credit Union Administration confirms as final without change, the interim final rule amending 12 CFR Part 750 published on June 24, 2011, 76 FR 36979.

[FR Doc. 2011–30313 Filed 11–29–11; 8:45 am]

BILLING CODE 7535–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2011–0994]

RIN 1625–AA08

Special Local Regulations; Orange Bowl International Youth Regatta, Biscayne Bay, Miami, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing special local regulations on the waters of Biscayne Bay in Miami, Florida during the Orange Bowl International Youth Regatta, a series of sailboat races. The Orange Bowl International Youth Regatta is scheduled to take place from Tuesday, December 27, 2011 through Friday, December 30, 2011. The regatta will be at four separate race courses. Approximately 50 to 200 participants will race on each race course. These special local regulations are necessary to provide for the safety of life on navigable waters during the regatta. The special local regulations establish four race areas, one around each race course. All persons and vessels that are not participating in the regatta are prohibited from entering, transiting through, anchoring in, or remaining within any of the race areas unless authorized by the Captain of the Port Miami or a designated representative.

DATES: This rule is effective from 9:30 a.m. on December 27, 2011 through 5 p.m. on December 30, 2011. This rule will be enforced daily from 9:30 a.m. until 5 p.m. on December 27, 2011 through December 30, 2011.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2011–0994 and are available online by going to *http://www.regulations.gov,* inserting USCG–2011–0994 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 Lieutenant Jennifer S. Makowski, Sector Miami Prevention Department, Coast Guard; telephone (305) 535–8724, email *Jennifer.S.Makowski@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 about the Orange Bowl International Youth Regatta until October 11, 2011. As a result, the Coast Guard did not have sufficient time to publish an NPRM and to receive public comments prior to the event. 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 regatta participants, participant vessels, spectators, and the general public.

Basis and Purpose

The legal basis for the rule is the Coast Guard's authority to establish special local regulations: 33 U.S.C. 1233.

The purpose of the rule is to insure safety of life on navigable waters of the United States during the Orange Bowl International Youth Regatta.

Discussion of Rule

From December 27, 2011 through December 30, 2011, the Coral Reef Yacht Club is hosting the Orange Bowl International Youth Regatta on Biscayne Bay in Miami, Florida. The regatta will take place at four separate race courses. Over 600 sailboats are expected to participate in the regatta, with an anticipated 50–200 vessels participating at each race course. Although this event occurs annually, and special local regulations have been promulgated in the Code of Federal Regulations at 33 CFR 100.701, these regulations do not: (1) Establish multiple race areas on Biscayne Bay for the regatta; (2) provide sufficient detail regarding the special local regulations that will be enforced during the regatta; (3) list the correct dates for this year's regatta; and (4)

identify the correct event sponsor. Therefore, the special local regulations set forth in 33 CFR 100.701 are inapplicable for this year's Orange Bowl International Youth Regatta.

The special local regulations consist of a series of race areas around the four race courses on Biscayne Bay in Miami, Florida during the Orange Bowl International Youth Regatta. These special local regulations will be enforced daily from 9:30 a.m. until 5 p.m. on December 27, 2011 through December 30, 2011. Persons and vessels are prohibited from entering, transiting through, anchoring, or remaining within any of the race areas unless authorized by the Captain of the Port Miami or a designated representative. Persons and vessels desiring to enter, transit through, anchor in, or remain within any of the race areas may contact the Captain of the Port Miami by telephone at (305) 535–4472, 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 race areas is granted by the Captain of the Port Miami or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Miami or a designated representative.

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 special local regulations will be enforced for a total of 30 hours; (2) although persons and vessel will not be able to enter, transit through, anchor in, or remain within any of the race areas without authorization from the Captain of the Port Miami or a designated representative, they may operate in the surrounding area during the enforcement periods; (3) persons and vessels may still enter, transit through, anchor in, or remain within the race areas if authorized by the Captain of the Port Miami or a designated representative; and (4) the Coast Guard will provide advance notification of the special local regulations 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 that portion of Biscayne Bay encompassed within the special local regulations from 9:30 a.m. on December 27, 2011 through 5 p.m. on December 30, 2011. 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)(h), of the Instruction. This rule involves special local regulations issued in conjunction with a regatta. Under figure 2–1, paragraph (34)(h), of the Instruction, an environmental analysis checklist and a categorical exclusion determination are not required for this rule.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233.

■ 2. Add a temporary § 100.T07–0994 to read as follows:

§ 100.T07–0994 Special Local Regulations; Orange Bowl International Youth Regatta, Biscayne Bay, Miami, FL.

(a) *Regulated Areas.* The following regulated areas are established as special local regulations. All coordinates are North American Datum 1983.

(1) *Race Area 1.* All waters of Biscayne Bay located within an 800 yard radius of position 25°43′48.36″ N, 80°13′03.30″ W.

(2) *Race Area 2.* All waters of Biscayne Bay located within a 1,400 yard radius of position 25°43′40.74″ N, 80°11′37.02″ W.

(3) *Race Area 3.* All waters of Biscayne Bay located within a 2,000 yard radius of position 25°42′11.40″ N, 80°12′44.52″ W.

(4) *Race Area 4.* All waters of Biscayne Bay located within a 2,000 yard radius of position 25°40′17.40″ N, 80°13′26.10″ W.

(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 Miami 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 Miami or a designated representative.

(2) Persons and vessels desiring to enter, transit through, anchor in, or remain within the regulated areas may contact the Captain of the Port Miami by telephone at (305) 535–4472, 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 regulated areas is granted by the Captain of the Port Miami or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Miami 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) *Enforcement Periods.* This rule will be enforced daily from 9:30 a.m. until 5 p.m. on December 27, 2011 through December 30, 2011.

Dated: November 2, 2011.

C.P. Scraba,

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

[FR Doc. 2011–30713 Filed 11–28–11; 11:15 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2011–0959]

Drawbridge Operation Regulations; Gulf Intracoastal Waterway (Algiers Alternate Route), Belle Chasse, LA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations; request for comments.

SUMMARY: The Commander, Eighth Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the SR 23 bridge across the Gulf Intracoastal Waterway (Algiers Alternate Route), mile 3.8, at Belle Chasse, Plaquemines Parish, Louisiana. This deviation will test a change to the drawbridge operation schedule to determine whether a permanent change to the schedule is needed. This test deviation will allow the bridge to open only on the hour during the day from Monday through Friday, while maintaining morning and afternoon maritime restrictions.

DATES: This deviation is effective from December 15, 2011 through January 17, 2012.

Comments and related material must be received by the Coast Guard on or before January 30, 2012.

ADDRESSES: You may submit comments identified by docket number USCG–2011–0959 using any one of the following methods:

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

(2) *Fax:* (202)–493–2251.

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

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

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

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email Donna Gagliano, Bridge Administration Branch, Eighth Coast Guard District, telephone (504) 671–2128, email *Donna.Gagliano@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202)–366–9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

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

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2011–0959), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online (*http://www.regulations.gov*), or by fax, mail or hand delivery, but please use only one of these means. If you submit a comment online via *http://www.regulations.gov,* it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a phone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* click on the ''submit a comment'' box, which will then become highlighted in blue. In the ''Keyword'' box insert ''USCG–2011–0959,'' click ''Search,'' and then click on the balloon shape in the ''Actions'' column. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* click on the ''read comments'' box, which will then become highlighted in blue. In the ''Keyword'' box insert ''USCG–2011–0959'' and click ''Search.'' Click the ''Open Docket Folder'' in the ''Actions'' column. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.

Privacy Act

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

Public Meeting

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

Basis and Purpose

The Coast Guard, at the request of the State of Louisiana, proposes to change the existing operating schedule for the SR 23 vertical lift bridge across the Gulf Intracoastal Waterway (Algiers Alternate Route), mile 3.8, at Belle Chasse, Plaquemines Parish, Louisiana. Due to an increase in vehicle traffic, State of Louisiana requested a change to the operation schedule.

Presently, under 33 CFR 117.451(b), states: The draw of the SR 23 Bridge, Algiers Alternate Route, mile 3.8 at Belle Chasse, shall open on signal; except that, from 6 a.m. to 8:30 a.m. and from 3:30 p.m. to 5:30 p.m. Monday through Friday, except Federal holidays, the draw need not be opened for the passage of vessels.

The test deviation would allow the bridge to open for the passage of vessels; except that from 6:30 a.m. until 8 p.m. Monday through Friday, the bridge need only open on the hour for the passage of vessels. The bridge need not open for the passage of vessels at 7 a.m., 8 a.m., 4 p.m. and 5 p.m. Monday through Friday. This proposal will allow the bridge to remain closed from 6:30 a.m. until 9 a.m. and from after the 3 p.m. opening until 6 p.m. Monday through Friday to facilitate the movement of vehicular traffic. Then from 8 p.m. until 6:30 a.m. Monday through Friday and at all times on weekend the bridge will open on signal.

We are testing these potential operating regulations adjustments to discover any outcome in vehicular traffic and water navigation as a result of the time adjustments.

The proposed change would allow for a set schedule of openings for vessels while minimally disrupting vehicular traffic during the morning and afternoon schedule. Also, the proposed schedule would allow additional time to clear vehicular traffic and minimize the delays caused by the openings during the heavy commute times. As a result very few vessels will be impacted, those vessels should be able to modify their transit accordingly as there is an alternate route. The vertical clearance of the bridge is 40 feet above mean high water in the closed-to-navigation position, so only vessels requiring ≤ 40 feet may transit the waterway. All vessels waiting during the closure will be allowed to pass during scheduled openings.

This deviation is effective from December 15, 2011 until January 17, 2012.

Coordination will be through Public Notice and Local Notice to Mariners upon date of publication in the **Federal Register**.

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 3, 2011.

David M. Frank,

Bridge Administrator.

[FR Doc. 2011–30636 Filed 11–29–11; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R06–OAR–2010–0776; FRL–9498–2]

Approval and Promulgation of Implementation Plans and Designation of Areas for Air Quality Planning; Louisiana; Baton Rouge Area: Redesignation to Attainment for the 1997 8-Hour Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is taking final action to approve the State of Louisiana's request to redesignate the Baton Rouge, Louisiana moderate 1997 8-hour ozone nonattainment area to attainment of the 1997 8-hour ozone standard. As a part of this action, EPA is also approving, as a revision to the Louisiana State Implementation Plan (SIP), the state's 1997 8-hour ozone maintenance plan with a 2022 Motor Vehicle Emissions Budget (MVEB) for the Baton Rouge Nonattainment Area (BRNA or BR), revisions to the Louisiana SIP that meet the Reasonably Available Control Technology (RACT) requirements (for nitrogen oxides (NO_X) and volatile organic compounds (VOCs)) for the 1-hour and 1997 8-hour ozone standard requirements, and a state rule establishing a maintenance plan contingency measure. EPA finds that with this final approval the area has a fully approved SIP that meets all of its applicable 1997 8-hour ozone requirements and 1-hour anti-backsliding requirements under section 110 and Part D of the Federal Clean Air Act (CAA or Act) for purposes of redesignation.

DATE: This rule is effective December 30, 2011.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R06–OAR–2010–0776. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *i.e.*, Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at the Air Planning Section, Air Planning Branch, Multimedia Planning and Permitting Division, U.S. Environmental Protection Agency, Region 6, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733. 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 is Monday through Friday, 8:30 to 4:30, excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Ms. Sandra Rennie, Air Planning Section (6PD–L), Environmental Protection Agency, Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733, telephone (214) 665–7367; fax number (214) 665–7263; email address *rennie.sandra@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us,'' and ''our'' means EPA.

Table of Contents

I. What is the background for this rule?
II. What comments did we receive on the proposed rule?
III. What actions is EPA taking?
IV. Statutory and Executive Order Reviews

I. What is the background for this rule?

The background for today's action is discussed in detail in EPA's August 30, 2011, proposal to approve Louisiana's redesignation request (76 FR 53853). In that proposed action, we noted that, under EPA regulations at 40 CFR part 50, the 1997 8-hour ozone standard is attained when the three-year average of the annual fourth-highest daily maximum 8-hour average ozone concentrations is less than or equal to 0.08 parts per million (ppm) (see 69 FR 23858, April 30, 2004, for more information). Under the CAA, EPA may redesignate a nonattainment area to attainment if sufficient complete, quality-assured data are available to determine that the area has attained the standard and if it meets the other CAA redesignation requirements in section 107(d)(3)(E).

The LDEQ, on August 31, 2010, submitted a request [1] to redesignate the Baton Rouge area to attainment for the 1997 8-hour ozone standard. EPA has previously determined that the BRNA ozone nonattainment area attained both the 1997 8-hour and 1-hour ozone standards. The EPA determined that the BRNA had attained the 1997 8-hour ozone standard on September 8, 2010, at 75 FR 54779. Complete, quality-assured monitoring data for 2006–2010 also show that the area continues to attain the 1997 8-hour ozone standard. EPA also determined that the BR area met the 1-hour ozone standard on February 10, 2010 (75 FR 6570). This determination was also based on complete, quality-assured, and certified ambient air quality monitoring data for the 2006–2008 ozone seasons, as well as certified data for 2009 and 2010 that indicate the area continues to attain the 1-hour ozone NAAQS. Preliminary data available for the 2011 ozone season indicate that the area continues to be in attainment for both ozone standards.[2]

Our proposed rule and Technical Support Document provide a detailed analysis of how Louisiana met the redesignation requirements and other CAA requirements. The state's Control Techniques Guidelines rule upon which this action depends, was signed on November 7, 2011, and will be published in a separate rulemaking. Implementation of Reformulated Gasoline (RFG) in the Baton Rouge 5-parish area remains stayed by court order. Implementation of RFG is not required for purposes of redesignation.

II. What comments did we receive on the proposed rule?

EPA provided a 30-day review and comment period, which closed on September 29, 2011. EPA received 3 comment letters in response to the proposed rulemaking, submitted on behalf of the Louisiana Chemical Association, Louisiana Mid-Continent Oil and Gas Association, and the Baton Rouge Area Chamber of Commerce, that expressed overall support for EPA's

[1] The submittal was supplemented by technical amendments on February 14, 2011, May 16, 2011, and June 6, 2011. All submitted documents are in the docket for this rulemaking.

[2] On September 22, 2011, EPA moved ahead to implement the 2008 8-hour ozone standard of 0.075 ppm. Memorandum from Gina McCarthy to Air Division Directors, Regions 1–10. EPA will continue to work with the state to implement this new standard.

proposed approval to redesignate the BR ozone nonattainment area to attainment for the 1997 8-hour ozone standard. The comment letters are available for review in the docket for this rulemaking.

III. What actions is EPA taking?

EPA is taking final action to approve several related actions under the Act for the BR ozone nonattainment area, consisting of Ascension, East Baton Rouge, Iberville, Livingston, and West Baton Rouge Parishes. Consistent with the Act, EPA is taking final action to approve a request from the state of Louisiana to redesignate the BRNA to attainment of the 1997 8-hour ozone standard.

EPA is taking final action to approve into the SIP, as meeting section 175A and 107(d)(3)(E)(iv) of the Act, Louisiana's maintenance plan for the BR area for the 1997 8-hour ozone NAAQS. The maintenance plan shows maintenance of the standard through 2022. Additionally, EPA has found adequate and is approving the 2022 MVEBs for NO_X and VOC. The submitted NO_X and VOC MVEB for the BR area is defined in Table 1 below.

TABLE 1—NO_X AND VOC MVEB

[Summer season tons per day]

Pollutant	2022
NO_X	6.96
VOC	7.55

We are also taking final action to approve a contingency measure for the maintenance plan.

Consequently, EPA is taking final action to approve the State's request to redesignate the area from nonattainment to attainment for the 1997 8-hour ozone NAAQS. After evaluating Louisiana's redesignation request, EPA has determined that with this final approval of the above-identified SIP elements and the maintenance plan, the area meets the redesignation criteria set forth in section 107(d)(3)(E) and section 175A of the Act. The final approval of this redesignation request changes the official designation in 40 CFR part 81 for the BR area from nonattainment to attainment for the 1997 8-hour ozone standard.

We find that the BR area meets all the applicable CAA requirements for purposes of redesignation of the 1997 8-hour standard that includes all of the antibacksliding CAA requirements for the BR 1-hour severe ozone nonattainment area. Therefore, along with this final redesignation to attainment for the 1997 8-hour ozone standard and our previous determination of attainment of the 1-hour ozone standard, the 1-hour anti-backsliding obligations to submit planning SIPs to meet the attainment demonstration reasonably available control measures (RACM) requirements, ROP and contingency measures requirements, cease to apply. In addition, after final redesignation to attainment for the 1997 8-hour ozone standard, EPA does not require the continued application of nonattainment New Source Review. Louisiana's Prevention of Significant Deterioration (PSD) program can apply in the Baton Rouge area so long as Louisiana interprets its SIP as applying PSD to the BRNA in these circumstances. As we noted in the proposal, Louisiana's PSD program will become effective in BRNA upon redesignation to attainment unless a SIP revision is necessary; then it must adopt and submit that to EPA for action.

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, redesignation of an area to attainment and the accompanying approval of a maintenance plan under section 107(d)(3)(E) are actions that affect the status of a geographical area and do not impose any additional regulatory requirements on sources beyond those imposed by State law. A redesignation to attainment does not in and of itself create any new requirements, but rather results in the applicability of requirements contained in the Clean Air Act for areas that have been redesignated to attainment. Moreover, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve State choices, provided that they meet the criteria of the Clean Air Act. Accordingly, these actions merely do not impose additional requirements beyond those imposed by State law and the Clean Air Act. For that reason, these actions:

- Are not ''significant regulatory actions'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Do not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Are 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.*);
- Do 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);
- Do not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Are 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);
- Are not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Do not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by December 20, 2010. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time

within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2).)

List of Subjects

40 CFR Part 52

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

40 CFR Part 81

Environmental protection, Air pollution control.

Dated: November 7, 2011.

Al Armendariz,

Regional Administrator, Region 6.

40 CFR parts 52 and 81 are 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 T—Louisiana

■ 2. Section 52.970 is amended as follows:

■ a. The table in paragraph (c) entitled, ''EPA Approved Louisiana Regulations in the Louisiana SIP'' is amended under Chapter 22, Control of Emissions of Nitrogen Oxides (NO_X), by adding a new entry for Section 2201, and, immediately following the entry for Section 2201.H.3, by adding a new entry for Section 2202;

■ b. The second table in paragraph (e) entitled, ''EPA-Approved Louisiana Nonregulatory Provisions and Quasi-Regulatory Measures'' is amended by adding a new entry at the end.

The additions read as follows:

§ 52.970 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED LOUISIANA REGULATIONS IN THE LOUISIANA SIP

State citation	Title/subject	State approval date	EPA approval date	Comments
*	*	*	*	*
Chapter 22—Control of Emissions of Nitrogen Oxides (NO_X)				
Section 2201	Affected Facilities in the Baton Rouge Nonattainment Area and the Region of Influence.	1/20/2010	11/30/11, [Insert FR page number where document begins].	Revisions to Section 2201 approved in the Louisiana Register January 20, 2010 (LR 36:60).
*	*	*	*	*
Section 2202	Contingency Plan	1/20/2010	11/30/11, [Insert FR page number where document begins].	Section 2202 approved in the Louisiana Register January 20, 2010 (LR 36:63).
*	*	*	*	*

(e) * * *

* * * * *

EPA-APPROVED LOUISIANA NONREGULATORY PROVISIONS AND QUASI-REGULATORY MEASURES

Name of SIP provision	Applicable geographic or nonattainment area	State submittal date/effective date	EPA approval date	Explanation
*	*	*	*	*
Baton Rouge Ozone Nonattainment Area Redesignation Request and Maintenance Plan.	Baton Rouge, LA	8/31/2010	11/30/11, [Insert FR page number where document begins].	

■ 3. Section 52.977 is amended by adding paragraph (d) to read as follows:

§ 52.977 Control strategy and regulations: Ozone.

* * * * *

(d) Redesignation for the 1997 8-hour Ozone Standard. Effective December 30, 2011, EPA has redesignated the Baton Rouge area to attainment for the 1997 8-hour ozone standard. With this final redesignation to attainment for the 1997 8-hour ozone NAAQS and the final determination of attainment for the 1-hour ozone NAAQS in paragraph (a) of this section, the 1-hour anti-backsliding obligations to submit planning SIPs to meet the attainment demonstration and reasonably available control measures requirements, the rate of progress and contingency measures requirements, and any other outstanding 1-hour requirements, cease to apply.

PART 81—[AMENDED]

■ 4. The authority citation for part 81 continues to read as follows:

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

■ 5. In § 81.319, the table entitled, ''Louisiana—Ozone (8-Hour Standard)''

is amended by: revising the entries for Baton Rouge Area; and adding a new footnote 2 at the end of the table.

The revisions and addition read as follows:

§ 81.319 Louisiana.

* * * * *

LOUISIANA—OZONE (8-HOUR STANDARD)

Designated area	Designation [a]		Category/classification	
	Date [1]	Type	Date [1]	Type
Baton Rouge Area:				
Ascension Parish	([2])	Attainment.		
East Baton Rouge Parish	([2])	Attainment.		
Iberville Parish	([2])	Attainment.		
Livingston Parish	([2])	Attainment.		
West Baton Rouge Parish	([2])	Attainment.		
* * *	*	*	*	*

[1] This date is June 15, 2004, unless otherwise noted.
[2] Effective December 30, 2011.

* * * * *

[FR Doc. 2011–30785 Filed 11–29–11; 8:45 am]
BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 090508897–1635–03]

RIN 0648–AX85

Atlantic Highly Migratory Species; Adjustments to the Atlantic Bluefin Tuna General and Harpoon Category Regulations

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

ACTION: Final rule.

SUMMARY: NMFS is adjusting the Atlantic bluefin tuna (BFT) fishery regulations to: Increase the General category maximum daily retention limit; allow the General category season to remain open until the January subquota is reached, or March 31, whichever happens first; and increase the Harpoon category daily incidental retention limit. This action is intended to enable more thorough utilization of the available U.S. BFT quota for the General and Harpoon (commercial handgear) categories; minimize bycatch and bycatch mortality to the extent practicable; expand fishing opportunities for participants in the commercial winter General category fishery; and increase NMFS' flexibility for setting the General category retention limit depending on available quota.

DATES: This rule is effective December 30, 2011, except for § 635.23(a)(4) and § 635.27(a)(1)(i)(A), which are effective *November 30, 2011.*

ADDRESSES: Supporting documents, including the Environmental Assessment, Regulatory Impact Review, and Final Regulatory Flexibility Analysis (EA/RIR/FRFA), are available from Sarah McLaughlin, Highly Migratory Species (HMS) Management Division, Office of Sustainable Fisheries (F/SF1), NMFS, 55 Great Republic Drive, Gloucester, MA 01930. These documents and others, such as the Fishery Management Plans described below, also may be downloaded from the HMS Web site at *www.nmfs.noaa.gov/sfa/hms/.*

FOR FURTHER INFORMATION CONTACT: Sarah McLaughlin or Tom Warren, (978) 281–9260.

SUPPLEMENTARY INFORMATION: Atlantic tunas are managed under the dual authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) and the Atlantic Tunas Convention Act (ATCA). ATCA requires the Secretary of Commerce (Secretary) to promulgate regulations, as may be necessary and appropriate, to implement recommendations of the International Commission for the Conservation of Atlantic Tunas (ICCAT). The authority to issue regulations under the Magnuson-Stevens Act and ATCA has been delegated from the Secretary to the Assistant Administrator for Fisheries, NMFS.

Background

Background information about the need for amendment of the regulations regarding the BFT General category maximum daily retention limit, General category season, and Harpoon category daily incidental retention limit was provided in the preamble to the proposed rule (74 FR 57128, November 4, 2009) and is not repeated here.

At the proposed rulemaking stage in 2009, the proposed rule was titled ''Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Season and Retention Limit Adjustments.'' As the rule has evolved through the notice and comment process, NMFS has determined that keeping the proposed rule title at this stage would confuse the regulated public; therefore, to clarify the purpose and content of the rulemaking, NMFS has changed the title of the rule to ''Atlantic Highly Migratory Species; Adjustments to the Atlantic Bluefin Tuna General and Harpoon Category Regulations.'' Any changes to the rule's provisions that were made between the proposed and final rule are discussed in depth below.

NMFS extended the original 45-day comment period on the proposed rule through March 31, 2010, based on public, Congressional, and non-governmental organization requests for NMFS to wait to complete any related final rulemaking until after the March 2010 meeting regarding the Convention on the International Trade in Endangered Species of Wild Flora and Fauna, and until the 2010 publication of new research.

NMFS delayed issuing a final rule pending a new ICCAT BFT stock assessment and subsequent ICCAT recommendation on BFT conservation and management in 2010, as well as the decision on a May 2010 petition to list BFT as threatened or endangered under the Endangered Species Act (ESA). In May 2011, NMFS determined that listing BFT as threatened or endangered under the ESA was not warranted, but listed BFT as a species of concern. NMFS will revisit the status of BFT under the ESA in 2013. Because the

concerns that led to NMFS addressing the BFT regulations in the 2009 proposed rule still exist, NMFS is now taking this final action.

Changes From the Proposed Rule

In the proposed rule, with regard to the General category January subquota, NMFS proposed to allow, annually, the General category to remain open from January 1 until the January subquota is determined to be fully harvested, rather than have a set period from January 1 through January 31, as allowed under the current regulations. To effect this change, NMFS proposed to adjust the time period for which the January subquota would be available, such that it would begin January 1 and end when the January subquota is projected to be reached, or May 31, whichever comes first. NMFS indicated that the action likely would lengthen the General category season only by a few weeks, with the duration of the extension dependent on weather conditions and availability of large medium and giant BFT to the fishery during the winter months.

As described in the Comments and Responses section below, following consideration of public comment on the potential impacts of extending the General category season through May of each year, NMFS has decided that the General category season should remain open until the January subquota is reached or March 31, whichever happens first, rather than May 31, as originally proposed. This action is within the scope of alternatives analyzed in the draft EA.

Provisions Implemented in This Final Rule

Adjustment of the General Category Maximum Possible Daily Retention Limit

NMFS implements in this final rule an increase to the General category maximum possible daily retention limit to five fish per vessel. NMFS may increase or decrease the actual allowed daily retention limit of large medium and giant BFT over a range from zero to a maximum of five per vessel via inseason action based on the determination criteria and other relevant factors provided under § 635.27(a)(8):

(i) The usefulness of information obtained from catches in the particular category for biological sampling and monitoring of the status of the stock.

(ii) The catches of the particular category quota to date and the likelihood of closure of that segment of the fishery if no adjustment is made.

(iii) The projected ability of the vessels fishing under the particular category quota to harvest the additional amount of BFT before the end of the fishing year.

(iv) The estimated amounts by which quotas for other gear categories of the fishery might be exceeded.

(v) Effects of the adjustment on BFT rebuilding and overfishing.

(vi) Effects of the adjustment on accomplishing the objectives of the fishery management plan.

(vii) Variations in seasonal distribution, abundance, or migration patterns of BFT.

(viii) Effects of catch rates in one area precluding vessels in another area from having a reasonable opportunity to harvest a portion of the category's quota.

(ix) Review of dealer reports, daily landing trends, and the availability of the BFT on the fishing grounds.

Adjustment of the General Category Season

NMFS implements an adjustment to the regulation that specifies the time period for which the General category January subquota is available, such that the period that begins January 1 would end upon the effective date of a closure notice that NMFS would file with the Office of the Federal Register when the quota apportioned to the period that begins January 1 is projected to be reached, or March 31, whichever comes first. In the future, NMFS will publish a closure action for the General category January subquota in the **Federal Register,** if necessary to close the fishery prior to March 31.

Adjustment of the Harpoon Category Daily Incidental Retention Limit

NMFS implements an increase to the Harpoon category daily incidental retention limit of large medium BFT from two to four per vessel. This action is intended to provide Harpoon category vessels a reasonable opportunity to harvest the allocated Harpoon category quota in its designated time frame (June 1 through November 15 of each year) and minimize the potential for dead discards to the extent practicable.

Comments and Responses

NMFS received approximately 6,000 written comments, the majority of which were sent through a campaign by a non-governmental organization (NGO) representing environmental interests. Fifteen letters were sent by individuals or organizations (including fishing industry, fishery management council, state, and NGOs), and oral comments were received from the approximately 15 attendees of public hearings in Gloucester, MA, and Silver Spring, MD. NMFS considered all comments received, and below, responds to comments made on the proposed rule. Similar or same comments from multiple individuals are grouped together by subject. In addition, NMFS received comments on issues that were not part of this rulemaking. These comments are summarized under ''Other Issues'' below.

Comment 1: The justification and rationale for an increase in the Harpoon category daily retention limit of large medium BFT is not valid (*i.e.,* the premise that catch has consistently been under the quota is not correct). In 2009, the Harpoon category BFT landings exceeded the baseline quota, and even with the 2009 adjustment to the baseline quota, 25 mt had to be transferred from the Reserve category in August 2009 to ensure that the harpooners did not exceed their quota. We take issue with NMFS' statement that ''While the recreational Angling category and the commercial Longline category have been able to fill their subquotas in recent years, the commercial handgear categories (General and Harpoon) have not.'' Furthermore, the 2010 quota is the lowest in nearly three decades, and starting next year, roll-over of underage will be limited to 10 percent of the baseline quota.

Response: NMFS is required under the Magnuson-Stevens Act and ATCA to provide U.S. fishing vessels with a reasonable opportunity to harvest the ICCAT recommended quota. For the General and Harpoon categories, on average, recent landings have been less than either the base or adjusted quotas. Over the last three years, the General category landed an average of 77 percent of its base quota and 60 percent of its adjusted quota, while the Harpoon category landed an average of 68 percent of its base quota and 44 percent of its adjusted quota. This action provides NMFS the option to implement a wider range of daily retention limits to facilitate the harvest of the available U.S. BFT quota, if conditions warrant. Use of such flexibility through the implementation of the higher daily retention limits for the General category will be contingent upon the availability of quota and subject to the determination criteria and other relevant factors outlined in § 635.27 (a)(8). The August 28, 2009, transfer to the Harpoon category (74 FR 44298) was conducted in accordance with the criteria mentioned above.

Comment 2: The reasoning underlying the proposed rule is flawed, as evidenced by NMFS' statement that ''These three effort controlling actions

would affect only when and where BFT mortality occurs, and not the magnitude.'' The measures are intended to facilitate the utilization of the U.S. quota, and will increase BFT fishing mortality in addition to affecting the timing and location of catch, and therefore NMFS should not implement the proposed measures.

Response: NMFS has determined that, when evaluating the effect of management measures, it is important to consider time scales as they relate to the action under consideration. Relevant scientific information, ICCAT recommendations (*e.g.,* quotas), and the Consolidated HMS FMP are structured principally on an annual basis. Although on a particular fishing day, a vessel may catch more or fewer BFT, the maximum fishing mortality is capped by the annual quota. This rule modifies neither the annual quota, nor the fishing mortality associated with that quota. Given the variability of the location of BFT, a higher daily retention limit may enable better alignment of catch with fish availability, while not increasing overall catch.

Comment 3: Even if catch is within the ICCAT established quota, that level of catch could lead to accelerated stock declines and further compromise the rebuilding program. NMFS should end overfishing and minimize bycatch. Limiting fishing mortality is even more important now that the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) opted not to prohibit international trade of BFT.

Response: NMFS agrees that limiting fishing mortality is important. NMFS does so within the limits of the ICCAT-recommended quota and in implementing its Magnuson-Stevens Act and ATCA obligations. The 2011 U.S. quota is consistent with the current ICCAT recommended total allowable catch, which is expected to allow for continued BFT stock growth under both the low and high stock recruitment scenarios considered by ICCAT's Standing Committee on Research and Statistics (SCRS). NMFS implements numerous regulatory measures and collects commercial landings data on a daily basis to ensure available quotas are not exceeded. Using its inseason management authority, NMFS will be able to monitor and make adjustments to the commercial fishery in a timely manner (close to 'real time'), as commercial data are required to be submitted within 24 hours of landing. Although BFT was not listed under CITES in 2010, international trade is highly regulated consistent with ICCAT requirements.

Comment 4: Increasing the daily retention limit could have negative economic consequences as the flood of fish on the market would likely lower the ex-vessel price of the fish.

Response: NMFS believes it is unlikely that any potentially implemented increase in the BFT daily retention limit would have significant, negative economic impacts on the ex-vessel price. The price for BFT exported to Japan is dependent on a number of factors, including: Quality, size, and global supply of BFT at the time. Increased revenues would depend on availability of large medium and giant BFT to the fishery, as well as the daily retention limit set by NMFS through inseason action. In 2010, 404 trips (20 percent of successful trips) landed three large medium or giant BFT. If each of these 404 trips landed five large medium or giant BFT instead of three, a total of 808 additional fish would have been landed (over the course of the fishing year under a limit of five fish). If the General category retention limit were increased to five for any portion of the fishing year, this action also could have positive socioeconomic impacts by allowing vessels to extend their range while remaining profitable.

Comment 5: The General category should not have a retention limit. NMFS should implement Alternative A3 (elimination of the maximum daily retention limit).

Response: Retention limits for the General category are necessary to ensure that the General category landings do not exceed their allocated proportion of the U.S. quota established in the Consolidated HMS FMP. Furthermore, retention limits allow NMFS to distribute fishing opportunities both temporally and geographically, thereby ensuring fishing in one area does not preclude opportunities in other areas. For these reasons, NMFS is not implementing the commenter's recommendation.

Comment 6: Increasing the General category trip limit to five large medium or giants would allow vessels capable of fishing further offshore to take advantage of the opportunity to do so if market conditions and weather permit. The increase in maximum daily retention limit should allow additional flexibility and a more reasonable opportunity for the General category to catch its share of the U.S. quota. NMFS should also increase the daily retention of large medium BFT in the Harpoon category to four per vessel.

Response: In this final rule, NMFS implements an increase to the maximum possible General category BFT daily retention limit to five fish per vessel as well as an increase to the daily incidental retention limit of large medium BFT from two to four per vessel. This action is intended to enable more thorough utilization of the available U.S. BFT quota for the General and Harpoon categories, minimize bycatch and bycatch mortality to the extent practicable, expand fishing opportunities for participants in the commercial winter General category fishery, and increase NMFS' flexibility for setting the General category retention limit depending on available quota.

Comment 7: The North Carolina Division of Marine Fisheries supports the proposed action to allow full access to the January subquota. The BFT fishery is very important to coastal North Carolina fishing communities during the winter months.

Response: The Agency is aware of the importance of the winter BFT fishery. NMFS agrees that enhanced access to the January subquota is warranted. Increasing access to the January subquota through March 31 will allow additional opportunities to harvest the available January subquota, reduce the potential for late spring gear conflict between fishery participants, and mitigate the potential impacts of any additional fishing effort during months previously unfished. This measure will provide participants in this region with an interest in harvesting BFT a reasonable opportunity to harvest the available quota consistent with the goals of the Consolidated HMS FMP.

Comment 8: NMFS should establish equal monthly General category time periods and subquotas (Alternative B3) rather than increasing the maximum retention limit to 5 fish (Alternative A2). The expanded seasonal opportunities of Alternative B3 far outweigh the benefits of high retention limits that often result in lower product quality and shorter seasons. Fishermen from all states would be equal and capable of traveling to wherever the BFT are. Alternative B3 does not discriminate between residents of different states, is fair and equitable to all such fishermen, is reasonably calculated to promote conservation, and does not allow any individuals, entities, or states to acquire an excessive share of BFT fishing privileges, as required by the Magnuson-Stevens Act.

Response: Alternative B3 (dividing the General category allocations equally between months) was not selected because the potential negative social and economic impacts outweigh the positive impacts and because NMFS believes the topic of quota allocation merits further consideration and analyses. The negative aspects of this

alternative are the potential for gear conflicts and a derby fishery, as well as the potential for the historical geographic distribution of the fishery to be dramatically altered. Although this alternative would provide some stability to the fishery by establishing a known amount of quota that would be available at the first of each month, if catch rates are high in the early portion of the month, these quotas could be harvested rapidly and may lead to derby style fisheries on the first of each month. The preferred alternative (B2b) provides additional fishing opportunities within available quotas while acknowledging the traditional fishery. Current regulations do not preclude General category vessels from traveling from one area to another.

Comment 9: The characteristics of BFT foraging aggregations make them susceptible to high levels of fishing mortality. In some instances, the majority of an entire cohort can be taken in a spatially and temporally discrete region and period, respectively. A large number of General category vessels with an increased limit in the middle of a large and aggressively feeding group of BFT could result in near elimination of that group, potentially having widespread age and/or genetic impacts on the stock.

Response: NMFS manages the General category BFT fishery principally through the overall General category quota and time period subquotas. Assuming there is no significant change in the selectivity of the fishery, the action would be consistent with ICCAT recommendations and stock assessments.

Comment 10: Although allowing the General category January subquota to be fished through May 31 will likely extend the season by a month or less, based on recent mortality information and available quota, concerns remain that this action would infringe on the de facto time-area closure that currently exists from February 1 through May 31. The majority of fish available to the fishery during this period are off the coast of the mid-Atlantic, and recent research has shown that these fish are primarily adolescents, interspersed with mature western BFT on their way to the Gulf of Mexico to breed. This aggregation therefore has a high reproductive value because the fish are within a year or two of spawning, or even more importantly, are in the middle of their migration to the spawning ground, and warrant heightened protection. As immigration of eastern BFT has decreased due to overfishing in the Mediterranean Sea, there has likely been a shift in frequency of the mid-Atlantic aggregation towards more fish of western origin. Increasing mortality in the region would therefore counter rebuilding of the western population.

Response: NMFS agrees with the commenter that the action would likely effectively lengthen the General category season by only a few weeks. The duration of the actual extension would depend on weather conditions and availability of large medium and giant BFT to the fishery during the winter months. NMFS has taken this comment into consideration and has modified the end date of the duration of access to the January subquota from May 31 to March 31. As indicated above, this is expected to mitigate any potential impacts to the species of any additional fishing effort during months previously unfished, as well as reduce the potential for late spring gear conflict between fishery participants (*i.e.,* if General category fishing activity continues through May while the Harpoon category must wait until June 1 to begin fishing).

Other Issues

NMFS received comments on the issues outlined under the six subheadings below. These suggestions are beyond the scope of this rulemaking. However, NMFS is undertaking a comprehensive review of BFT management to determine whether existing management measures need to be adjusted more broadly to meet the multiple goals for the BFT fishery, and these issues may be considered through future actions.

1. Reduction of Minimum Size

NMFS should consider lowering the minimum fish size to 65 inches for the General and Harpoon categories. Lowering of the minimum size could be achieved in a resource neutral fashion with a modest transfer/sacrifice (possibly temporary, possibly permanent) of giant BFT quota to the medium category. It would still leave the United States with the largest minimum size of any ICCAT Contracting Party. Another commenter noted that the majority of available fish are currently 65 to 73 inches (curved fork length) and suggested that management should be modified to reflect this availability of smaller fish.

2. Modification of Pelagic Longline Trip Limits

NMFS should have increased the incidental pelagic longline trip limits to a maximum of five fish with a directed catch of 12,000 lb. As interactions with BFT increase over the next several years, NMFS needs a plan for dealing with increased interactions in light of efforts to revitalize the pelagic longline fishery for swordfish.

3. Modification of Permit Category Restrictions and Quota Use

NMFS should allow vessels in the General and Charter Headboat categories the opportunity to participate in both the Angling category and General category on the same trip or fishing day. The conservative U.S. quotas protect the resource and the mandate of the Magnuson-Stevens Act and ATCA is to provide maximum opportunities to catch these quotas. NMFS also received comment that because of the current inactivity of at least two of the purse seine vessels, the associated purse seine quota should be used to account for pelagic longline discards and NMFS should allow increased incidental landings of BFT by longlines. NMFS should authorize the use of harpoon gear by Charter/Headboat category vessels when they do not have paying passengers onboard.

4. General Category Season

NMFS should reopen the General category fishery in May instead of June.

5. Elimination or Curtailment of the BFT Fishery

NMFS received comment that the entire BFT fishery should be closed, that pelagic longlining in the Gulf of Mexico should be prohibited at all times, or that pelagic longlining in the Gulf of Mexico should be prohibited during the spawning period (last week of April through first week of June), or from March to September.

6. Validity of Current Quota

NMFS received comment that evaluation of the proposed measures with respect to the current quotas would result in an incorrect conclusion, due to an underlying concern that the current quota is not valid, due to a retrospective pattern in the stock assessment. Specifically, the comment states that if the United States had been catching its quota in recent years, the western BFT biomass would be approximately 30 percent lower than its already depleted current level. It follows that this rule could lead to accelerated declines and compromise the ICCAT rebuilding program even more than it has already been compromised.

Classification

The Assistant Administrator for Fisheries, NMFS, has determined that this final action is consistent with the Magnuson-Stevens Act, ATCA, and

other applicable law, and is necessary to achieve domestic management objectives under the Consolidated HMS FMP.

The Assistant Administrator for Fisheries (AA) finds good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in effectiveness for this action. This wavier applies only to those provisions related to the General category fishery. This action would increase the General category maximum possible BFT daily retention limit from three to five fish (with limit adjustments to be executed via inseason actions as appropriate following consideration of determination criteria at § 635.27(a)(8)). It also increases NMFS' flexibility and range for setting the General category retention limit depending on available quota. This action would also extend the duration of time over which General category participants may fish the available General category January subquota, from January 1 through January 31 to January 1 through March 31 of each year. These provisions are consistent with ICCAT recommendations and the Consolidated HMS FMP and provide the General category BFT fishery with potential beneficial economic impacts. If these provisions are delayed to allow for the 30-day delay in implementation, the General category BFT fishery would open on January 1, 2012, but would be limited to the current January timeframe and retention limit range. This would prevent the fishery from fully realizing the economic benefits of this rule. For these reasons, the AA finds good cause to waive the 30-day delay in effectiveness.

This final rule has been determined to be not significant for purposes of Executive Order 12866.

In compliance with section 604 of the Regulatory Flexibility Act (RFA), a Final Regulatory Flexibility Analysis (FRFA) was prepared for this rule. The FRFA incorporates the Initial Regulatory Flexibility Analysis (IRFA), a summary of the significant issues raised by the public comments in response to the IRFA, and NMFS responses to those comments, and a summary of the analyses completed to support the action. The full FRFA and analysis of economic and ecological impacts are available from NMFS (see **ADDRESSES**). A summary of the FRFA follows.

In compliance with section 604(a)(1) of the RFA, the purpose of this rulemaking is, consistent with the Consolidated HMS FMP objectives, the Magnuson-Stevens Act, ATCA, and other applicable law, to adjust regulations for the BFT commercial handgear fisheries. This action is intended to enable more thorough utilization of the available U.S. BFT quota for the General and Harpoon categories; minimize bycatch and bycatch mortality to the extent practicable; expand fishing opportunities for participants in the commercial winter General category fishery; and increase NMFS' flexibility for setting the General category retention limit depending on available quota.

Section 604(a)(2) of the RFA requires agencies to summarize significant issues raised by the public in response to the IRFA, a summary of the agency's assessment of such issues, and a statement of any changes made as a result of the comments.

NMFS received numerous comments on the proposed rule (74 FR 57128, November 4, 2009) during the comment period. A summary of these comments and the Agency's responses are included in Chapter 14 of the EA/RIR/FRFA and are included in this final rule. Although NMFS did not receive comment specifically on the IRFA, NMFS received some comments expressing concern that increasing the General category daily retention limit could have negative economic consequences from oversupplying the market, which could result in lower ex-vessel prices. For more information, see comment #4 in the section entitled ''Comments and Responses.''

Section 604(a)(3) of the RFA requires agencies to provide an estimate of the number of small entities to which the rule would apply. The implementation of the ICCAT-recommended baseline annual U.S. BFT quota would apply to all participants in the Atlantic BFT fisheries, all of which are considered small entities, because they either had average annual receipts less than $4.0 million for fish-harvesting, average annual receipts less than $6.5 million for charter/party boats, 100 or fewer employees for wholesale dealers, or 500 or fewer employees for seafood processors. These are the Small Business Administration (SBA) size standards for defining a small versus large business entity in this industry. As shown in Table 7 of the EA/RIR/FRFA, for 2008 there were 9,871 vessels permitted to land and sell BFT under four commercial BFT quota categories (including charter/headboat vessels), with 4,721 vessels in the General category, 4,827 in the Charter/Headboat category, and 26 in the Harpoon category. For 2010, 8,052 vessels were permitted to land and sell BFT under four commercial BFT quota categories (including charter/headboat vessels), with 3,849 vessels in the General category, 4,174 in the Charter/Headboat category, and 29 in the Harpoon category.

Under section 604(a)(4) of the RFA, agencies are required to describe any new reporting, record-keeping and other compliance requirements. The action does not contain any new collection of information, reporting, record keeping, or other compliance requirements.

Under section 604(a)(5) of the RFA, agencies are required to describe any alternatives to the rule which accomplish the stated objectives and which minimize any significant economic impacts. These impacts are discussed below and in Chapters 4 and 6 of the EA/RIR/FRFA. Additionally, the Regulatory Flexibility Act (5 U.S.C. 603 (c) (1)–(4)) lists four general categories of ''significant'' alternatives that would assist an agency in the development of significant alternatives. These categories of alternatives are: (1) Establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities; (3) use of performance rather than design standards; and (4) exemptions from coverage of the rule for small entities.

In order to meet the objectives of this rule, consistent with the Magnuson-Stevens Act, ATCA, and the ESA, NMFS cannot establish differing, or clarifications, consolidations, or simplifications to, compliance requirements for small entities or exempt small entities from compliance requirements. Thus, there are no alternatives discussed that fall under the first, third, and fourth categories described above. NMFS does not know of any performance or design standards that would satisfy the aforementioned objectives of this rulemaking while, concurrently, complying with the Magnuson-Stevens Act. As described below, NMFS analyzed several different alternatives in this rulemaking and provides rationale for identifying the preferred alternatives to achieve the desired objective. The FRFA assumes that each vessel within a category will have similar catch and gross revenues to show the relative impact of the action on vessels.

The alternatives considered and analyzed are described below. The IRFA indicated that in 2008, the annual gross revenues from the commercial BFT fishery were approximately $5.0 million. The commercial quota categories and their 2008 gross revenues were General ($4.0 million), Harpoon ($313,781), Purse Seine ($0), and

Longline ($722,016). Using data from 2010, the year for which the most recent, complete revenue data are available, the annual gross revenues from the commercial BFT fishery were approximately $8.9 million. The commercial categories and their 2010 gross revenues are General ($7.8 million), Harpoon ($202,643), Purse Seine ($0), and Longline ($878,908).

General Category Maximum Daily Retention Limit

Alternative A1, the status quo alternative, would maintain the current maximum daily retention limit of three large medium BFT. The status quo alternative could result in negative economic impacts to the extent that the daily retention limit may constrain large medium and giant BFT landings. The inability of the General category to land and sell its full allotted quota results in decreased optimum yield.

Alternative A2, an increase in the maximum possible daily retention limit to five fish per vessel, could have positive economic impacts if NMFS sets the daily retention limit to four or five fish via inseason action, due to the increased potential to land additional large medium and giant BFT rather than discarding fish in excess of the current maximum daily retention limit (*e.g.,* if a fourth commercial size BFT is caught in one day). The IRFA indicated that, based on 2008 data, ex-vessel revenues per trip could increase on average by approximately $8,500 per active vessel (2 fish × the 2008 average fish weight of 500 lb × $8.44 General category ex-vessel average price/lb), depending on availability of large medium and giant BFT to the fishery. Using 2010 data, ex-vessel revenues per trip could increase on average by approximately $5,250 per active vessel (2 fish × the 2010 average fish weight of 379 lb × $6.93 General category ex-vessel average price/lb), depending on availability of large medium and giant BFT to the fishery. Allowing a higher maximum daily retention limit could also reduce the trip costs per fish landed, and thus improve profitability of trips when additional fish are available. Alternative A2 is the preferred alternative, as it would increase opportunities for General and Charter/Headboat category vessels within the General category quota, which is set consistent with ICCAT recommendations and the Consolidated HMS FMP.

Alternative A3, elimination of the maximum daily retention limit, would have positive economic impacts associated with the increased potential to land all large medium and giant BFT in excess of the current maximum daily retention limit rather than discarding them. Although this alternative would provide the most positive economic impacts, it is not preferred because of the potential negative ecological impact of a relatively large potential increase in BFT mortality, including undersized fish.

General Category Season

Under Alternative B1, the status quo alternative, the General category season would end on January 31 of each fishing year or when the General category January subquota is harvested, whichever happens first. Under this alternative, NMFS anticipates neutral impacts on General and Charter/Headboat category vessels.

Under both Alternative B2, as proposed, and preferred Alternative B2b, which would allow the General category to remain open until the date NMFS determines that the available January subquota has been reached (or is projected to be reached) or March 31, whichever happens first, NMFS anticipates that overall economic impacts of this alternative to the General category and Charter/Headboat BFT fishery as a whole would be neutral since the same overall amount of the General category quota would be landed and the value of the General category quota would not be changed. However, General category fishermen in the southern region (more than 1,000 vessels) would be positively affected by this alternative as it would allow increased opportunities to land and sell BFT commercially and increased utilization of existing investment in gear and equipment, especially if quota is still available for harvest after January 31.

Under Alternative B3, which would establish a January through December General category season and establish 12 equal monthly General category time periods and subquotas (of 8.3 percent each), resulting impacts would be mixed, but positive overall. Winter fishery participants would benefit from increased opportunities to harvest large medium and giant BFT, if available, during the months of February through March. General category and Charter/Headboat category participants in the New England area, or those participants that pursue BFT in the summer months, might experience some adverse economic impacts due to the shift in quota to the earlier (winter) portion of the season. However, these effects would be mitigated by the effects of the carrying forward of unharvested quota from one time period to the next. This is not the preferred alternative at this time as NMFS believes the topic of quota allocation merits further consideration and analyses.

Harpoon Category Daily Incidental Retention Limit

Alternative C1, the status quo alternative, would maintain the current incidental daily retention limit of two large medium BFT. The status quo alternative could result in negative economic impacts to the extent that the incidental limit constrains large medium BFT landings. The inability of the Harpoon category to land and sell its full allotted quota results in decreased optimum yield.

Alternative C2, an increase in the incidental daily retention limit to four large medium BFT, would have positive economic impacts associated with the increased potential to land additional large medium BFT rather than discarding fish in excess of the current incidental limit (*e.g.,* if a third large medium is caught while pursuing giant BFT). The IRFA indicated that, based on 2008 data, ex-vessel revenues per trip could increase on average by approximately $4,600 per active vessel (2 fish × the 2008 average Harpoon category fish weight of 360 lb × $6.36 Harpoon category ex-vessel average price/lb), depending on availability of large medium BFT to the fishery. Using 2010 data, ex-vessel revenues per trip could increase on average by approximately $3,000 per active vessel (2 fish × the 2010 average Harpoon category fish weight of 260 lb × $5.75 Harpoon category ex-vessel average price/lb), depending on availability of large medium BFT to the fishery. Allowing a higher daily incidental retention limit could also reduce the trip costs per fish landed, and thus improve profitability of trips when additional fish are available. Alternative C2 is the preferred alternative as it would increase opportunities for Harpoon category vessels to land the Harpoon category quota while balancing concerns regarding BFT stock health.

Alternative C3, elimination of the incidental limit, would have positive economic impacts associated with the increased potential to land all large medium BFT in excess of the current incidental limit rather than discarding them. Although this alternative would provide the most positive economic impacts, it is not preferred because of the potential negative ecological impact of a relatively large potential increase in large medium BFT mortality.

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that, for each rule or group of related rules for which an agency is required to prepare a FRFA, the agency

shall publish one or more guides to assist small entities in complying with the rule, and shall designate such publications as ''small entity compliance guides.'' The agency shall explain the actions a small entity is required to take to comply with a rule or group of rules. Copies of the compliance guide are available from NMFS (see **ADDRESSES**).

List of Subjects in 50 CFR Part 635

Fisheries, Fishing, Fishing vessels, Foreign relations, Imports, Penalties, Reporting and recordkeeping requirements, Treaties.

Dated: November 23, 2011.

Eric C. Schwaab,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 635 is amended as follows:

PART 635—ATLANTIC HIGHLY MIGRATORY SPECIES

■ 1. The authority citation for part 635 continues to read as follows:

Authority: 16 U.S.C. 971 *et seq.;* 16 U.S.C. 1801 *et seq.*

■ 2. In § 635.23, paragraphs (a)(4) and (d) are revised to read as follows:

§ 635.23 Retention limits for BFT.

* * * * *

(a) * * *

(4) To provide for maximum utilization of the quota for BFT, NMFS may increase or decrease the daily retention limit of large medium and giant BFT over a range from zero (on RFDs) to a maximum of five per vessel. Such increase or decrease will be based on the criteria provided under § 635.27(a)(8). NMFS will adjust the daily retention limit specified in paragraph (a)(2) of this section by filing an adjustment with the Office of the Federal Register for publication. In no case shall such adjustment be effective less than 3 calendar days after the date of filing with the Office of the Federal Register, except that previously designated RFDs may be waived effective upon closure of the General category fishery so that persons aboard vessels permitted in the General category may conduct tag-and-release fishing for BFT under § 635.26.

* * * * *

(d) *Harpoon category.* Persons aboard a vessel permitted in the Atlantic Tunas Harpoon category may retain, possess, or land an unlimited number of giant BFT per day. An incidental catch of only four large medium BFT per vessel per day may be retained, possessed, or landed.

* * * * *

■ 3. In § 635.27, paragraph (a)(1)(i)(A) is revised to read as follows:

§ 635.27 Quotas.

(a) * * *

(1) * * *

(i) * * *

(A) January 1 through the effective date of a closure notice filed by NMFS announcing that the January subquota is reached, or projected to be reached under § 635.28(a)(1), or until March 31, whichever comes first—5.3 percent (25.2 mt);

* * * * *

[FR Doc. 2011–30726 Filed 11–29–11; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 101228634–1149–02]

RIN 0648–XA825

Fisheries of the Northeastern United States; Bluefish Fishery; Quota Transfer

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

ACTION: Temporary rule; quota transfer.

SUMMARY: The State of Florida is transferring a portion of its 2011 commercial bluefish quota to New York State. By this action, NMFS adjusts the quotas and announces the revised commercial quota for each state involved.

DATES: Effective November 29, 2011, through December 31, 2011.

FOR FURTHER INFORMATION CONTACT: Carly Bari, Fishery Management Specialist, (978) 281–9224.

SUPPLEMENTARY INFORMATION: Regulations governing the bluefish fishery are found at 50 CFR part 648, subpart J. The regulations require annual specification of a commercial quota that is apportioned among the coastal states from Florida through Maine. The process to set the annual commercial quota and the percent allocated to each state are described in § 648.160.

The final rule implementing Amendment 1 to the Bluefish Fishery Management Plan, which was published on July 26, 2000 (65 FR 45844), provided a mechanism for bluefish quota to be transferred from one state to another. Two or more states, under mutual agreement and with the concurrence of the Administrator, Northeast Region, NMFS (Regional Administrator), can transfer or combine bluefish commercial quota under § 648.160(f). The Regional Administrator is required to consider the criteria in § 648.160(f)(1) in the evaluation of requests for quota transfers or combinations.

Florida has agreed to transfer 200,000 lb (90,718.5 kg) of its 2011 commercial quota to New York. This transfer was prompted by the diligent efforts of state officials in New York not to exceed the commercial bluefish quota. The Regional Administrator has determined that the criteria in § 648.160(f)(1) have been met. The revised bluefish quotas for calendar year 2011 are: Florida, 743,117 lb (337,072.2 kg); and New York, 1,173,624 lb (532,346.9 kg).

Classification

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

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

Dated: November 23, 2011.

Alan D. Risenhoover,

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

[FR Doc. 2011–30852 Filed 11–29–11; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 76, No. 230
Wednesday, November 30, 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–2011–1258; Directorate Identifier 2011–NM–184–AD]

RIN 2120–AA64

Airworthiness Directives; Learjet Inc. Model 60 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 Learjet Inc. Model 60 airplanes. This proposed AD was prompted by two incidents of swapped fire extinguishing wires. This proposed AD would require inspecting the electrical leads routed to the fire extinguishing containers for proper identification and missing labels, and to ensure the electrical leads are connected to the correct squibs; and corrective actions if necessary. We are proposing this AD to prevent the extinguishing agent of the fire extinguishing container from being delivered to the wrong engine in the event of an engine fire, and a consequent uncontrolled fire.

DATES: We must receive comments on this proposed AD by January 17, 2012.

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

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

For service information identified in this proposed AD, contact Learjet, Inc., One Learjet Way, Wichita, Kansas 67209–2942; telephone (316) 946–2000; fax (316) 946–2220; email *ac.ict@aero.bombardier.com;* Internet *http://www.bombardier.com.* You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, 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: James Galstad, Aerospace Engineer, Mechanical Systems and Propulsion Branch, ACE–116W, FAA, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas 67209; *phone:* (316) 946–4135; *fax:* (316) 946–4107; *email: james.galstad@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2011–1258; Directorate Identifier 2011–NM–184–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

Discussion

We received a report of two incidents of swapped left and right fire extinguishing wires. Due to the locations of the forward and aft squibs of the fire extinguishing containers, it is possible to reverse the electrical wiring between the left and right squibs. Incorrect wire labeling and improper wiring of the squibs could cause the extinguishing agent of the fire extinguishing container to be delivered to the wrong engine in the event of an engine fire. This condition, if not corrected, could result in an uncontrolled fire.

Relevant Service Information

We reviewed Bombardier Service Bulletin 60–26–4, dated May 2, 2011. The service information describes procedures for inspecting the electrical leads routed to the fire extinguishing containers for proper identification and missing labels, and to ensure the electrical leads are connected to the correct squibs; and corrective actions if necessary. The corrective actions include correcting wiring labels with a permanent marker or replacing the labels with new heat shrink tubing or heat rated tape and identifying them properly, and correcting the wire routing.

FAA's Determination

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

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in the service information described previously.

Costs of Compliance

We estimate that this proposed AD affects 232 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
Inspection	3 work-hours × $85 per hour = $255	0	$255	$59,160

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

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Corrective actions	1 work-hour × $85 per hour = $85	$8	$93

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Learjet Inc.: Docket No. FAA–2011–1258; Directorate Identifier 2011–NM–184–AD.

(a) Comments Due Date

We must receive comments by January 17, 2012.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Learjet Inc. Model 60 airplanes, certificated in any category, serial numbers 60–002 through 60–366 inclusive.

(d) Subject

Joint Aircraft System Component (JASC)/ Air Transport Association (ATA) of America Code 2620, Extinguishing system.

(e) Unsafe Condition

This AD was prompted by two incidents of swapped fire extinguishing wires, which could cause the extinguishing agent of the fire extinguishing container to be delivered to the wrong engine in the event of an engine fire, and a consequent uncontrolled fire. We are issuing this AD to correct the unsafe condition on these products.

(f) Compliance

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

(g) Inspection and Corrective Actions

Within 300 flight hours after the effective date of this AD, or at the next auxiliary power unit (APU) removal, whichever occurs first: Inspect the electrical leads routed to the fire extinguishing containers for proper identification and missing labels, and to ensure the electrical leads are connected to the correct squibs, as specified in Bombardier Service Bulletin 60–26–4, dated May 2, 2011. Do the inspection in accordance with paragraph 3., ''Accomplishment Instructions,'' of Bombardier Service Bulletin 60–26–4, dated May 2, 2011. If any misidentification is found, or if any label is missing, or if the electrical leads are not connected to the correct squibs, as specified in Bombardier Service Bulletin 60–26–4, dated May 2, 2011: Before further flight, do all applicable corrective actions, in accordance with paragraph 3., ''Accomplishment Instructions,'' of Bombardier Service Bulletin 60–26–4, dated May 2, 2011.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Wichita Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in the Related Information section of this AD.

(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.

(i) Related Information

(1) For more information about this AD, contact James Galstad, Aerospace Engineer, Mechanical Systems and Propulsion Branch, ACE–116W, Wichita Aircraft Certification Office, FAA, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas 67209; *phone:* (316) 946–4135; *fax:* (316) 946–4107; *email: james.galstad@faa.gov.*

(2) For service information identified in this AD, contact Learjet, Inc., One Learjet Way, Wichita, Kansas 67209–2942; telephone (316) 946–2000; fax (316) 946–2220; email ac.ict@aero.bombardier.com; Internet *http://www.bombardier.com.* You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call (425) 227–1221.

Issued in Renton, Washington, on November 22, 2011.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–30822 Filed 11–29–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–1257; Directorate Identifier 2011–NM–124–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 Boeing Company Model 777–200, –200LR, and –300ER series airplanes. This proposed AD was prompted by a report from the manufacturer indicating that the lowered ceiling support structure of Section 41, in airplanes incorporating the overhead space utilization (OSU) option, was found to be under-strength when subjected to a 9.0 g forward load. This proposed AD would require installing new structural members in and new tie rod(s) and attach fittings on the left and right sides of the lowered ceiling support structure. We are proposing this AD to prevent the forward lowered ceiling panels and support structure from becoming dislodged during an occurrence of a 9.0 g forward load and consequent injury to personnel or interference with an emergency evacuation.

DATES: We must receive comments on this proposed AD by January 17, 2012.

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

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

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, 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: Ana Martinez Hueto, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057–3356; *phone:* (425) 917–6592; *fax:* (425) 917–6591; *email: ana.m.hueto@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2011–1257; Directorate Identifier 2011–NM–124–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

Discussion

We received a report from the manufacturer indicating that the lowered ceiling support structure of Section 41, in airplanes incorporating the OSU option, was found to be under-strength when subjected to a 9.0 g forward load. This condition, if not corrected, could cause the forward lowered ceiling panels and support structure to become dislodged during an occurrence of a 9.0 g forward load and consequent injury to personnel or interference with an emergency evacuation.

Relevant Service Information

We reviewed Boeing Special Attention Service Bulletin 777–25–0482, dated February 24, 2011. This service information describes procedures for installing new structural members and new tie rod(s) and attach fittings on the left and right sides of the lowered ceiling support structure.

FAA's Determination

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

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in the service information described previously.

Costs of Compliance

We estimate that this proposed AD affects 4 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
Inspection and Installation	19 work-hours × $85 per hour = $1,615	$13,329	$14,944	$59,776

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

The Boeing Company: Docket No. FAA–2011–1257; Directorate Identifier 2011–NM–124–AD.

(a) Comments Due Date

We must receive comments by January 17, 2012.

(b) Affected ADs

None.

(c) Applicability

(1) This AD applies to the Boeing Company Model 777–200, –200LR, and –300ER series airplanes, certificated in any category, as identified in Boeing Special Attention Service Bulletin 777–25–0482, dated February 24, 2011.

(d) Subject

Joint Aircraft System Component (JASC)/Air Transport Association (ATA) of America Code 25: Equipment/Furnishings.

(e) Unsafe Condition

This AD was prompted by a report from the manufacturer indicating that the lowered ceiling support structure of Section 41, in airplanes incorporating the overhead space utilization (OSU) option, was found to be under-strength when subjected to a 9.0 g forward load. We are issuing this AD to prevent the forward lowered ceiling panels and support structure from becoming dislodged during an occurrence of a 9.0 g forward load and consequent injury to personnel or interference with an emergency evacuation.

(f) Compliance

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

(g) Installation of Lowered Ceiling Support Structure

Within 60 months after the effective date of this AD, install new structural members and new tie rod(s) and attach fittings on the left and right sides of the lowered ceiling support structure in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 777–25–0482, dated February 24, 2011.

(h) Alternative Methods of Compliance (AMOCs)

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

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

(i) Related Information

(1) For more information about this AD, contact Ana Martinez Hueto, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057–3356; *phone:* (425) 917–6592; *fax:* (425) 917–6591; *email: ana.m.hueto@faa.gov.*

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P. O. Box 3707, MC 2H–65, Seattle, 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 22, 2011.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–30821 Filed 11–29–11; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2010–0671; FRL–9498–5]

Approval and Promulgation of Implementation Plans; Illinois; Volatile Organic Compound Emission Control Measures for Chicago and Metro-East St. Louis Ozone Nonattainment Areas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: On July 29, 2010, September 16, 2011, and September 29, 2011, the Illinois Environmental Protection Agency (IEPA) submitted several volatile organic compound (VOC) rules for approval into its State Implementation Plan (SIP). The purpose of these rules is to satisfy the Clean Air Act's (the Act) requirement that States revise their SIPs to include reasonably available control technology (RACT) for sources of VOC emissions in moderate ozone nonattainment areas. Illinois' VOC rules provide RACT requirements for the Chicago and Metro-East St. Louis 8-hour ozone nonattainment areas. These rules are approvable because they are consistent with the Control Technique Guideline (CTG) documents issued by EPA in 2006, 2007, and 2008 and satisfy the RACT requirements of the Act.

DATES: Comments must be received on or before December 30, 2011.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2010–0671, by one of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Email: aburano.douglas@epa.gov.*
- *Fax:* (312) 408–2279.
- *Mail:* Douglas Aburano, Chief, Attainment Planning and Maintenance Section (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.
- *Hand Delivery:* Douglas Aburano, Chief, Attainment Planning and Maintenance Section (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, 18th floor, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office's normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. EPA–R05–OAR–2010–0671. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or email. 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 instructions on submitting comments, go to Section I of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. We recommend that you telephone Steven Rosenthal at (312) 886–6052 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Steven Rosenthal, Environmental Engineer, Attainment Planning & Maintenance Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6052, *rosenthal.steven@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA. This supplementary information section is arranged as follows:

I. What should I consider as i prepare my comments for EPA?
II. What action is EPA taking today?
III. What is the purpose of this action?
IV. What is EPA's analysis of Illinois' submitted VOC rules?
V. Statutory and Executive Order Reviews

I. What should I consider as I prepare my comments for EPA?

When submitting comments, remember to:

1. Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date, and page number).
2. Follow directions—EPA may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
3. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
4. Describe any assumptions and provide any technical information and/or data that you used.
5. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
6. Provide specific examples to illustrate your concerns, and suggest alternatives.
7. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
8. Make sure to submit your comments by the comment period deadline identified.

II. What action is EPA taking today?

EPA is proposing to approve into the Illinois SIP several new VOC rules at 35 Illinois Adm. Code 211, 218, and 219, which set out RACT requirements for categories of VOC sources in two ozone nonattainment areas. These rules correspond to and are consistent with the source categories and control recommendations in the CTGs issued by EPA in 2006, 2007, and 2008. Illinois adopted new rules for industrial cleaning solvents, flat wood paneling coatings, flexible packaging printing materials, lithographic printing materials, letterpress printing materials,

paper, film and foil coatings, metal furniture coatings, large appliance coatings, miscellaneous metals and plastic parts coatings, auto and light-duty truck coatings, miscellaneous industrial adhesives, and fiberglass boat manufacturing materials. Illinois also adopted several other related revisions, which were mostly corrections to improve the effectiveness of its existing VOC rules.

III. What is the purpose of this action?

The primary purpose of these rules is to satisfy the requirement in section 182(b) of the Act that VOC RACT rules be adopted for nonattainment areas for the source categories covered by the CTG documents issued by EPA in 2006, 2007, and 2008. The Chicago and Metro-East St. Louis areas are classified as moderate nonattainment for the 8-hour ozone national ambient air quality standard. See 40 CFR 81.314.

Section 182(b)(2) of the Act requires that for areas classified as moderate or above for ozone nonattainment States must revise their SIPs to adopt RACT requirements for VOC sources that are covered by CTGs. RACT is defined as the lowest emissions limitation 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 53762, September 17, 1979). A CTG provides information on determining RACT for a source category including recommendations on control options and enforcement provisions for the category.

IV. What is EPA's analysis of Illinois' submitted VOC rules?

As discussed previously, EPA issued new CTGs in 2006, 2007, and 2008. EPA has reviewed Illinois' new VOC rules for the source categories covered by these CTGs, and proposes to find that these rules are consistent with the control measures, definitions, recordkeeping and test methods in these CTGs and applicable EPA RACT guidance at *http://www.epa.gov/ttn/naaqs/ozone/ozonetech/#ref.* Therefore EPA is proposing to approve these rules as meeting the RACT requirements in the Act. The definitions in 35 Illinois Adm. Code Part 211 apply to both the Chicago and Metro-East St. Louis 8-hour ozone nonattainment areas. 35 Illinois Adm. Code Part 218 contains the volatile organic material (VOM), which is the same as VOC, emission standards and limitations for specified categories of VOM sources in the Chicago Area and Part 219 contains the VOM emission standards and limitations for the same categories of VOM sources in the Metro-East St. Louis Area. The General Provisions for Parts 218 and 219 include test methods and procedures to ensure enforceability of the VOM limits. A brief discussion of these rules follows.

(1) Section 211—Definitions

Revisions to this section primarily consist of new definitions that are needed to support the new and revised rules. These definitions are consistent with EPA RACT guidance and are approvable.

(2) Sections 218.187 and 219.187—Other Industrial Solvent Cleaning Operations

These new regulations are based on EPA's 2006 CTG for Industrial Cleaning Solvents. The requirements of these sections apply to all cleaning operations that emit 500 pounds of VOM per month. This section contains VOM content limits for cleaning solutions, depending upon the type of cleaning being performed. Compliance can also be achieved by using a cleaning solution that does not exceed 8.00 millimeters of mercury (mmHg) or by use of add-on control (*i.e.,* an afterburner or carbon adsorber) that achieves 85 percent control. Work practices (*e.g.* cover open containers) are also required to further reduce emissions. Recordkeeping requirements are also included to establish applicability and whether subject sources are in compliance.

(3) Sections 218.204–218.219 and 218.204–218.219—Coating Operations

Illinois' surface coating regulations being proposed for approval include requirements for applicability, emissions limits, control techniques, and work practices. These regulations are based on the relevant 2006, 2007, and 2008 CTGs. For example, based upon the applicability cutoffs for the surface coating rules, which are contained in sections 218.208 and 219.208, the various surface coating emission limits apply to sources with emissions of VOMs (resulting from the application of surface coatings) equal to or greater than 15 pounds (6.8 kilograms) per day, or an equivalent level of 2.7 tons per 12 month rolling period.

The categories of Illinois' surface coating regulations being proposed for approval in this action are identified below.

Flat Wood Paneling—These regulations have been revised based on EPA's 2006 CTG for Flat Wood Paneling Coatings. Illinois' VOM content limits are 2.1 pounds VOM/gallon of coating or 2.9 pounds VOM/gallon of solids, which are consistent with the CTG. When compliance is achieved by the use of add-on control, the required overall control efficiency of 90 percent is also consistent with the CTG.

Large Appliance Coatings—These regulations have been revised based on EPA's 2007 CTG for Large Appliance Coatings. Emission limits, *e.g.* 2.3 pounds VOM/gallon for general, one component coatings, are consistent with the CTG. When compliance is achieved by the use of add-on control, the required overall control efficiency of 90 percent is also consistent with the CTG.

Metal Furniture Coatings—These regulations have been revised based on EPA's 2007 CTG for Metal Furniture Coatings. Emission limits, *e.g.* 2.3 pounds VOM/gallon for general, one component coatings, are consistent with the CTG. When compliance is achieved by the use of add-on control, the required overall control efficiency of 90 percent is also consistent with the CTG.

Paper, Film, and Foil Coatings—These regulations have been revised based on EPA's 2007 CTG for Paper, Film, and Foil Coatings. Illinois' VOM content limits are 0.20 pounds VOM/pound of solids applied for pressure sensitive tape and label surface coatings, and 0.40 pounds VOM/pound solids applied for all other paper coatings, which are consistent with the CTG. When compliance is achieved by the use of add-on control, the required overall control efficiency of 90 percent is also consistent with the CTG.

Miscellaneous Metal and Plastic Parts Coatings—These regulations have been revised based on EPA's 2008 CTG for Miscellaneous Metal Products Coatings and Plastic Parts Coatings. Emission limits, *e.g.* 2.3 pounds VOM/gallon for general, one component coatings, are consistent with the CTG. When compliance is achieved by the use of add-on control, the required overall control efficiency of 90 percent is also consistent with the CTG.

Automobile and Light-duty Truck Assembly Coatings—These regulations have been revised based on EPA's 2008 CTG for Auto and Light-Duty Truck Assembly Coatings. Emission limits, *e.g.* 1.44 pounds VOM/gallon coating solids deposited for topcoat operations, are consistent with the CTG. As specified in the CTG, compliance with these limits is based on EPA's ''Protocol for Determining the Daily VOC Emission Rate of Automobile and Light-Duty Truck Primer-Surfacer and Topcoat Operations.'' This testing protocol considers the VOM content limit, the transfer efficiency and the efficiency of add-on control to establish compliance with the applicable emission limit.

(4) Graphic Arts

Illinois' graphic arts regulations being proposed for approval in this action include applicability and control requirements, and are based on the relevant 2006 CTGs. The categories of Illinois graphic arts regulations being proposed for approval in this action are identified below.

Sections 218.401–404 and 219.401–404—Flexible Package Printing

These regulations have been revised based on EPA's 2006 CTG for Flexible Packaging Printing Materials. Subject printing lines may comply by meeting limits of 0.8 pounds VOM per pound of solids applied or 0.16 pounds VOM per pound of ink and coatings applied.

Alternatively, compliance can be achieved by the use of add-on control achieving an overall reduction in VOM emissions ranging from 65 percent to 80 percent, depending upon when the printing line and control device were constructed. Work practices to reduce emissions from the use of VOM containing cleaning materials are also required. Recordkeeping requirements are also specified to establish applicability and compliance with the applicable limits.

Sections 218.405–411 and 219.405–411—Lithographic Printing

These regulations are based on EPA's 2006 CTG for Lithographic Printing. The control requirements for cleaning materials and fountain solutions apply if the combined emissions of VOM exceed 15 pounds per day. The add-on control requirements for heatset web offset printing operations apply if the combined emissions of VOM from all lithographic printing lines at the source ever exceed 100 pounds per day. The fountain solution is subject to a percent VOM limit, based upon the temperature and whether or not the fountain solution contains alcohol. The cleaning materials must not exceed 70 percent by weight VOM or the VOM composite partial pressure must be less than 10 mmHg. An add-on control device on a subject heatset dryer must achieve a 90 percent or 95 percent reduction of VOM emissions, depending on the installation date of the add-on control device, or alternatively can comply by not exceeding an outlet concentration of 20 parts per million by volume (ppmv), as carbon. Recordkeeping requirements are also specified to establish applicability and compliance with the applicable limits.

Sections 218.412–417 and 219.412–417—Letterpress Printing

These regulations are based on EPA's 2006 CTG for Letterpress Printing. The control requirements for cleaning materials apply if the combined emissions of VOM exceed 15 pounds per day. The add-on control requirements for heatset web letterpress printing operations apply if the combined emissions of VOM from all heatset web letterpress printing lines have a total potential to emit 25 tons or more of VOM per year. The cleaning materials must not exceed 70 percent by weight VOM or the VOM composite partial pressure must be less than 10 mmHg. An add-on control device on a subject heatset dryer must achieve a 90 percent or 95 percent reduction of VOM emissions, depending on the installation date of the add-on control device, or alternatively can comply by not exceeding an outlet concentration of 20 ppmv, as carbon. Recordkeeping requirements are also specified to establish applicability and compliance with the applicable limits.

(5) Sections 218.900–218.904 and 218.900–904—Miscellaneous Industrial Adhesives

These new regulations are based on EPA's 2008 CTG for Miscellaneous Industrial Adhesive Application Operations. The control requirements for miscellaneous industrial adhesive application operations apply if the combined emissions of VOM from all such operations equal or exceed 15 pounds per day. Subject adhesive application operations must either meet the specific VOM content limitations, depending upon the substrate being bonded (*e.g.* 0.3 pounds VOM per gallon of adhesive for bonding metal) or use an add-on control system that achieves an overall VOM reduction of at least 85 percent. Specific adhesive application methods (*e.g.* electrostatic spray) and work practices are also required to reduce emissions. Recordkeeping requirements are also specified to establish applicability and compliance with the applicable limits.

(6) Sections 218.890–218.904 and 219.890–904—Fiberglass Boat Manufacturing Materials

These new regulations are based on EPA's 2008 CTG for Fiberglass Boat Manufacturing Materials. The control requirements for fiberglass boat manufacturing operations apply if the combined emissions of VOM from all such operations equal or exceed 15 pounds per day. This rule covers open molding and gel coat operations, resin and gel coat mixing operations, and resin and gel coat application equipment cleaning operations. Emission limits are consistent with the CTG, as are VOC content and vapor pressure limits applicable to cleaning activities in fiberglass boat manufacturing.

Subject facilities can comply by using specified monomer VOM content limits (*e.g.* production resin applied via atomized spray would need to comply with a weighted average monomer VOM content limit of 28 percent by weight) and a non-monomer VOM content limit of 5 percent. An emission averaging option is also available.

The VOM containing cleaning solutions for routine cleaning of application equipment must either be no more than 5 percent VOM, by weight, or the composite vapor pressure must be no more than 0.50 mmHg. Also, mixing containers that are 55 gallons, or greater, must be covered. Recordkeeping requirements are also specified to establish applicability and compliance with the applicable limits.

V. Statutory and Executive Order Reviews

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

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

• Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the 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 rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: November 17, 2011.

Susan Hedman,

Regional Administrator, Region 5.

[FR Doc. 2011–30844 Filed 11–29–11; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CG Docket Nos. 11–116 and 09–158; CC Docket No. 98–170; FCC 11–106; DA 11–1860]

Empowering Consumers to Prevent and Detect Billing for Unauthorized Charges (''Cramming''); Consumer Information and Disclosure; Truth-in-Billing and Billing Format

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; extension of reply comment period.

SUMMARY: In this document, the Commission extends the deadline to for filing reply comments on the Commission's Notice of Proposed Rulemaking (NPRM) seeking comment on various proposals designed to assist consumers in detecting and preventing the placement of unauthorized charges on the their telephone bills, an unlawful and fraudulent practice commonly referred to as cramming. The extension will facilitate the development of a full record given the importance of the issues in this proceeding.

DATES: Reply comments are due on or before December 5, 2011.

ADDRESSES: You may submit reply comments, identified by CG Docket No. 11–116 by any of the following methods:

• *Federal Communications Commission's Web site:* Follow the instructions for submitting comments.

• *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) *by email: FCC504@fcc.gov* or *phone:* (202) 418–0530 or TTY: (202) 418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: John B. Adams, FCC, Consumer and Governmental Affairs Bureau, Consumer Policy Division, at (202) 418–2854 (voice), or e-mail *JohnB.Adams@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Order, document DA 11–1860, adopted on November 4, 2011, and released on November 4, 2011, in CG Docket Nos. 11–116 and 09–158, and CC Docket No. 98–170, which extends the reply comment filing deadline established in FCC 11–106, published at 76 FR 52625, August 23, 2011. The full text of document DA 11–1860 and copies of any subsequently filed documents in this matter will be available for public inspection and copying during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street SW., Room CY–A257, Washington, DC 20554. They may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., Portals II, 445 12th Street SW., Room CY–B402, Washington, DC 20554, *telephone:* (202) 488–5300, *fax:* (202) 488–5563, or *Internet: http://www.bcpiweb.com.* The full text of document DA 11–1860 may also be downloaded at *http://www.fcc.gov.* To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an e-mail to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY). Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415 and 1.419, interested parties may file reply comments on or before the dates indicated in the **DATES** section of this document. Comments may be filed using: (1) The Commission's Electronic Comment Filing System (ECFS); or (2) by filing paper copies. All filings should reference the docket number of this proceeding, CG Docket No. 11–116.

• *Electronic Filers:* Comments may be filed electronically using the Internet by accessing the ECFS: *http://fjallfoss.fcc.gov/ecfs2/.* Filers should follow the instructions provided on the website for submitting comments. In completing the transmittal screen, ECFS filers should include their full name, U.S. Postal Service mailing address, and CG Docket No. 11–116.

• *Paper Filers:* Parties who choose to file by paper must file an original and one copy 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. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

• All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th Street SW., Room TW–A325, Washington, DC 20554. The filing hours are 8 a.m. to 7 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes or boxes must be disposed of before entering the building.

• Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.

Background

Document FCC 11–106 established a comment deadline of October 24, 2011 and a reply comment deadline of November 21, 2011. On October 27, 2011, the National Association of State Utility Consumer Advocates (NASUCA) requested that the reply comment deadline be extended by 30 days because of the volume of initial comments and the occurrence of NASUCA's annual conference during the reply comment period. The Commission grants NASUCA's request in part.

As stated in § 1.46(a) of the Commission's rules, 47 CFR 1.46(a), the Commission's policy is that extensions of time are not routinely granted. In the interest of encouraging development of a full record, the Commission believes

that an extension of time is in the public interest and that a 14-day extension will provide adequate time for development of reply comments. The Commission grants a 14-day extension of the reply comment deadline.

Ordering Clauses

Pursuant to sections 4(i) and 4(j) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), (j), and § § 0.141, 0.361, and 1.46 of the Commission's rules, 47 CFR 0.141, 0.361, 1.46, that the Motion for Extension of Time to File Reply Comments filed by the National Association of State Utility Consumer Advocates *is granted* to the extent indicated herein and *is otherwise denied,* and the deadline for filing reply comments in response to document FCC 11–106 *is extended* to December 5, 2011.

Federal Communications Commission.

William Freedman,

Deputy Chief, Consumer and Governmental Affairs Bureau.

[FR Doc. 2011–30783 Filed 11–29–11; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R1–ES–2011–0096; 4500030114]

RIN 1018–AX38

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for the Southern Selkirk Mountains Population of Woodland Caribou (Rangifer tarandus caribou)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to designate critical habitat for the southern Selkirk Mountains population of woodland caribou (*Rangifer tarandus caribou*) under the Endangered Species Act of 1973, as amended (Act). In total, approximately 375,562 acres (151,985 hectares) are being proposed for designation as critical habitat. The proposed critical habitat is located in Boundary and Bonner counties in Idaho, and Pend Oreille County in Washington.

DATES: We will accept comments received on or before January 30, 2012. Please note that if you are using the Federal eRulemaking Portal (see **ADDRESSES**, below), the deadline for submitting an electronic comment is 11:59 p.m. Eastern Standard Time on this date. We must receive requests for public hearings, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by January 17, 2012.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Keyword box, enter Docket No. FWS–R1–ES–2011–0096, which is the docket number for this rulemaking. Then, in the Search panel on the left side of the screen, under the Document Type heading, click on the Proposed Rules link to locate this document. You may submit a comment by clicking on ''Submit a Comment or Submission.''

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, *Attn:* FWS–R1–ES–2011–0096; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, MS 2042–PDM; Arlington, VA 22203.

We request that you send comments only by the methods described above. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see the **PUBLIC COMMENTS** section below for more information).

FOR FURTHER INFORMATION CONTACT: Brian T. Kelly, State Supervisor, U.S. Fish and Wildlife Service, Idaho Fish and Wildlife Office, 1387 S. Vinnell Way, Room 368, Boise, ID 83709; telephone (208) 378–5243; facsimile (208) 378–5262. If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at (800) 877–8339.

SUPPLEMENTARY INFORMATION:

Public Comments

We intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or information from other concerned government agencies, the scientific community, industry, or other interested party concerning this proposed rule. We particularly seek comments concerning:

(1) The reasons why we should or should not designate habitat as ''critical habitat'' under section 4 of the Act (16 U.S.C. 1531 *et seq.*) including whether there are threats to the southern Selkirk Mountains population of woodland caribou from human activity, the degree of which can be expected to increase due to the designation, such that the designation of critical habitat may not be prudent.

(2) Specific information on:

(a) The amount and distribution of the southern Selkirk Mountains woodland caribou habitat in the United States;

(b) What areas occupied at the time of listing contain the physical and biological features essential to the conservation of the species should be included in the designation and why; and

(c) Special management considerations or protections that the features essential to the conservation of southern Selkirk Mountains woodland caribou identified in this proposal may require, including managing for the potential effects of climate change; and

(d) What areas not occupied at the time of listing are essential for the conservation of the species and why.

(3) Land use designations and current or planned activities in the subject areas and their possible impacts on proposed critical habitat.

(4) Any probable economic, national security, or other relevant impacts of designating any area that may be included in the final designation. We are particularly interested in any impacts on small entities or families, and the benefits of including or excluding areas that exhibit these impacts.

(5) Information on the projected and reasonably likely impacts of climate change on southern Selkirk Mountains woodland caribou and the proposed critical habitat.

(6) Whether any specific areas we are proposing for critical habitat designation should be considered for exclusion under section 4(b)(2) of the Act, and whether the benefits of potentially excluding any specific area outweigh the benefits of including that area under section 4(b)(2) of the Act and why.

(7) Whether we could improve or modify our approach to designating critical habitat in any way to provide for greater public participation and understanding, or to better accommodate public concerns and comments.

You may submit your comments and materials concerning this proposed rule by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**.

We will post your entire comment—including your personal identifying information—on *http://www.regulations.gov.* You may request at the top of your document that we

withhold personal information, such as your name, street address, phone number, or email address from public review; however, we cannot guarantee that we will be able to do so.

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *http://www.regulations.gov,* or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Idaho Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Background

In this proposed rule for designation of critical habitat, we intend to discuss only those topics directly relevant to the designation of critical habitat for this species. For more detailed information on the biology of and threats to the southern Selkirk Mountains population of woodland caribou, please refer to the final listing rule published in the **Federal Register** on February 26, 1984 (49 FR 7390), and the Southern Selkirk Mountain Caribou 5-Year Review completed by the Service on December 2, 2008 (USFWS 2008a). Detailed information on the southern Selkirk Mountains population of woodland caribou directly relevant to designation of critical habitat is discussed under the *Primary Constituent Elements* section below.

Species Information

Woodland caribou are a subspecies of caribou with a historically wide distribution across Canada. In British Columbia, Canada (B.C.) there are three recognized ecotypes of woodland caribou: Mountain (alpine; arboreal lichen winter feeding group), northern (lives in central and northern B.C.), and boreal (restricted to the lowland plains of northeastern B.C.). The mountain ecotype of woodland caribou is the ecotype found in the United States (U.S.). Each ecotype is generally differentiated by the type of habitat occupied, movement patterns, and feeding behavior. Ecotypes are described as classes of populations adapted to different landscapes or environments as expressed by their movements and feeding behavior (COSEWIC 2002, p. 13).

The mountain ecotype of woodland caribou, to which the endangered southern Selkirk Mountains population belongs, occurs in high elevations (generally above 4,000 feet (ft) (1,220 meters (m)), steep terrain of the mountainous southeastern and east-central portions of B.C., and the Selkirk Mountains of northern Idaho and northeastern Washington (USFWS 1994, p. 6; USFWS 2008a, p. 2). They primarily occupy old-growth western red cedar (*Thuja plicata*)/hemlock (*Tsuga heterophylla*) and Engelmann spruce (*Picea engelmannii* or *P. glauca* x *engelmannii*)/subalpine fir (*Abies lasiocarpa*) forests that typically have high snow levels. Unlike other caribou, mountain caribou do not aggregate into large herds (USFWS 1994, p. 11). They have been characterized as ''shy'' forest dwellers, coming together only in small groups that do not migrate over great distances. The largest groups are encountered during the rut and late winter, whereas spring and summer groups are generally small (MCTAC 2002, p. 4). This is likely a predator-avoidance tactic (Paquet 1997, p. 9; Seip *et al.* 1994, p. 77). In contrast to the seasonal, long-distance migrations undertaken by some caribou subspecies, mountain caribou make strong seasonal elevational movements in response to seasonal habitat factors, such as snow level, food availability, and predator avoidance.

The density of caribou populations in B.C. appears to be related to their ability to become spatially separated from predators during the summer months, when the abundance of wolves is largely determined by the availability of other prey species. Consequently, caribou that migrate to alpine habitats during the summer reduce their exposure to predators (Bergerund *et al.,* 1984 and Seip, 1992 *in* Seip *et al.* 1994, p. 77). Prior to the increase in moose abundance in B.C. during the 1900's, it is likely that higher densities of caribou were able to coexist with wolves. However, when moose numbers increased, caribou that lived in close proximity to moose habitat were eliminated or greatly reduced, and the caribou remaining today represent animals that were more effective at spacing away from moose and wolves in summer. It appears the effectiveness of predator avoidance strategies is the dominant factor that determines the natural population density of caribou populations in B.C. (Seip *et al.* 1994, p. 78).

Geographic Range

Currently, the entire global population of the southern Selkirk Mountains population of woodland caribou occurs within B.C., Idaho, and Washington, where they are considered to be at risk of extirpation (USFWS 2008a, p. 10). The southern Selkirk Mountains woodland caribou population is now the southernmost extant population of mountain caribou and the last remaining mountain caribou population in the U.S. (IDFG CWCS Appendix F 2005, p. 373; USFWS 2008a, p. 12). In Idaho, caribou have historically been reported from the 1880s as far south as the St. Joe River and at Elk City near the Clearwater River (Evans 1960, pp. 59–64), and also in the city of St. Maries as recently as 1959 (Evans 1960, p. 93). The current range extends approximately 484 miles (mi) (779 kilometer (km)) in a northwest to southeast direction from the north end of the Hart Ranges in B.C. to the south end of the Selkirk Mountains in Idaho and Washington (see Figure 1).

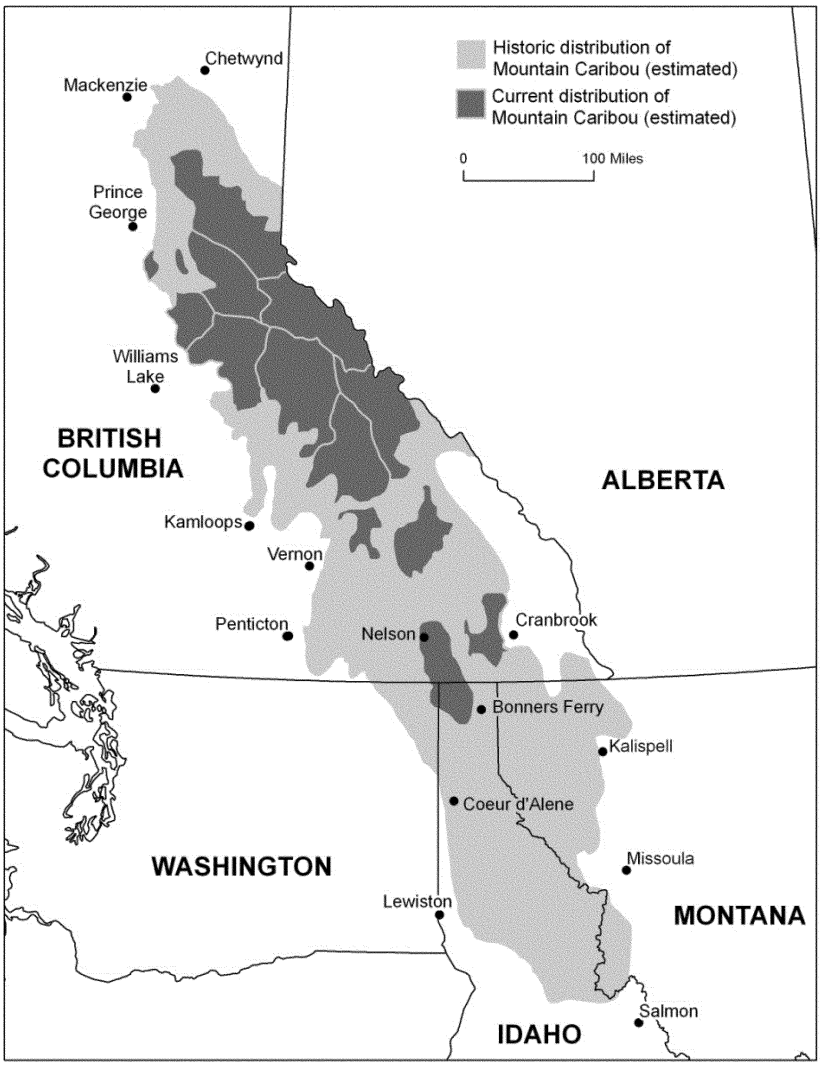


Figure 1. Historical and current distribution of mountain caribou

The southern Selkirk Mountains woodland caribou population is separated by 30–60 mi (48–96 km) from the next closest local populations to the north and east in B.C. (USFWS 2008a, p. 12). Although caribou numbers in the southern Selkirk Mountains population have fluctuated over the last few decades, augmentation efforts between 1987 and 1990, and 1996 and 1998, from northern caribou herds in B.C. has allowed this herd to have a modest increase (average of 7 percent) in population over the last 5 to 10 years (USFWS 2008a, pp. 15–16). Annual surveys are conducted by Idaho Fish and Game (IDFG), with both fixed-wing aircraft and a helicopter, using standard survey protocols developed for caribou (Wakkinen *et al.* 2009, pp. 3, 5–6). In June 2009, IDFG estimated this population to be approximately 46 animals; 3 of which were located within the U.S. portion of the range (Wakkinen *et al.* 2009, pp. 6–7). This represents an increase from the 30 individuals estimated at the time of listing (49 FR 7390–7394). Preliminary estimates reported from surveys conducted in late winter 2011 indicate the population to be approximately 36 animals; however, IDFG reports low confidence in that estimate due to poor weather conditions that limited aerial surveys (Wakkinen 2011, pers. comm.).

Ecology and Habitat

Southern Selkirk Mountains caribou are closely tied to old-growth coniferous forests of the Interior Wet-belt ecosystem of B.C. and the United States. Their survival depends on the ability to spread out over large areas of suitable habitat where it is difficult for predators to find them (Stevenson *et al.,* 2001, p. 1). Mountain caribou habitat is defined as old-growth forests (generally more than 100–150 years old), which support abundant arboreal lichens (the key winter food source of mountain caribou) (Stevenson *et al.* 2001, p. 1; USFWS 2008a, p. 20).

All caribou are principally grazers, and exhibit selective foraging behaviors for grasses, flowering plants, horsetails, willow and dwarf birch leaves and tips, sedges, and lichens in spring and summer (Paquet 1997, pp. 13, 16). For southern Selkirk Mountains caribou, the fall and early winter diet consists largely of dried grasses, sedges, willow and dwarf birch tips, and arboreal lichens (Paquet 1997, p. 13). When the snow deepens, their diet consists almost exclusively of arboreal lichens, which are usually the only food available

(Paquet 1997, p. 13; MCTAC 2002, p. 11).

Southern Selkirk Mountains caribou habitat is typically represented by a combination of two vegetation zones: The cedar/hemlock zone at lower elevations and the subalpine fir/Engelmann spruce zone at higher elevations. Caribou also require transition areas and corridors between these two vegetation zones. In general, mountain caribou seasonal habitats consist of early winter, late winter, spring, calving, summer, and fall habitats, which are primarily within the above vegetation zones (Servheen and Lyon 1989, p. 235; USFS 2004, p. 18; USFWS 2008a, p. 20). Early-winter and late-winter habitats are usually considered to be the most important habitats to caribou, and represent the most limiting type of habitat on the landscape within the recovery area (USFS 2004, p. 19). These seasonal habitats are described under the *Physical and Biological Features* section below.

Previous Federal Actions

In 1980, the Service received petitions to list the South Selkirk Mountains population of woodland caribou as endangered under the Endangered Species Act from the Idaho Department of Fish and Game (IDFG) and Dean Carrier, a U.S. Forest Service (USFS) staff biologist and former chairman of the International Mountain Caribou Technical Committee (IMCTC). At that time, the population was believed to consist of 13 to 20 animals (48 FR 1722–1726). Following a review of the petition and other data readily available, the southern Selkirk Mountains woodland caribou population in northeastern Washington, northern Idaho, and southeastern B.C. was listed as endangered under the Act's emergency procedures on January 14, 1983 (48 FR 1722–1726). A second emergency rule was published on October 25, 1983 (48 FR 49245–49249), and a final rule listing the southern Selkirk Mountains woodland caribou population as endangered was published on February 29, 1984 (49 FR 7390–7394). The designation of critical habitat was determined to be not prudent at that time, since increased poaching could result from the publication of maps showing areas used by the species. A Management Plan/Recovery Plan for Selkirk Caribou was approved by the Service in 1985 (USFWS 1985), and revised in 1994 (USFWS 1994).

Notices of 90-day findings on two petitions to delist the southern Selkirk Mountains population of woodland caribou were published in the **Federal Register** on November 29, 1993 (58 FR 62623), and November 1, 2000 (65 FR 65287). Both petitions were submitted by Mr. Peter B. Wilson, representing the Greater Bonners Ferry Chamber of Commerce, Bonners Ferry, Idaho. Our response to both petitions stated that the petitions did not present substantial scientific or commercial information indicating that delisting of the woodland caribou may be warranted.

On August 17, 2005, a complaint was filed in Federal district court challenging two biological opinions issued by the Service, and USFS management actions within southern Selkirk Mountains caribou habitat and the recovery area. The plaintiffs included Defenders of Wildlife, Conservation Northwest, the Lands Council, Selkirk Conservation Alliance, Idaho Conservation League, and Center for Biological Diversity. The lawsuit challenged, in part, nonjeopardy biological opinions on the USFS Land and Resource Management Plans for the Idaho Panhandle (IPNF) and Coleville (CNF) National Forests, and the USFS' failure to comply with the incidental take statements in the biological opinions.

In December 2005, the Court granted a preliminary injunction prohibiting snowmobile trail grooming within the caribou recovery area on the IPNF during the winter of 2005–2006. In November 2006, the Court granted a modified injunction restricting snowmobiling and snowmobile trail grooming on portions of the IPNF within the southern Selkirk Mountains caribou recovery area. On February 14, 2007, the Court ordered a modification of the current injunction to add a protected caribou travel corridor connecting habitat in the U.S. portion of the southern Selkirk Mountains with habitat in B.C. This injunction is currently in effect, pending the completion of section 7 consultation on the IPNF's proposed winter travel plan.

On April 11, 2006, a notice of initiation of 5-year reviews for 70 species in Idaho, Oregon, Washington and Hawaii, and Guam was published in the **Federal Register** (69 FR 18345–8348), including the southern Selkirk Mountains population of woodland caribou. The Southern Selkirk Mountains Caribou Population 5-Year Review was completed December 5, 2008 (USFWS, 2008a).

On December 6, 2002, the Defenders of Wildlife, Lands Council, Selkirk Conservation Alliance, and Center for Biological Diversity (plaintiffs) petitioned the Service to designate critical habitat for the endangered southern Selkirk Mountains population of woodland caribou. On February 10, 2003, we acknowledged receipt of the plaintiff's petition, and stated we were unable to address the petition at that time due to budgetary constraints. On January 15, 2009, a complaint for declaratory and injunctive relief (*Defenders of Wildlife et al.,* v. *Salazar,* CV–09–15–EFS) was filed in Federal District Court, alleging that the Service's failure to make a decision more than 6 years after the petition was submitted violated the Administrative Procedure Act (5 U.S.C. 551–559, 701–706). In a stipulated settlement agreement, we agreed to make a critical habitat prudency determination, and if determined to be prudent, to submit a proposed critical habitat rule to the **Federal Register** on or before November 20, 2011, and a final critical habitat rule by November 20, 2012.

Prudency Determination

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12), require that, to the maximum extent prudent and determinable, the Secretary designate critical habitat at the time the species is determined to be endangered or threatened. The final rule listing the southern Selkirk Mountains population of woodland caribou as an endangered species (49 FR 7390; February 29, 1984) states that designation of critical habitat would not be prudent, because critical habitat designation would require publication and extensive publicity of the precise areas occupied by the herd and the kind of habitat utilized. As a result, there would be a serious risk of facilitating poaching, which was identified as an important cause of the decline of the herd. A designation of critical habitat is not prudent when one or both of the following situations exist: (1) The species is threatened by taking or other human activity, and the identification of critical habitat can be expected to increase the degree of threat to the species, or (2) such designation of critical habitat would not be beneficial to the species (50 CFR 424.12(a)(1)(i) and (ii)). As we agreed in the settlement agreement, we have re-evaluated our previous ''not prudent'' finding regarding critical habitat designation for the southern Selkirk Mountains woodland caribou population and the information supporting our previous findings. We have also evaluated information and analysis that has become available to us subsequent to publication of the February 29, 1984, final rule. We have reviewed the best available information and now determine the designation of critical

habitat for the southern Selkirk Mountains population of woodland caribou would not be expected to increase the degree of threat by poaching, since increased education and awareness have made illegal poaching less of a threat than at the time of listing. Accordingly, we no longer find designation of critical habitat to be ''not prudent'' under our regulations, and have determined that the designation is prudent.

As stated above, section 4(a)(3) of the Act requires the designation of critical habitat concurrently with the species' listing ''to the maximum extent prudent and determinable.'' Our regulations at 50 CFR 424.12(a)(2) state that critical habitat is not determinable when one or both of the following situations exist:

(i) Information sufficient to perform required analyses of the impacts of the designation is lacking, or

(ii) The biological needs of the species are not sufficiently well known to permit identification of an area as critical habitat.

We reviewed the available information pertaining to the biological needs of this species and habitat characteristics where the species occurs. This and other information represent the best scientific data available, and the available information is sufficient for us to identify areas to propose as critical habitat. Therefore, we conclude that the designation of critical habitat is determinable for the southern Selkirk Mountains woodland caribou population.

Recovery Plan

The recovery strategy identified in the Selkirk Mountains Woodland Caribou Recovery Plan (USFWS 1994), is to maintain the existing two herds in the Selkirk ecosystem and establish a third herd in Washington State, and secure and manage at least 443,000 acres (ac) (179,000 hectares (ha)) of suitable and potential habitat in the Selkirks to support a self-sustaining population. Approximately 47 percent of the suitable and potential habitat identified in the recovery plan occurs within B.C., and 53 percent is within the U.S. (USFWS 1994, p. 4). Population modeling would be used to determine the projected size of a recovered population, and, pending environmental analysis, the existing herds would be augmented with mountain caribou from B.C. translocated to the western portion of the Selkirk Mountains in Washington (USFWS 1994, pp. 24–25). The recovery plan acknowledged some uncertainty about recovery objectives, and identified the need for monitoring to demonstrate the efficacy, or lack thereof, of the recovery plan. The intent was for the recovery plan to evolve into a biologically sound document using adaptive management, to help identify the specific objectives needed to ensure population viability and sustainability (USFWS 1994, p. 27).

The specific recovery tasks related to habitat (USFWS 1994, pp. 30–35) included:

- Conducting inventories;
- Determining habitat capability;
- Reducing the impacts of fire;
- Reducing impacts of insects and disease;
- Reducing impacts of timber management;
- Reducing or eliminating impacts of recreational activities;
- Establishing the recovery zone boundary; and
- Securing habitat.

Information needed to verify recovery objectives (USFWS 1994, pp. 36–42) included:

- Researching habitat needs;
- Determining caribou habitat relations;
- Evaluating timber management practices related to caribou habitat;
- Evaluating the effects of roads and motorized vehicles on caribou and their habitats;
- Developing, implementing, and validating the cumulative effects model;
- Conducting population research;
- Determining recovery goals and objectives;
- Determining the amount of habitat needed for a recovered population; and
- Establishing caribou in the western portion of the Selkirks in Washington.

The specific details of these objectives are available in the recovery plan, which has been provided as supplementary information to this proposed rule at *http://www.regulations.gov.*

5-Year Review

A 5-year review of a listed species is required by section 4(c)(2) of the Act, and considers all new available information concerning the population status of the species and the threats that affect it. This process can serve as an integral component of tracking recovery implementation, updating scientific understanding, and evaluating the status of the species. The Service conducts these periodic reviews to ensure the listing classification of a species as threatened or endangered is accurate. The 5-year status review considers the best scientific and commercial information that has become available since the original listing determination or last review, such as: species biology, habitat conditions, conservation measures, threat status and trends, and any other new information. The Service publishes a notice in the **Federal Register** announcing the initiation of these reviews, and provides the public an opportunity to submit relevant information regarding the species and its threats.

The 2008 Southern Selkirk Mountains Population of Woodland Caribou 5-Year Review acknowledged that the recovery criteria in the recovery plan (USFWS 1994) do not reflect the best available and most up to date information on the biology of the species and its habitat (USFWS 2008, p. 15). Since 1994, a great deal of information has been collected regarding caribou and their habitat, the effects of threats such as habitat fragmentation, predation and human access, and various options and approaches for recovery efforts. As is discussed in more detail in the Geographic Range section above, the southern Selkirk Mountains caribou population has been augmented twice over the last two decades. Between 1987 and 1990, the population was augmented with 60 animals from source herds in B.C., which were placed in the Idaho portion of the Selkirk ecosystem, establishing a second herd within the recovery area (USFWS 2008, p. 15). Over the last decade, the number of caribou in Idaho has dwindled, and the bulk of the population primarily occupy habitat in the B.C. portion of the recovery area, although there is continued movement back and forth across the B.C. and U.S. border. Between 1996 and 1998, the southern Selkirk Mountains population was augmented with 43 animals; some were placed in Washington and some were placed just north of the border in B.C. Unfortunately, the augmentation effort coincided with a high mountain lion population in the Selkirk ecosystem, and a number of the transplanted caribou were thought to have been lost to predation, although definitive data on many mortalities was lacking. Although neither the 1996 nor 1998 augmentations resulted in a long-term improvement in caribou distribution throughout the recovery area, the effort succeeded in maintaining and enhancing the number of caribou in the population as a whole, which was estimated at 46 animals in 2008 (USFWS 2008, pp. 15–16).

The current recovery plan establishes the actions and conservation objectives needed to recover the southern Selkirk Mountains population of the woodland caribou. The proposed critical habitat designation will support those objectives by identifying the specific geographic areas in the southern Selkirk

Mountains in Washington, and areas in Idaho, that (1) Were occupied at the time of listing (*i.e.,* within the area of normal utilization described in the final listing rule (49 FR 7390; February 29, 1984)); (2) provide the physical or biological features essential to the conservation of the species; and (3) may require special management considerations or protection. The recovery plan also states that for recovery, woodland caribou in the Selkirks must be distributed over a wider area than at present (USFWS 1994, p. 36). Optimally, this would include habitat in both B.C. and the U.S. We are not proposing to designate unoccupied critical habitat since we are unable to identify any specific areas in the U.S. that are outside the geographical area occupied by the southern Selkirk Mountains caribou at the time of listing that are essential to the conservation of the species.

Critical Habitat

Background

Critical habitat is defined in section 3 of the Act as:

(1) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features

(a) Essential to the conservation of the species, and

(b) Which may require special management considerations or protection; and

(2) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the requirement that Federal agencies ensure, in consultation with the Service, that any action they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Such designation does not allow the government or public to access private lands. Such designation does not require implementation of restoration, recovery, or enhancement measures by non-Federal landowners. Where a landowner requests Federal agency funding or authorization for an action that may affect a listed species or critical habitat, the consultation requirements of section 7(a)(2) of the Act would apply, but even in the event of a destruction or adverse modification finding, the obligation of the Federal action agency and the landowner is not to restore or recover the species, but to implement reasonable and prudent alternatives to avoid destruction or adverse modification of critical habitat.

Under the first prong of the Act's definition of critical habitat, areas within the geographical area occupied by the species at the time it was listed are included in a critical habitat designation if they contain physical or biological features (1) Which are essential to the conservation of the species, and (2) which may require special management considerations or protection. For these areas, critical habitat designations identify, to the extent known using the best scientific and commercial data available, those physical or biological features that are essential to the conservation of the species (such as space, food, cover, and protected habitat). In identifying those physical or biological features within an area, we focus on the principal biological or physical constituent elements (primary constituent elements such as roost sites, nesting grounds, seasonal wetlands, water quality, tide, soil type) that when combined compose the features essential to the conservation of the species.

Under the second prong of the Act's definition of critical habitat, we can designate critical habitat in areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. For example, an area currently occupied by the species but that was not occupied at the time of listing may be essential to the conservation of the species and may be included in the critical habitat designation. We designate critical habitat in areas outside the geographical area occupied by a species only when a designation limited to its range would be inadequate to ensure the conservation of the species.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific data available. Further, our Policy on Information Standards Under the Endangered Species Act (published in the **Federal Register** on July 1, 1994 (59 FR 34271)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658)), and our associated Information Quality Guidelines, provide criteria, establish procedures, and provide guidance to ensure that our decisions are based on the best scientific data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

When we are determining which areas should be designated as critical habitat, our primary source of information is generally the information developed during the listing process for the species. Additional information sources may include the recovery plan for the species, articles in peer-reviewed journals, conservation plans developed by States and counties, scientific status surveys and studies, biological assessments, other unpublished materials, or experts' opinions or personal knowledge.

Habitat is often dynamic, and species may move from one area to another over time. We recognize that critical habitat designated at a particular point in time may not include all of the habitat areas that we may later determine are necessary for the recovery of the species (*e.g.,* see *Climate Change* discussion below). For these reasons, a critical habitat designation does not signal that habitat outside the designated area is unimportant or may not be required for recovery of the species. Areas that are important to the conservation of the species, both inside and outside of the critical habitat designation, will continue to be subject to: (1) Conservation actions implemented under section 7(a)(1) of the Act, (2) regulatory protections afforded by the requirement in section 7(a)(2) of the Act for Federal agencies to ensure their actions are not likely to jeopardize the continued existence of any endangered or threatened species, and (3) the prohibitions of section 9 of the Act if actions occurring in these areas may

affect the species. Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans (HCPs), or other species conservation planning efforts if new information available at the time of these planning efforts calls for a different outcome.

Climate Change

Climate change will be a particular challenge for biodiversity because the interaction of additional stressors associated with climate change and current stressors may push species beyond their ability to survive (Lovejoy 2005, pp. 325–326). The synergistic implications of climate change and habitat fragmentation are the most threatening facet of climate change for biodiversity (Hannah *et al.* 2005, p. 4). Current climate change predictions for terrestrial areas in the Northern Hemisphere indicate warmer air temperatures, more intense precipitation events, and increased summer continental drying (Field *et al.* 1999, pp. 1–3; Hayhoe *et al.* 2004, p. 12422; Cayan *et al.* 2005, p. 6; Intergovernmental Panel on Climate Change (IPCC) 2007, p. 1181). In the Pacific Northwest, regionally averaged temperatures have risen 0.8 degrees Celsius (C) (1.5 degrees Fahrenheit (F)) over the last century (as much as 2 degrees C (4 degrees F) in some areas), and are projected to increase by another 1.5 to 5.5 degrees C (3 to 10 degrees F) over the next 100 years (Mote *et al.* 2003, p. 54; Karl *et al.* 2009, p. 135). In addition, climate change may lead to increased frequency and duration of severe storms and droughts (Golladay *et al.* 2004, p. 504; McLaughlin *et al.* 2002, p. 6074; Cook *et al.* 2004, p. 1015).

We anticipate that these changes could directly impact southern Selkirk Mountains caribou by modifying the factors that affect the abundance, distribution, and quality of caribou habitat, the ability of caribou to move between seasonal habitats, and their ability to avoid predation. Climate change may also have impacts on caribou by affecting external factors such as increased disease and insect outbreaks, increased fire occurrence, and changes in snow depth. The impacts from these effects could lead to increased habitat fragmentation and changes in forest composition, changes in forage ability and abundance, and changes in predation, which are each important to caribou survival. Because of the close ties between caribou movement and seasonal snow conditions, seasonal shifts in snow conditions will likely be significant to the caribou (Utzig 2005, pp. 4, 8).

Review of climate change modeling presented in Utzig (2005, p. 5) demonstrated projected shifts in habitats within the present range of mountain caribou in Canada. Projections for 2055 indicate a significant decrease in alpine habitats, which is loosely correlated with the distribution of the arboreal lichens on which mountain caribou depend. The projected biogeoclimatic zone distributions indicate a significant increase in the distribution of western red cedar (*Thuja plicata*) in the mid-term with a shift up in elevation and northward in the longer term. Subalpine fir (*Abies lasiocarpa*) distribution tends to shift up in elevation, with long-term decreasing presence in the south and on the drier plateau portions of the present range. However, both tree species maintain significant presence in the area presently occupied by mountain caribou, and their increased distributions to the north may indicate the potential for range expansion for caribou in those northern areas (Utzig 2005, p. 5). The predictions for 2085 indicate an increase in drier vegetation types at lower elevations, potentially causing an increase in other ungulate species such as deer, moose, and elk. This may result in increased predator numbers in response to increased prey availability, and increased predation on caribou (Utzig 2005, p. 4). However, further data would be necessary to confirm this hypothesis, and if confirmed, specific management and mitigation measures would need to be developed. Utzig (2005, p. 10) also identifies several uncertainties in the paper's conclusion (*e.g.,* it is impossible to reliably predict specific ecosystem changes and to reliably predict potential impacts), and acknowledges that caribou managed to survive in the last glacial period as well as intervening climate change over the last 10,000 years.

The movement of mountain caribou is closely tied to changes in snow depth and consolidation in the snow pack, allowing access to arboreal lichens in winter. In general, climate change projections suggest reduced snowpacks and shorter winters, particularly at lower elevations (Utzig 2005, p. 7). Snowpack depth is significant in determining the height at which arboreal lichens occur on trees, and the height at which caribou are able to access lichens in the winter. These arboreal lichens are also dependent upon factors influenced by climate, including humidity and stand density (Utzig 2005, p. 7).

The information currently available on the effects of global climate change and increasing temperatures does not make sufficiently precise estimates of the location and magnitude of the effects, nor are we currently aware of any climate change information specific to the habitat of the southern Selkirk Mountains caribou that would indicate what areas may become important to the species in the future. Therefore, we are unable to determine what additional areas, if any, may be appropriate to include in the proposed critical habitat designation for this species to address the effects of climate change. We are, however, soliciting comments on this challenging management issue; all comments related to climate change will be fully considered in our final determination.

Physical or Biological Features

In accordance with sections 3(5)(A)(i) and 4(b)(1)(A) of the Act and the regulations at 50 CFR 424.12, in determining which areas within the geographical area occupied at the time of listing to designate as critical habitat, we consider the physical or biological features essential to the conservation of the species, which may require special management considerations or protection. These include, but are not limited to:

(1) Space for individual and population growth and for normal behavior;

(2) Food, water, air, light, minerals, or other nutritional or physiological requirements;

(3) Cover or shelter;

(4) Sites for breeding, reproduction, or rearing (or development) of offspring; and

(5) Habitats that are protected from disturbance or are representative of the historical, geographical, and ecological distributions of a species.

We derive the specific physical or biological features required for the southern Selkirk Mountains caribou from studies of this species' habitat, ecology, and life history as described below. Additional information can be found in the final listing rule published in the **Federal Register** on February 26, 1984 (49 FR 7390), the 1994 Revised Recovery Plan for the Selkirk Mountains Woodland Caribou, and the Southern Selkirk Mountains Caribou Population 5-Year Review completed by the Service on December 2, 2008 (USFWS 2008a). We have determined that the following

physical or biological features are essential for the southern Selkirk Mountains caribou population.

Space for Individual and Population Growth and for Normal Behavior

The southern Selkirk Mountains caribou population requires large contiguous areas of high-elevation forest summer and winter habitat, with little or no vehicle access and disturbance, so they can spread out at low densities (*i.e.,* 30–50 caribou/250,000 ac (100,000 ha)) and avoid predators (Seip and Cichowski 1996, p. 79; Stevenson *et al.* 2001, p. 1). Mountain caribou strongly prefer old-growth forests to young forests in all seasons (Stevenson *et al.* 2001, p. 1).

The primary long-term threat to the southern Selkirk Mountains caribou is the ongoing loss and fragmentation of contiguous old-growth forests and forest habitats due to a combination of timber harvest, wildfires, and road development. The effects associated with habitat loss and fragmentation are: (1) Reduction of the amount of space available for caribou, limiting the ecological carrying capacity; (2) reduction of the arboreal lichen supply, affecting the caribou's key winter food source; (3) potential impacts to caribou movement patterns; (4) potential effects to the caribou's use of remaining fragmented habitat because suitable habitat parcels will be smaller and discontinuous; and (5) increased susceptibility of caribou to predation as available habitat is compressed and fragmented (Stevenson *et al.* 2001, p. 10; MCTAC 2002, pp. 20–22; Cichowski *et al.* 2004, pp. 10, 19–20; Apps and McLellan 2006, pp. 92–93; Wittmer *et al.* 2007, pp. 576–577).

Forest management practices have been a concern for caribou habitat management for more than 25 years (Stevenson *et al.* 2001, p. 1; MCTAC 2002, p. 17). In the last decade, timber harvest has moved into high-elevation mature and old-growth forest habitat types due to more roads and more powerful machinery capable of traversing difficult terrains (Stevenson *et al.* 2001, p. 10). The habitat requirements of mountain caribou are incompatible with most currently used forest management practices (Stevenson *et al.* 2001, p. 1). Timber harvesting can reduce and fragment areas creating a patchwork of different age classes of forest stands, all linked with a network of roads. This patchwork may contain enough lichens to support a caribou herd, but will not allow the herd to effectively avoid predators in the southern Selkirk ecosystem (Stevenson *et al.* 2001; p. 1). A patchwork of habitat within forests draws other ungulates such as moose (*Alces alces*), elk (*Cervus elaphus*), and deer (*Odocoileus* spp.) into close proximity with caribou, and consequently brings in predators such as mountain lions (*Felis concolor*), wolves (*Canis lupus*), coyotes (*Canis latrans*), wolverines (*Gulo gulo luscus*), black bears (*Ursus americanus*), and grizzly bears (*Ursus arctos*) (Seip and Cichowski 1996, p. 79; Wittmer *et al.* 2005; pp. 414–417)

The southern Selkirk Mountains caribou use habitat as an important means of limiting the effect of predation by spreading out over large areas at high elevations that other ungulate species avoid (Seip and Cichowski 1996, p. 79; MCTAC 2002, pp. 20–21; Kinley and Woods 2006, all). By dispersing over large areas, caribou become unprofitable prey (*i.e.,* it is not worth a predator's energy investment to seek out prey when there are so few animals in a large area, which is often in deep snow). The amount of habitat required by a caribou population to make them an unpredictable prey to predators may be significantly more than the habitat needed to obtain sufficient winter forage of lichens (Stevenson *et al.* 2001, p. 15). To adequately provide for their habitat needs, large contiguous areas of mature to old-growth western hemlock/western red cedar forests and subalpine fir and Engelmann spruce forests, and the connecting habitat in-between, are required. In order for the southern Selkirk Mountains caribou population to be able to use these areas, the habitats need to be connected, particularly during winter when the energy costs of moving through deep snow can be high (Stevenson *et al.* 2001, p. 15).

Therefore, based on the information above, we identify suitable, large contiguous areas of habitat that allows caribou to spread out at low densities, avoid predators, and obtain sufficient winter forage of lichens, as a physical or biological feature (PBF) for the southern Selkirk Mountains caribou.

Food, Water, Air, Light, Minerals, or Other Nutritional or Physiological Requirements

Arboreal hair lichens comprise a critical winter food source, and the southern Selkirk Mountains caribou diet is almost entirely lichens from November to May (Servheen and Lyon 1989, p. 235; Stevenson *et al.* 2001, p. 1; USFS 2004, p. 18), since they represent the only food source available (Paquet 1997, p. 13). Lichens are pulled from the branches of conifers, picked from the surface of the snow after being blown out of trees by wind, or are grazed from wind-thrown branches and trees. The two kinds of lichens commonly eaten by the south Selkirk caribou are *Bryoria* spp. and *Alectoria sarmentosa;* both are most commonly found in high-elevation climax forests on old trees (Paquet 1997, p. 14). These lichens are extremely slow-growing, and are typically abundant only in mature or old-growth forests (125 years or older) (Paquet 1997, p. 2). Relative humidity, wetting and drying cycles, and amount of light are ultimately the controlling factors of lichen growth.

During the spring and summer, the southern Selkirk Mountains caribou move to lower elevations to forage on grasses, flowering plants, horsetails, willow and dwarf birch leaves and tips, sedges, and lichens in subalpine meadows (Paquet 1997, p. 13, 16), and on huckleberry leaves (USFS 2004, p. 18). The fall and early winter diet consists largely of dried grasses, sedges, willow and dwarf birch tips, and arboreal lichens.

Therefore, based on the information above, we identify arboreal hair lichens, *Bryoria* spp. and *Alectoria sarmentosa,* which occur on mature to old-growth trees, or are available having been blown out of trees, to be an essential winter season PBF for this species. These lichens also represent a PBF for female caribou that move into higher elevations during the June–July calving season (see discussion below).

Sites for Breeding, Reproduction, or Rearing (or Development) of Offspring

In spring (May to July) the southern Selkirk Mountains caribou move to areas with green vegetation, which become the primary food source. These areas may overlap with early and late winter ranges at mid to lower elevations (Servheen and Lyon 1989, p. 235; MCTAC 2002, p. 11), and vegetation in these areas allow caribou to recover from the effects of winter (USFWS 1994, p. 7). Pregnant females will move to these spring habitats for forage, but during the calving season in early June to July, the need to avoid predators influences habitat selection. Areas selected for calving are typically at high-elevation, old-growth forest ridgetops that can be food limited, but are more likely to be predator free (USFWS 1994, p. 8; MCTAC 2002, p. 11). Arboreal lichen becomes the primary food source for pregnant females and females with calves, since green forage is unavailable in these secluded and high-elevation habitats.

Therefore, based on the information above, we identify large contiguous areas of high-elevation, old-growth forest ridgetops, which are likely to be predator limited, and have sufficient

forage of lichens to support a pregnant cow, or cow-calf pair, to be a PBF for this species.

Habitats That Are Protected From Disturbance or Are Representative of the Historical, Geographical, and Ecological Distributions of a Species

In general, seasonal habitats of the southern Selkirk Mountains caribou consist of early winter, late winter, spring, calving, summer, and fall habitats primarily within two vegetation zones: Western hemlock/western red cedar and subalpine fir/Engelmann spruce forests (USFS 2004, p. 18; USFWS 2008a, p. 20). Caribou typically make the longest landscape movements during the early winter period, which may range from several miles (kilometers) to about 30 mi (48 km) (USFS 2004, p. 22). Early winter is a period of rapid snow accumulation and generally extends from November to mid/late January. During this time, the southern Selkirk Mountains caribou generally inhabit mature to old-growth western hemlock/western red cedar forests, the lower limits of the subalpine fir and Engelmann spruce forests, and the ecotone (a zone of transition between two different ecosystems) between these two forest types (USFWS 2008a, p. 20). These habitats generally occur between 4,000 and 6,200 ft (about 1,220–1,900 m) in elevation, and have a more closed-overstory canopy (70 percent or more) to intercept snow (USFS 2004, p. 18, USFWS 2008a, p. 20).

Caribou seek out these more closed timber stands where they feed on a combination of lichen on wind-thrown trees, and lichens that have fallen from standing trees (litterfall) (MCTAC 2002, p. 10). If available, shrubs and other forbs that remain accessible in snow wells under large trees are also consumed. A conifer canopy that intercepts snow and allows access to feeding sites is important (MCTAC 2002, p. 10) until the snow pack consolidates and the caribou can move to higher elevations (USFS 2004, p. 18). However, these elevational shifts can be quite variable within and between years, depending on snow levels (Apps *et al.* 2001, p. 67; Kinley *et al.* 2007; p. 94). All mountain caribou experience the poorest mobility and food availability of any season during early winter because of the typically deep, soft snow (MCTAC 2002, p. 10).

Late winter generally starts around mid-January and extends to approximately April. During this time, the snowpack is deep (up to 16 ft (5 m) on ridge tops) and firm enough to support the animal's weight, which allows easier movement. These upper slopes and ridge tops are generally higher than 6,000 ft (1,830 m) in elevation, support mature to old stands of subalpine fir and Engelmann spruce with relatively open canopies (approximately 10 to 50 percent canopy cover), and have high levels of arboreal lichen (USFWS 1994, p. 6; MCTAC 2002, p. 10; USFS 2004, p. 18; Kinley and Apps, 2007, p. 15; USFWS 2008a, p. 20).

Spring is usually from May to July, when caribou move to areas that have green vegetation to recover from the effects of winter (Servheen and Lyon 1989, p. 235; USFWS 1994, p. 7). July to mid-October is considered to be the summer habitat season for caribou. Southern Selkirk Mountains caribou spend the summer in higher elevational alpine and subalpine areas with high forage availability (USFWS 1994, p. 8). Early summer in open-canopied stands provide forbs and huckleberry (*Vaccinium* spp.) leaves. Summer range includes Engelmann spruce/subalpine fir forests and western hemlock/western red cedar forests (Stevenson *et al.* 2001, p. 1; Kinley and Apps 2007, p. 15). In the Selkirk Mountains, the shallow slopes used in late summer are characteristically high-elevation benches, secondary stream bottoms and riparian areas, and seeps where forage is lush and abundant (Servheen and Lyon 1989, p. 236).

Fall habitat (generally October into November) use by southern Selkirk Mountains caribou is driven primarily by the availability of forage vegetation as vascular plants disappear. Caribou may gradually move to western hemlock dominated forests. It is during this time of year when southern Selkirk Mountains caribou are making the transition from green forage to arboreal lichens (Servheen and Lyon, 1989, p. 236). As winter nears, the annual cycle of habitat use by the southern Selkirk Mountains caribou population repeats itself.

Increasing levels of winter recreational activities (*e.g.,* snowmobiling) within the southern Selkirk Mountains caribou recovery area, which includes the Colville National Forests (CNF) in Washington and Idaho Panhandle National Forests (IPNF) in Idaho, is an emerging threat to the southern Selkirk Mountains caribou. The numbers and distribution of recreational snowmobilers has increased over the last l0–15 years, due in part to improved snowmobile technology and the increasing popularity of the sport. Snowmobiling activities have the potential to displace caribou from suitable habitat, resulting in additional energy expenditure by caribou when they vacate an area to avoid disturbance (Tyler 1991, p. 191). This results in an effective loss of habitat availability temporarily, and potentially for the long term if caribou abandon areas characterized by chronic disturbance.

Therefore, based on the information above, we identify large contiguous areas of old-growth or mature forests, at high-elevation (4,000 ft (about 1,220 m) or greater) and transitional areas that connect habitats essential to meet the life history requirements of the southern Selkirk Mountains population of woodland caribou, and have little to no disturbance from vehicles or other forest activities, as physical or biological features for southern Selkirk Mountains caribou.

Primary Constituent Elements for the Southern Selkirk Mountains Caribou

Under the Act and its implementing regulations, we are required to identify the physical and biological features essential to the conservation of the southern Selkirk Mountains caribou population in areas occupied at the time of listing, focusing on the features' primary constituent elements. We consider primary constituent elements to be the specific compositional elements of physical and biological features that are essential to the conservation of the species.

Based on our current knowledge of the physical or biological features and habitat characteristics required to sustain the mountain caribou's vital life-history functions, we determine that the primary constituent elements specific to the southern Selkirk Mountains caribou population are:

i. Mature to old-growth western hemlock (*Tsuga heterophylla*)/western red cedar (*Thuja plicata*) climax forest, and subalpine fir (*Abies lasiocarpa*)/Engelmann spruce (*Picea engelmanni*) climax forest over 4,000 ft (1,220 m) in elevation; these habitats typically have 70 percent or greater canopy closure.

ii. Ridge tops with deep (up to 16 ft (5 m)) snowpack that are generally 6,000 ft (1,830 m) in elevation or higher, in mature to old stands of subalpine fir (*Abies lasiocarpa*)/Engelmann spruce (*Picea engelmanni*) climax forest, with relatively open (approximately 50 percent) canopy.

iii. Arboreal hair lichen growth in high enough amounts to support southern Selkirk Mountains caribou herds.

iv. High-elevation benches and shallow slopes, secondary stream bottoms, riparian areas, and seeps, and subalpine meadows with succulent forbs and grasses, flowering plants,

horsetails, willow, huckleberry, dwarf birch, sedges and lichens. Southern Selkirk Mountains caribou, including pregnant females, use these areas for feeding during the spring and summer seasons.

v. Transition zones that connect the habitats described above and that facilitate seasonal caribou movements between habitat types.

The physical or biological features for the southern Selkirk Mountains caribou are, therefore, the arrangement of the above habitat types and their components and transition zones on the landscape in a manner that supports seasonal movement, feeding, breeding, and sheltering needs. Each of the seasonal use areas creates space on the landscape that allows caribou to spread out and avoid predators. These areas also have little or no disturbance from forest practices, roads, or recreational activities.

The final listing rule states that the southern Selkirk Mountains population of woodland caribou is the only caribou population that is still known to regularly occupy the conterminous U.S., and is found in northern Idaho and northeastern Washington. This population also occurs in southern B.C. (49 FR 7390; February 29, 1984). The final rule describes the ''area of normal utilization'' in the U.S. (starting from the B.C. border), as: (1) Southward along Kootenay Lake and the Kootenay River to the town of Bonners Ferry, Idaho; (2) southward along U.S. Highway 95 to the Pend Oreille River; (3) westward and northward along the Pend Oreille River; and (4) across the Idaho-Washington State line to the Washington–B.C. border (49 FR 7390; February 29, 1984). With this proposed designation of critical habitat, we intend to conserve the physical and biological features essential to the conservation of the species, through the identification of the primary constituent elements sufficient to support the life-history functions of the species. All areas proposed for designation as critical habitat were occupied at the time of listing and contain those physical or biological features essential to the conservation of the species, which may require special management considerations or protections.

Special Management Considerations or Protection

When designating critical habitat, we assess whether the specific areas within the geographical area occupied by the species at the time of listing contain features that are essential to the conservation of the species and which may require special management considerations or protection.

A comprehensive discussion of the threats affecting the species is included in the Southern Selkirk Mountains Caribou Population 5–Year Review (USFWS 2008a), the Idaho Comprehensive Wildlife Conservation Strategy (2005), and the Revised Selkirk Mountains Woodland Caribou Recovery Plan (USFWS 1994). The features essential to the conservation of this species, described above, may require special management considerations or protections to reduce the following threats: Habitat fragmentation of contiguous old-growth forests due to forest management practices and activities, wildfire, disturbances such as roads and recreation, and altered predator/prey dynamics.

Special management considerations or protection are required within critical habitat areas to address these threats, which are occurring within each of the subunits proposed for designation. Management activities that could ameliorate these threats include (but are not limited to) conservation measures and actions to minimize the effects of forest management practices on these features, actions to minimize the potential for wildfire and the implementation of rapid response measures when wildfire occurs, road and recreational area closures as appropriate to avoid or minimize the potential for disturbance-related impacts, and reducing opportunities for predator-caribou interactions.

Existing Conservation Measures

Land and resource management plans (LRMPs) for the IPNF and CNF have been revised to incorporate management objectives and standards to address the above threats, as a result of section 7 consultation between the USFWS and USFS (USFWS 2001a, b). Standards for caribou habitat management have been incorporated into the IPNF's 1987 and CNF's 1988 LRMP, respectively, to avoid the likelihood of jeopardizing the continued existence of the species, contribute to caribou conservation, and ensure consideration of the biological needs of the species during forest management planning and implementation actions (USFS 1987, pp. II–6, II–27, Appendix N; USFS 1988, pp. 4–10 to 4–17, 4–38, 4–42, 4–73 to 4–76, Appendix I).

These efforts contribute to the protection of the essential physical or biological features by: (1) Retaining old-growth cedar/hemlock stands; (2) analyzing timber management actions on a site-specific basis to consider potential impacts to caribou habitat; (3) avoiding road construction through old-growth forest stands unless no other reasonable access is available; (4) placing emphasis on road closures and habitat mitigation based on caribou needs and requirements; (5) containing and controlling wildfires within southern Selkirk Mountains caribou management areas to prevent loss of coniferous species in all size classes; and (6) managing winter recreation in the CNF in Washington, with specific attention to snowmobile use within the Sullivan Lake Ranger District.

Criteria Used To Identify Critical Habitat

As required by section 4(b) of the Act, we use the best scientific and commercial data available to designate critical habitat. We review available information pertaining to the habitat requirements of the species. In accordance with the Act and its implementing regulation at 50 CFR 424.12(e), we consider whether designating additional areas—outside those currently occupied as well as those occupied at the time of listing—is necessary to ensure the conservation of the species. The areas we are proposing to designate as critical habitat generally follow the recovery areas identified in the recovery plan (USFWS 1994), which are all within the geographical area occupied at the time of listing. Therefore, we are not currently proposing to designate any areas outside the geographical area occupied at the time of listing, because we believe occupied areas are sufficient for the conservation of the species. The occupied areas identified at the time of listing in 1984 contain sufficient physical or biological features to support the life-history functions essential for the conservation of the species.

We reviewed available information and supporting data that pertains to the habitat requirements of the southern Selkirk Mountains caribou. These sources of information included, but were not limited to, the final listing noticed published in the **Federal Register** on February 29, 1984 (49 FR 7390–7394), the 1985 Management/Recovery Plan for Selkirk Caribou (USFWS 1985) and appendices, the Revised Recovery Plan for the Selkirk Mountains Woodland Caribou (USFWS 1994), and the Southern Selkirk Mountains Caribou Population 5–Year Review (USFWS 2008a). Additional Service documents used include the Biological Opinion and Conference Opinion for the Modified Idaho Roadless Rule for USDA Forest Service Regions 1 and 4 (USFWS 2008b), and

Biological Opinions for the continued implementation of both the CNF and IPNF LRMPs (USFWS 2001a, b). Other information included the Idaho Comprehensive Wildlife Conservation Strategy (2005), research published in peer-reviewed articles, academic theses, agency reports, habitat modeling assessments, telemetry data, and mapping information from U.S. and Canadian sources. We also used regional Geographic Information System (GIS) data (such as species occurrence data, land use, elevation, topography, aerial imagery, soil data, and land ownership maps) for area calculations and mapping.

We used the following criteria to select areas occupied by southern Selkirk Mountains caribou at the time of listing for inclusion in critical habitat:

(a) The geographical area occupied by the southern Selkirk Mountains caribou at the time of listing (1984) as identified in the final listing rule (49 FR 7390–7394).

(b) Areas representative of the distribution of the southern Selkirk Mountains caribou seasonal habitat needs throughout the geographical area occupied at the time of listing, with the goal of maintaining the species' range of habitat and genetic variability.

(c) Areas that provide the essential physical or biological features necessary to support the species' life-history requirements under varying environmental conditions.

(d) Areas that provide connectivity between mountain caribou habitat to provide for seasonal movement and genetic variability.

Our first step in delineating proposed critical habitat was to identify areas that provide for the conservation of the southern Selkirk Mountains caribou within the geographic region described as the approximate area of normal utilization in the listing rule (49 FR 7390–7394; February 29, 1984). This includes portions of the CNF in Washington, and the IPNF in Idaho, and some Priest Lake Endowment Lands managed by the state of Idaho's Department of Lands (IDL).

Critical habitat boundaries were initially identified above 4,000 ft (about 1,220 m) in elevation, which corresponds to the elevation above which the woodland caribou are generally known to occur within the southern Selkirk Mountains ecosystem in Idaho and Washington (Layser 1974, p. 25–26; USFWS 1994, p. 6; USFWS 2008a, p. 2). Using a Geographical Information System (GIS), we mapped the area described as occupied in the 1984 final listing (49 FR 7390–7394), and delineated areas at 4,000 ft (1,220 m) and above using a 32.8 ft (10 m) digital elevation model. We overlayed seasonal telemetry radiolocations of caribou collected in the southern Selkirk Mountain ecosystems (B.C., Idaho, and Washington), from 1987 through 2004 by the IDFG, Washington Department of Fish and Wildlife, and the Fish and Wildlife Compensation Program (Columbia Basin) in B.C. To further refine proposed critical habitat boundaries, we overlaid the currently defined Recovery Area boundaries, caribou movement corridors mapped by the IPNF (USFS 2004, pp. 22–23), and results of the seasonal habitat suitability model developed by Kinley and Apps (2007, entire) for the southern Selkirk Mountains ecosystem.

After delineating areas above 4,000 ft (1,220 m) utilizing the above methods, we filtered the results to remove isolated patches and some larger areas along the southern boundary in Washington and Idaho because they either lacked PCEs, were adjacent to Schweitzer ski resort (which has a large footprint on the landscape and fragments/isolates areas above 4,000 ft (about 1,220 m) in Idaho), or had relatively low historical utilization based on telemetry data. We included certain areas below 4,000 ft (about 1,220 m) in elevation where seasonal connectivity between habitats was required. These include areas within the IPNF north of Upper Priest Lake north to the Canadian border, along the east and west banks of the Priest River.

When determining proposed critical habitat boundaries, we made every effort to avoid including developed areas such as lands covered by buildings, pavement, and other structures because such lands lack physical or biological features for the southern Selkirk Mountains caribou. The scale of the maps we prepared under the parameters for publication within the Code of Federal Regulations may not reflect the exclusion of such developed lands. Any such lands inadvertently left inside critical habitat boundaries shown on the maps of this proposed rule have been excluded by text in the proposed rule and are not proposed for designation as critical habitat. Therefore, if the critical habitat is finalized as proposed, a Federal action involving these lands would not trigger section 7 consultation with respect to critical habitat and the requirement of no adverse modification, unless the specific action would affect the PBFs in the adjacent critical habitat.

One unit, which contains two subunits, is being proposed for designation based on sufficient elements of the essential physical or biological features being present to support the southern Selkirk Mountains caribou population life-history processes.

Proposed Critical Habitat Designation

We are proposing one unit containing two subunits as critical habitat for the southern Selkirk Mountains caribou population. The critical habitat area described below constitutes our best assessment of areas that meet the definition of critical habitat for the southern Selkirk Mountains caribou population. Within the Selkirk Mountains Critical Habitat Unit, we have identified two subunits: (1) Bonner and Boundary Counties, Idaho; and (2) Pend Oreille County, Washington.

The approximate size and ownership of each proposed critical habitat subunit is identified in table 1. Each subunit was occupied at the time of listing in 1984.

TABLE 1. Proposed critical habitat unit and subunits for the southern Selkirk Mountains population of woodland caribou. [Area estimates reflect all land within critical habitat unit boundaries, values are rounded to the nearest whole numbers.]

SELKIRK MOUNTAINS CRITICAL HABITAT UNIT

[Southern Selkirk Mountains Caribou (*Rangifer tarandus caribou*)]

Critical habitat subunit	Land ownership by type	Size of unit in acres (hectares)
1. Bonner and Boundary Counties, Idaho	Federal	222,971 ac (90,233 ha).
	State	65,218 ac (26,393 ha).
	Private	15,379 ac (6,223 ha).
	Subunit Total	303,568 ac (122,849 ha).
2. Pend Oreille County, Washington	Federal	71,976 ac (29,128 ha).
	State	0.

SELKIRK MOUNTAINS CRITICAL HABITAT UNIT—Continued

[Southern Selkirk Mountains Caribou (*Rangifer tarandus caribou*)]

Critical habitat subunit	Land ownership by type	Size of unit in acres (hectares)
	Private	0.
	Subunit total	71,976 ac (29,128 ha).
Ownership Totals	Federal	294,947 ac (119,361 ha).
	State	65,236 ac (26,400 ha).
	Private	15,379 ac (6,224 ha).
Unit Total		375,562 ac (151,985 ha).

Note: Totals may not sum due to rounding.

The following section presents a brief description of the Selkirk Mountains Critical Habitat Unit, land ownership use within the Unit, and why this Unit meets the definition of critical habitat for the southern Selkirk Mountains caribou. Since this information is also relevant to each of the two subunits, the subunits are not individually described. The overall unit and subunit boundaries are depicted on the maps included in this proposed rule.

Selkirk Mountain Critical Habitat Unit

The Selkirk Mountains Critical Habitat Unit consists of 375,562 ac (151,985 ha) and is divided into two subunits: Subunit 1 in Bonner and Boundary Counties, Idaho; and subunit 2 in Pend Oreille County, Washington. The Selkirk Mountains Critical Habitat Unit consists of land higher than 4,000 ft (1,220 m) in elevation, and is generally bounded by State Highway 31 and 20 to the west and south in Washington, U.S. Highway 2 to the south in Idaho, U.S. Highway 2/95 to the east in Idaho, and the U.S./Canadian border to the north. Land ownership within the Unit consists of 294,947 ac (119,361 ha) of Federal land (primarily USFS), 65,236 ac (26,400 ha) of State of Idaho land, and 15,379 ac (6,224 ha) of private land. The Federal land is administered by both the Colville and Idaho Panhandle National Forests, with a small segment of land managed by the Bureau of Land Management. The Selkirk Mountains Critical Habitat Unit was occupied at the time of listing (49 FR 7390–7394; February 29, 1984), and contains all of the physical or biological features essential to the conservation of the southern Selkirk Mountains caribou population.

The primary land uses within the Selkirk Mountains Critical Habitat Unit include Federal, State, and private forest management activities and recreational activities throughout the year, including, but not limited to, snowmobiling, off-highway vehicle (OHV) use, backcountry skiing, and hunting. Special management considerations or protections needed within the Unit would need to address habitat fragmentation of contiguous old-growth forests due to forest practices and activities, wildfire, disturbances such as roads and recreation, and altered predator/prey dynamics.

Effects of Critical Habitat Designation

Section 7 Consultation

Section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that any action they fund, authorize, or carry out is not likely to jeopardize the continued existence of any endangered or threatened species, or result in the destruction or adverse modification of designated critical habitat of such species. In addition, section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any action which is likely to jeopardize the continued existence of any species proposed to be listed under the Act or result in the destruction or adverse modification of proposed critical habitat. Since the southern Selkirk Mountains caribou is listed as endangered, Federal agencies already consult with the Service in areas currently occupied by caribou, or if the species may be indirectly or directly affected by the action, to ensure that their actions do not jeopardize the continued existence of the species.

Decisions by the Fifth and Ninth Circuit Courts of Appeals have invalidated our definition of ''destruction or adverse modification'' (50 CFR 402.02) (see *Gifford Pinchot Task Force* v. *U.S. Fish and Wildlife Service,* 378 F. 3d 1059 (9th Cir. 2004) and *Sierra Club* v. *U.S. Fish and Wildlife Service et al.,* 245 F.3d 434, 442 (5th Cir. 2001)), and we do not rely on this regulatory definition when analyzing whether an action is likely to destroy or adversely modify critical habitat. Under the statutory provisions of the Act, we determine destruction or adverse modification on the basis of whether, with implementation of the proposed Federal action, the affected critical habitat would continue to serve its intended conservation role for the species.

If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must enter into consultation with us. Examples of actions that are subject to the section 7 consultation process are actions on State, tribal, local, or private lands that require a Federal permit (such as a permit from the U.S. Army Corps of Engineers under section 404 of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or a permit from the Service under section 10 of the Act) or that involve some other Federal action (such as funding from the Federal Highway Administration, Federal Aviation Administration, or the Federal Emergency Management Agency). Federal actions not affecting listed species or critical habitat, and actions on State, tribal, local, or private lands that are not federally funded or authorized, do not require section 7 consultation.

As a result of section 7 consultation, we document compliance with the requirements of section 7(a)(2) through our issuance of:

(1) A concurrence letter for Federal actions that may affect, but are not likely to adversely affect, listed species or critical habitat; or

(2) A biological opinion for Federal actions that may affect, or are likely to adversely affect, listed species or critical habitat.

When we issue a biological opinion concluding that a project is likely to jeopardize the continued existence of a listed species or destroy or adversely modify critical habitat, we provide reasonable and prudent alternatives to the project, if any are identifiable. We define ''reasonable and prudent alternatives'' (at 50 CFR 402.02) as alternative actions identified during consultation that:

(1) Can be implemented in a manner consistent with the intended purpose of the action,

(2) Can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction,

(3) Are economically and technologically feasible, and

(4) Would, in the Director's opinion, avoid the likelihood of jeopardizing the continued existence of the listed species or avoid the likelihood of destroying or adversely modifying critical habitat.

Reasonable and prudent alternatives can vary from slight project modifications to extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative are similarly variable.

Regulations at 50 CFR 402.16 require Federal agencies to reinitiate consultation on previously reviewed actions in instances where we have listed a new species or subsequently designated critical habitat that may be affected and the Federal agency has retained discretionary involvement or control over the action (or the agency's discretionary involvement or control is authorized by law). Consequently, Federal agencies sometimes may need to request reinitiation of consultation with us on actions for which formal consultation has been completed, if those actions with discretionary involvement or control may affect subsequently listed species or designated critical habitat.

Application of the ''Adverse Modification'' Standard

The key factor related to the adverse modification determination is whether, with implementation of the proposed Federal action, the affected critical habitat would continue to serve its intended conservation role for the species. Activities that may destroy or adversely modify critical habitat are those that alter the physical or biological features to an extent that appreciably reduces the conservation value of the critical habitat for the southern Selkirk Mountains caribou. As discussed above, the role of critical habitat is to support life-history needs of the species and provide for the conservation of the species.

Section 4(b)(8) of the Act requires us to briefly evaluate and describe, in any proposed or final regulation that designates critical habitat, activities involving a Federal action that may destroy or adversely modify such habitat, or that may be affected by such designation.

Activities that may affect critical habitat, when carried out, funded, or authorized by a Federal agency, should result in consultation for the southern Selkirk Mountains population of woodland caribou. These activities include, but are not limited to:

(1) Actions that would reduce or remove mature old-growth vegetation (greater than 100–125 years old) within the cedar hemlock zone at lower elevations (below 4,000 ft (1,220 m)) and within subalpine fir/Engelmann spruce zone at higher elevations stands (at or greater than 4,000 ft (1,220 m)), including the ecotone between these two forest habitats. Such activities could include, but are not limited to, forest stand thinning, timber harvest, and fuels treatment of forest stands. These activities could significantly reduce the abundance of arboreal lichen habitat, such that the landscape's ability to produce adequate densities of arboreal lichen to support persistent mountain caribou populations is at least temporarily diminished.

(2) Actions that would cause permanent loss or conversion of old-growth coniferous forest on a scale proportionate to the large landscape used by mountain caribou. Such activities could include, but are not limited to, recreational area developments, certain types of mining activities, and associated road building. Such activities could eliminate and fragment mountain caribou and arboreal lichen habitat.

(3) Actions that would increase traffic volume and speed on roads within mountain caribou critical habitat. Such activities could include, but are not limited to, transportation projects to upgrade roads or development, or development of a new tourist destination. These activities could reduce connectivity within the old-growth coniferous forest landscape for mountain caribou.

(4) Actions that would increase recreation in mountain caribou recovery areas. Such activities could include, but are not limited to, recreational developments that facilitate winter access into mountain caribou habitat units, or management activities that increase recreational activities within mountain caribou habitat throughout the year, such as snowmobiling, OHV use, and backcountry skiing. These activities have the potential to displace caribou from suitable habitat or increase their susceptibility to predation. Displacement of caribou may result in additional energy expenditure by caribou when they vacate an area to avoid disturbance, and an effective loss of habitat availability temporarily and potentially in the long-term, where caribou abandon areas affected by chronic disturbance.

Mountain caribou strongly prefer old-growth forests to young forests in all seasons. In designated critical habitat, management actions that alter vegetation structure or condition in young forests over limited areas may not represent an adverse effect to caribou critical habitat. However, an adverse effect could result if these types of management activities reduce and fragment areas in a manner that creates a patchwork of different age classes or prevents young forests from achieving old-growth habitat characteristics. For example, a commercial thinning or fuels reduction project in a young forest may not require formal consultation, whereas a commercial thinning or fuels reduction project conducted within an old-growth forest may be an adverse effect to mountain caribou critical habitat and would require formal consultation. Federal agencies should examine the scale of their activities to determine whether direct or indirect alteration of habitat would occur to an extent that the value of critical habitat for the conservation of the mountain caribou would be appreciably diminished.

Exemptions

Application of Section 4(a)(3) of the Act

The Sikes Act Improvement Act of 1997 (Sikes Act) (16 U.S.C. 670a) required each military installation that includes land and water suitable for the conservation and management of natural resources to complete an integrated natural resource management plan (INRMP) by November 17, 2001. An INRMP integrates implementation of the military mission of the installation with stewardship of the natural resources found on the base. Each INRMP includes:

(1) An assessment of the ecological needs on the installation, including the need to provide for the conservation of listed species;

(2) A statement of goals and priorities;

(3) A detailed description of management actions to be implemented to provide for these ecological needs; and

(4) A monitoring and adaptive management plan.

Among other things, each INRMP must, to the extent appropriate and applicable, provide for fish and wildlife management; fish and wildlife habitat enhancement or modification; wetland protection, enhancement, and restoration where necessary to support fish and wildlife; and enforcement of applicable natural resource laws.

The National Defense Authorization Act for Fiscal Year 2004 (Pub. L. 108–136) amended the Act to limit areas eligible for designation as critical

habitat. Specifically, section 4(a)(3)(B)(i) of the Act (16 U.S.C. 1533(a)(3)(B)(i)) now provides: ''The Secretary shall not designate as critical habitat any lands or other geographical areas owned or controlled by the Department of Defense (DOD), or designated for its use, that are subject to an integrated natural resources management plan prepared under section 101 of the Sikes Act (16 U.S.C. 670a), if the Secretary determines in writing that such plan provides a benefit to the species for which critical habitat is proposed for designation.''

There are no DOD lands with a completed INRMP within the proposed critical habitat designation.

Exclusions

Application of Section 4(b)(2) of the Act

Section 4(b)(2) of the Act states that the Secretary shall designate and make revisions to critical habitat on the basis of the best available scientific data after taking into consideration the economic impact, national security impact, and any other relevant impact of specifying any particular area as critical habitat. The Secretary may exclude an area from critical habitat if he determines that the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat, unless he determines, based on the best scientific data available, that the failure to designate such area as critical habitat will result in the extinction of the species. In making that determination, the statute on its face, as well as the legislative history, are clear that the Secretary has broad discretion regarding which factor(s) to use and how much weight to give to any factor.

Under section 4(b)(2) of the Act, we may exclude an area from designated critical habitat based on economic impacts, impacts on national security, or any other relevant impacts. In considering whether to exclude a particular area from the designation, we must identify the benefits of including the area in the designation, identify the benefits of excluding the area from the designation, and determine whether the benefits of exclusion outweigh the benefits of inclusion. If the analysis indicates that the benefits of exclusion outweigh the benefits of inclusion, the Secretary may exercise his discretion to exclude the area only if such exclusion would not result in the extinction of the species.

Exclusions Based on Economic Impacts

Under section 4(b)(2) of the Act, we consider the economic impacts of specifying any particular area as critical habitat. In order to consider economic impacts, we are preparing an analysis of the economic impacts of the proposed critical habitat designation and related factors. The proposed critical habitat areas include Federal, State, and private lands, some of which are used for timber harvest and motorized winter recreation (*e.g.,* snowmobiling, cross-country skiing). Other land uses that may be affected will be identified as we develop the draft economic analysis for the proposed designation.

We will announce the availability of the draft economic analysis as soon as it is completed, at which time we will seek public review and comment. At that time, copies of the draft economic analysis will be available for downloading from the Internet at *http://www.regulations.gov,* or by contacting the Idaho Fish and Wildlife Office directly (see **FOR FURTHER INFORMATION CONTACT**). During the development of a final designation, we will consider economic impacts, public comments, and other new information, and areas may be excluded from the final critical habitat designation under section 4(b)(2) of the Act and our implementing regulations at 50 CFR 424.19.

Exclusions Based on National Security Impacts

Under section 4(b)(2) of the Act, we consider whether there are lands owned or managed by the Department of Defense (DOD) where a national security impact might exist. In preparing this proposal, we have determined that the lands within the proposed designation of critical habitat for the southern Selkirk Mountains population of woodland caribou are not owned or managed by the DOD, and, therefore, we anticipate no impact to national security. Consequently, the Secretary does not propose to exercise his discretion to exclude any areas from the final designation based on impacts on national security.

Exclusions Based on Other Relevant Impacts

Under section 4(b)(2) of the Act, we consider any other relevant impacts, in addition to economic impacts and impacts on national security. We consider a number of factors including whether the landowners have developed any HCPs or other management plans for the area, or whether there are conservation partnerships that would be encouraged by designation of, or exclusion from, critical habitat. In addition, we look at any Tribal issues, and consider the government-to-government relationship of the United States with Tribal entities. We also consider any social impacts that might occur because of the designation.

In preparing this proposal, we have determined that there are currently no HCPs or other management plans for southern Selkirk Mountains caribou, and the proposed designation does not include any Tribal lands or trust resources. We anticipate no impact to Tribal lands, partnerships, or HCPs from this proposed critical habitat designation. Accordingly, the Secretary does not propose to exercise his discretion to exclude any areas from the final designation based on other relevant impacts.

Peer Review

In accordance with our joint policy published in the **Federal Register** on July 1, 1994 (59 FR 34270), we will seek the expert opinions of at least three appropriate and independent specialists regarding this proposed rule. The purpose of peer review is to ensure that our critical habitat designation is based on scientifically sound data, assumptions, and analyses. We have invited these peer reviewers to comment during this public comment period on our specific assumptions and conclusions in this proposed designation of critical habitat.

We will consider all comments and information received during this comment period on this proposed rule during our preparation of a final determination. Accordingly, the final decision may differ from this proposal.

Public Hearings

Section 4(b)(5) of the Act provides for one or more public hearings on this proposal, if requested. Requests must be received within 45 days after the date of publication of this proposed rule in the **Federal Register**. Such requests must be sent to the address shown in **FOR FURTHER INFORMATION CONTACT**. We will schedule public hearings on this proposal, if any are requested, and announce the dates, times, and places of those hearings, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the hearing.

Required Determinations

Regulatory Planning and Review—Executive Order 12866

The Office of Management and Budget (OMB) has determined that this rule is not significant and has not reviewed this proposed rule under Executive Order 12866 (Regulatory Planning and Review). OMB bases its determination upon the following four criteria:

(a) Whether the rule will have an annual effect of $100 million or more on

the economy or adversely affect an economic sector, productivity, jobs, the environment, or other units of the government.

(b) Whether the rule will create inconsistencies with other Federal agencies' actions.

(c) Whether the rule will materially affect entitlements, grants, user fees, loan programs, or the rights and obligations of their recipients.

(d) Whether the rule raises novel legal or policy issues.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA; 5 U.S.C. 801 *et seq.*), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effects of the rule on small entities (small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the RFA to require Federal agencies to provide a certification statement of the factual basis for certifying that the rule will not have a significant economic impact on a substantial number of small entities.

At this time, we lack the available economic information necessary to provide an adequate factual basis for the required RFA finding. Therefore, we defer the RFA finding until completion of the draft economic analysis prepared under section 4(b)(2) of the Act and Executive Order 12866. The proposed critical habitat areas include Federal, State, and private lands, some of which are used for timber harvest and motorized winter recreation (*e.g.,* snowmobiling, cross-country skiing). Other land uses that may be affected will be identified as we develop the draft economic analysis for the proposed designation.

This draft economic analysis will provide the required factual basis for the RFA finding. Upon completion of the draft economic analysis, we will announce availability of the draft economic analysis of the proposed designation in the **Federal Register** and reopen the public comment period for the proposed designation. We will include with this announcement, as appropriate, an initial regulatory flexibility analysis or a certification that the rule will not have a significant economic impact on a substantial number of small entities accompanied by the factual basis for that determination. We have concluded that deferring the RFA finding until completion of the draft economic analysis is necessary to meet the purposes and requirements of the RFA. Deferring the RFA finding in this manner will ensure that we make a sufficiently informed determination based on adequate economic information and provide the necessary opportunity for public comment.

Energy Supply, Distribution, or Use—Executive Order 13211

Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use) requires agencies to prepare Statements of Energy Effects when undertaking certain actions. Since there are no energy facilities within the footprint of the proposed critical habitat boundaries, we do not expect the designation of this proposed critical habitat to significantly affect energy supplies, distribution, or use. Therefore, this action is not a significant energy action, and no Statement of Energy Effects is required. However, we will further evaluate this issue as we conduct our economic analysis, and review and revise this assessment as warranted.

Unfunded Mandates Reform Act

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), we make the following findings:

(1) This rule will not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or tribal governments, or the private sector, and includes both ''Federal intergovernmental mandates'' and ''Federal private sector mandates.'' These terms are defined in 2 U.S.C. 658(5)–(7). ''Federal intergovernmental mandate'' includes a regulation that ''would impose an enforceable duty upon State, local, or tribal governments'' with two exceptions. It excludes ''a condition of Federal assistance.'' It also excludes ''a duty arising from participation in a voluntary Federal program,'' unless the regulation ''relates to a then-existing Federal program under which $500,000,000 or more is provided annually to State, local, and tribal governments under entitlement authority,'' if the provision would ''increase the stringency of conditions of assistance'' or ''place caps upon, or otherwise decrease, the Federal Government's responsibility to provide funding,'' and the State, local, or Tribal governments ''lack authority'' to adjust accordingly. At the time of enactment, these entitlement programs were: Medicaid; Aid to Families with Dependent Children work programs; Child Nutrition; Food Stamps; Social Services Block Grants; Vocational Rehabilitation State Grants; Foster Care, Adoption Assistance, and Independent Living; Family Support Welfare Services; and Child Support Enforcement. ''Federal private sector mandate'' includes a regulation that ''would impose an enforceable duty upon the private sector, except (i) a condition of Federal assistance or (ii) a duty arising from participation in a voluntary Federal program.''

The designation of critical habitat does not impose a legally binding duty on non-Federal Government entities or private parties. Under the Act, the only regulatory effect is that Federal agencies must ensure that their actions do not destroy or adversely modify critical habitat under section 7. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply, nor would critical habitat shift the costs of the large entitlement programs listed above onto State governments.

(2) We do not believe that this rule will significantly or uniquely affect small governments. The lands being proposed for critical habitat designation are predominantly owned by the State of Idaho, the U.S. Forest Service, and the Bureau of Land Management. None of these government entities fit the definition of ''small governmental jurisdiction.'' Therefore, a Small Government Agency Plan is not required. However, we will further evaluate this issue as we conduct our economic analysis, and review and revise this assessment as warranted.

Takings—Executive Order 12630

In accordance with Executive Order 12630 (''Government Actions and Interference with Constitutionally Protected Private Property Rights''), this rule is not anticipated to have

significant takings implications. As discussed above, the designation of critical habitat affects only Federal actions. Critical habitat designation does not affect landowner actions that do not require Federal funding or permits, nor does it preclude development of habitat conservation programs or issuance of incidental take permits to permit actions that do require Federal funding or permits to go forward. Due to current public knowledge of the species protections and the prohibition against take of the species both within and outside of the proposed areas, we do not anticipate that property values will be affected by the critical habitat designation. However, we have not yet completed the economic analysis for this proposed rule. Once the economic analysis is available, we will review and revise this preliminary assessment as warranted, and prepare a Takings Implication Assessment.

Federalism—Executive Order 13132

In accordance with Executive Order 13132 (Federalism), this proposed rule does not have significant Federalism effects. A Federalism summary impact statement is not required. In keeping with Department of the Interior and Department of Commerce policy, we requested information from, and coordinated development of, this proposed critical habitat designation with appropriate State resource agencies in Washington and Idaho. The designation of critical habitat in areas currently occupied by the southern Selkirk Mountains caribou may impose nominal additional regulatory restrictions to those currently in place and, therefore, may have little incremental impact on State and local governments and their activities. The designation may have some benefit to these governments because the areas that contain the physical or biological features essential to the conservation of the species are more clearly defined, and the elements of the features of the habitat necessary to the conservation of the species are specifically identified. This information does not alter where and what federally sponsored activities may occur. However, it may assist local governments in long-range planning (rather than having them wait for case-by-case section 7 consultations to occur).

Where State and local governments require approval or authorization from a Federal agency for actions that may affect critical habitat, consultation under section 7(a)(2) would be required. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency.

Civil Justice Reform—Executive Order 12988

In accordance with E.O. 12988 (Civil Justice Reform), the Office of the Solicitor has determined that the rule does not unduly burden the judicial system and that it meets the requirements of sections 3(a) and 3(b)(2) of the Order. We have proposed designating critical habitat in accordance with the provisions of the Act. This proposed rule uses standard property descriptions and identifies the elements of physical and biological features essential to the conservation of the species within the designated areas to assist the public in understanding the habitat needs of the southern Selkirk Mountains caribou population.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rule does not contain any new collections of information that require approval by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This rule will not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

It is our position that, outside the jurisdiction of the U.S. Court of Appeals for the Tenth Circuit, we do not need to prepare environmental analyses pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) in connection with designating critical habitat under the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This position was upheld by the U.S. Court of Appeals for the Ninth Circuit (*Douglas County* v. *Babbitt,* 48 F.3d 1495 (9th Cir. 1995), cert. denied 516 U.S. 1042 (1996)).]

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES**. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to tribes.

We have determined that there are no tribal lands that were occupied by woodland caribou at the time of listing that contain the features essential for conservation of the species, and no tribal lands unoccupied by the species at the time of listing that are essential for the conservation of the southern Selkirk mountain caribou population. Therefore, we are not proposing to designate critical habitat for the southern Selkirk Mountains caribou on tribal lands.

References Cited

A complete list of references cited in this rulemaking is available on the Internet at *http://www.regulations.gov* and upon request from the Idaho Fish

and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Author(s)

The primary authors of this package are staff members of the Idaho Fish and Wildlife Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

2. In § 17.11(h), revise the entry for ''Caribou, woodland'' under ''Mammals'' in the List of Endangered and Threatened Wildlife to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
MAMMALS							
*	*	*	*	*	*		*
Caribou, woodland ...	*Rangifer tarandus caribou*.	Canada, U.S. (AK, ID, ME, MI, MN, MT, NH, VT, WA, WI).	Canada (south-eastern British Columbia bounded by the Canada-U.S. border, Columbia River, Kootenay River, Kootenay Lake, and Kootenai River, U.S. (ID, WA).	E	1984, 128E, 136, 143	17.95(a)	NA
*	*	*	*	*	*		*

3. In § 17.95, amend paragraph (a) by adding an entry for ''Woodland caribou, (*Rangifer tarandus caribou*), Southern Selkirk Mountains Population'' in the same alphabetical order that the species appears in the table at § 17.11(h), to read as follows:

§ 17.95 Critical habitat—fish and wildlife.

* * * * *

(a) Mammals.

* * * * *

Woodland Caribou (*Rangifer tarandus caribou)* Southern Selkirk Mountains Population

(1) Critical habitat units are depicted for Bonner and Boundary Counties, Idaho, and Pend Oreille County, Washington, on the maps below.

(2) Within these areas, the primary constituent elements of the physical and biological features essential to the conservation of the southern Selkirk Mountains population of woodland caribou consist of components:

i. Mature to old growth western hemlock (*Tsuga heterophylla*)/western red cedar (*Thuja plicata*) climax forest, and subalpine fir (*Abies lasiocarpa*)/Engelmann spruce (*Picea engelmanni*) climax forest over 4,000 ft (1,220 m) in elevation; these habitats typically have 70 percent or greater canopy closure.

ii. Ridge tops with deep (up to 16 ft (5 m)) snowpack that are generally 6,000 ft (1,830 m) in elevation or higher, in mature to old stands of subalpine fir (*Abies lasiocarpa*)/Engelmann spruce (*Picea engelmanni*) climax forest, with relatively open (approximately 50 percent) canopy.

iii. Arboreal hair lichen growth in high enough amounts to support southern Selkirk Mountains woodland caribou herds.

iv. High-elevation benches and shallow slopes, secondary stream bottoms, riparian areas, and seeps, and subalpine meadows with succulent forbs and grasses, flowering plants, horsetails, willow, huckleberry, dwarf birch, sedges, and lichens.

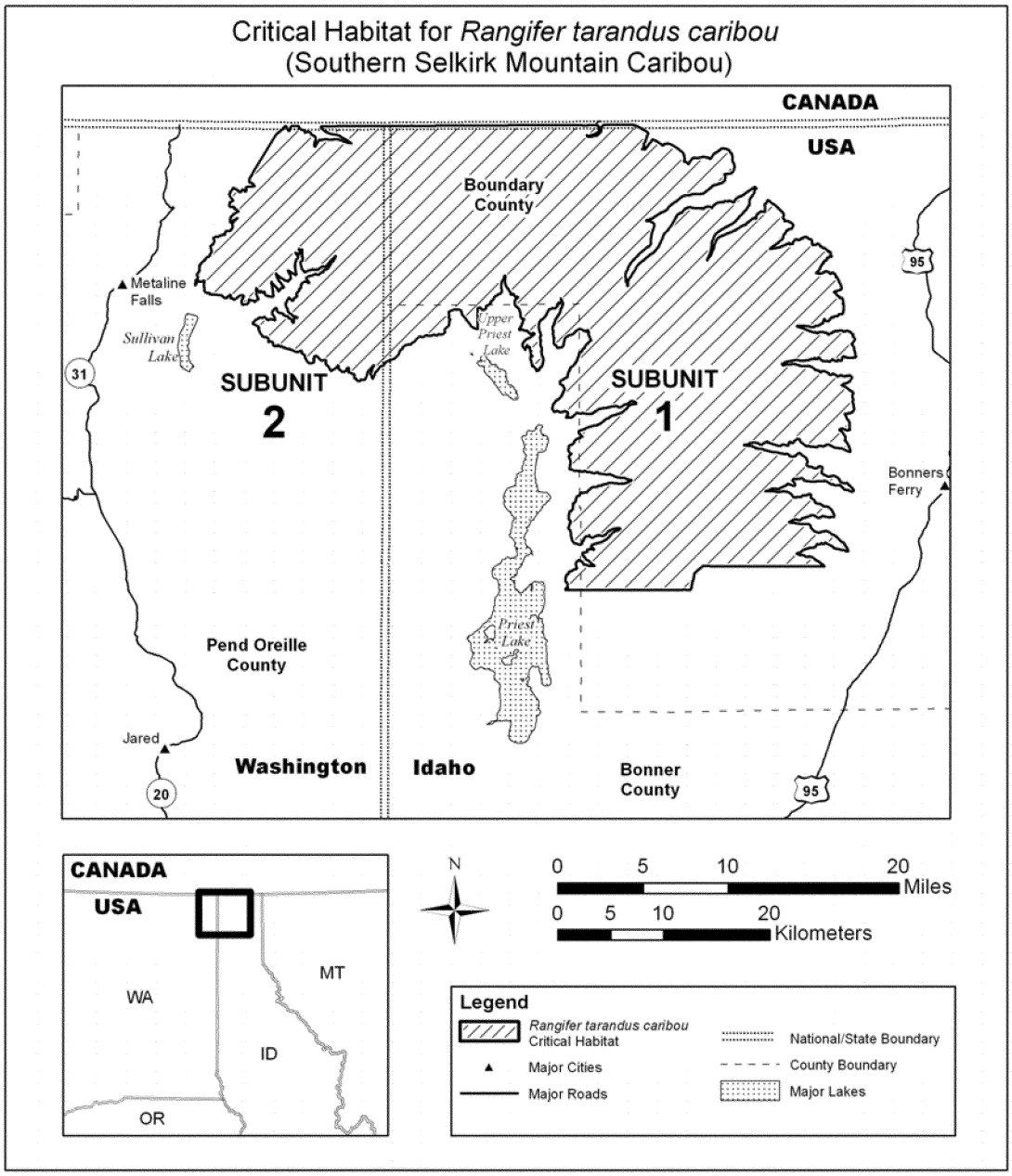
v. Transition zones that connect the habitats described above and that facilitate seasonal caribou movements between habitat types.

(3) Critical habitat does not include manmade structures (such as buildings, fire lookout stations, roads, and other paved areas) and the land on which they are located existing within the legal boundaries on the effective date of this rule.

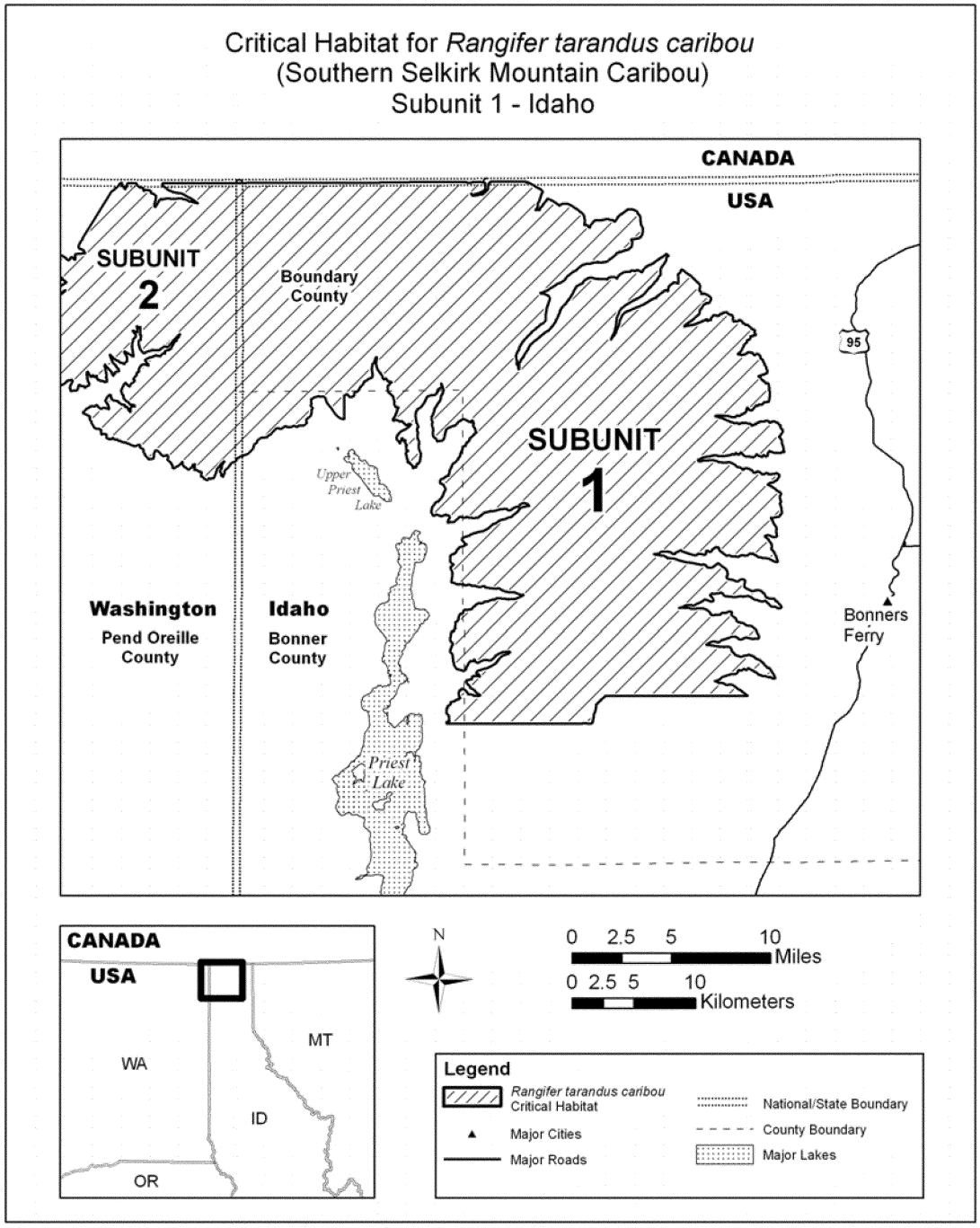
(4) Critical habitat map units. Data layers defining map units were created using digital elevation models, caribou radiotelemetry points, and caribou habitat suitability models, and were then mapped using Universal Transverse Mercator (UTM) coordinates.

(5) **Note:** Index map follows:

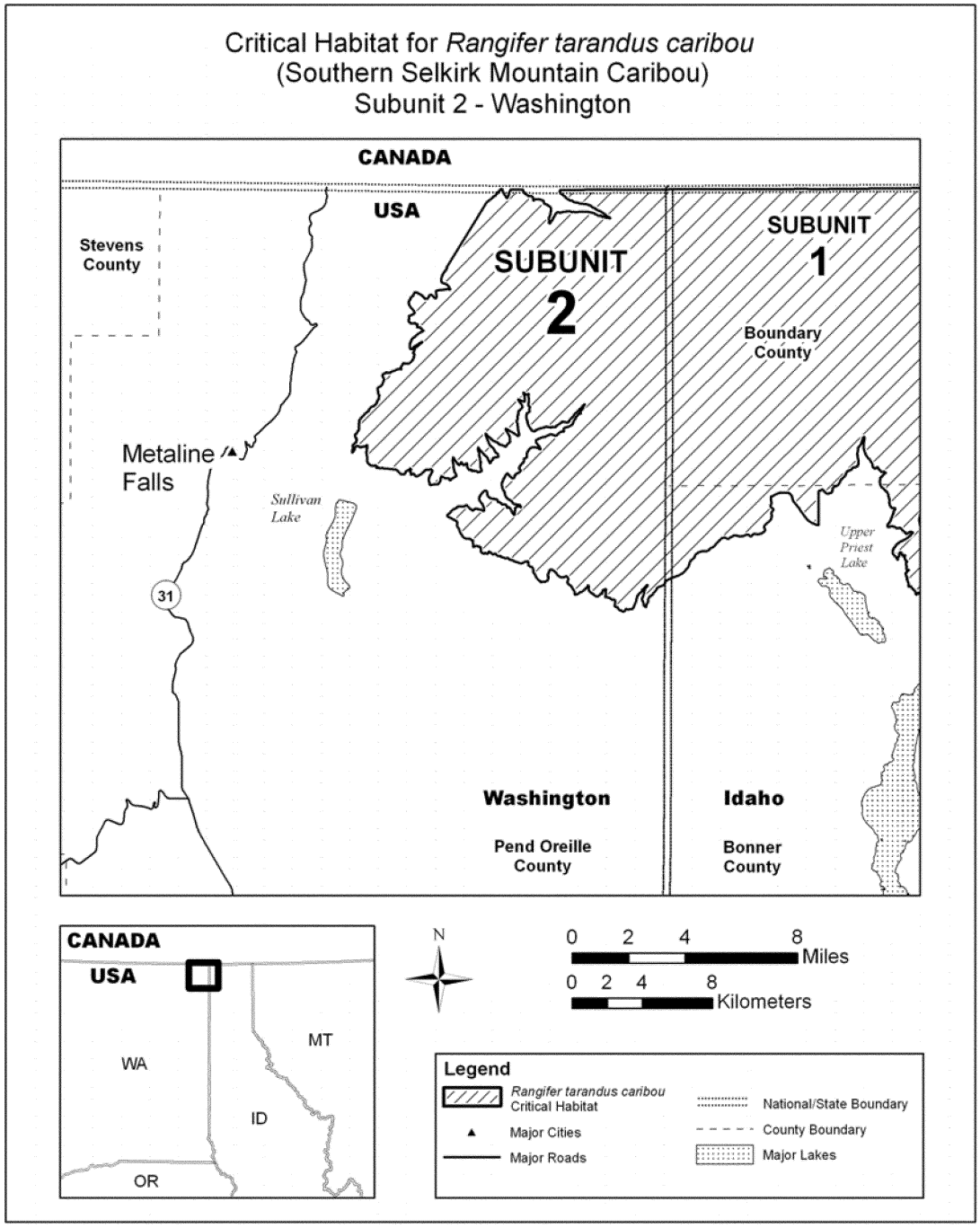
BILLING CODE 4310–55–P



(6) Subunit 1: Bonner and Boundary Counties, Idaho. Map of Subunit 1, Bonner and Boundary Counties, Idaho, follows:



(8) Subunit: Pend Oreille County, Washington. Map of Subunit 2, Pend Oreille County, Washington, follows:


Critical Habitat for Rangifer tarandus caribou
(Southern Selkirk Mountain Caribou)
Subunit 2 - Washington
CANADA
USA
Stevens County
SUBUNIT 2
SUBUNIT 1
Boundary County
Metaline Falls
Sullivan Lake
Upper Priest Lake
31
Washington
Pend Oreille County
Idaho
Bonner County
CANADA
USA
WA
MT
ID
OR
N
0 2 4 8 Miles
0 2 4 8 Kilometers
Legend
Rangifer tarandus caribou Critical Habitat
Major Cities
Major Roads
National/State Boundary
County Boundary
Major Lakes

* * * * *

Dated: November 16, 2011.

Rachel Jacobson,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2011–30451 Filed 11–29–11; 8:45 am]

BILLING CODE 4310–55–C

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 111102663–1682–01]

RIN 0648–BB60

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Resources of the Gulf of Mexico; Commercial Reef Fish Fishery of the Gulf of Mexico; Control Date

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

ACTION: Advanced notice of proposed rulemaking; request for comments.

SUMMARY: This notice announces that the Gulf of Mexico Fishery Management Council (Council) is considering creating additional restrictions limiting participation in the Red Snapper Individual Fishing Quota (IFQ) Program. If such management measures are implemented, the Council is considering January 1, 2012, as a possible control date. Anyone entering the program after the control date will not be assured of future access should a management regime that limits participation in the program be prepared and implemented. NMFS invites comments on the establishment of this control date.

DATES: Comments must be submitted by December 30, 2011.

ADDRESSES: You may submit comments on the proposed rule identified by ''NOAA–NMFS–2011–0273'' by any of the following methods:

- *Electronic submissions:* Submit electronic comments via the Federal e-Rulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Susan Gerhart, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

Instructions: All comments received are a part of the public record and will generally be posted to *http://www.regulations.gov* without change. All Personal Identifying 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.

To submit comments through the Federal e-Rulemaking Portal: *http://www.regulations.gov,* click on ''submit a comment,'' then enter ''NOAA–NMFS–2011–0273'' in the keyword search and click on ''search''. To view posted comments during the comment period, enter ''NOAA–NMFS–2011–0273'' in the keyword search and click on ''search''. NMFS will accept anonymous comments (enter N/A in the required field if you wish to remain anonymous). You may submit attachments to electronic comments in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

Comments received through means not specified in this rule will not be considered.

FOR FURTHER INFORMATION CONTACT: Susan Gerhart, *telephone:* (727) 824–5305, or *email: Susan.Gerhart@noaa.gov.*

SUPPLEMENTARY INFORMATION: Beginning January 1, 2012, all U.S. citizens or permanent resident aliens are eligible to receive transfers of Red Snapper IFQ shares or allocation. A Gulf of Mexico (Gulf) commercial reef fish permit will still be required to harvest, land, and sell red snapper. This notice is to inform current and potential participants of the Gulf Red Snapper IFQ Program that possession of IFQ shares or allocation after this date may not ensure participation under future management of the program. The Council is considering a provision to require shareholders to ''use'', as defined by the provision, all or some portion of their allocation, or be subject to losing their shares. Other options include re-establishing a requirement to possess a Gulf commercial reef fish permit to receive shares or allocation under the program. If the Council prepares an amendment to the Fishery Management Plan (FMP) for Reef Fish Resources in the Gulf to restrict participation in the Gulf Red Snapper IFQ Program in relation to this control date, an analysis of the specific biological, economic, and social effects of the action will be prepared at that time. Those analyses would be contained in that subsequent amendment to the FMP and would be made available to the public at that time.

Publication of the control dates in the **Federal Register** informs participants of the Council's considerations, and gives notice to anyone entering the fishery after the control date they would not be assured of future access should a management regime be implemented using the control date as a means to restrict participation. Implementation of any such program would require preparation of an amendment to the respective FMP and publication of a notice of availability and proposed rule in the **Federal Register** with pertinent public comment periods.

Since the first control date notice of November 1, 1989, 54 FR 46755 (November 7, 1989), the Council has established a total of five control dates for various aspects of the Gulf of Mexico reef fish fishery. As stated in the accompanying notices, they were intended to provide additional notice to the public that the Council was considering certain future management actions potentially restricting public access to fishery resources. The most recent control date was December 31, 2008, 74 FR 11517 (March 19, 2008), which related to potential future actions to address overcapacity in the commercial sector of the reef fish fishery. The current notice does not supersede any of the prior notices, and is intended only to provide additional public notice of potential future action being considered relative to the red snapper IFQ program.

The establishment of a control date does not commit the Council or NMFS to any particular management regime. The Council may or may not make use of this control date as part of the requirements for participation in the IFQ Program. Fishermen are not guaranteed future participation in the program, regardless of their entry date. The Council may take action that would affect participants who were in the program prior to the control date or the Council may choose to take no further action to control entry or access to the IFQ program.

This notification also gives the public notice that interested participants should locate and preserve records that substantiate and verify their participation in the Gulf reef fish fishery.

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

Dated: November 25, 2011.

Patricia A. Montanio,

Acting Deputy Assistant Administrator for Operations, National Marine Fisheries Service.

[FR Doc. 2011–30854 Filed 11–29–11; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 76, No. 230
Wednesday, November 30, 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 HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0400]

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2011–0014]

Approaches to Reducing Sodium Consumption; Establishment of Dockets; Request for Comments, Data, and Information; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS; Food Safety and Inspection Service, USDA.

ACTION: Notice; extension of comment period for the submission of comments, data, and information.

SUMMARY: The Food and Drug Administration (FDA) and the Food Safety and Inspection Service (FSIS) are extending the comment period to January 27, 2012, for the notice entitled ''Approaches to Reducing Sodium Consumption; Establishment of Dockets; Request for Comments, Data, and Information,'' that appeared in the **Federal Register** of September 15, 2011 (76 FR 57050). In that notice, FDA and FSIS requested comments on research, data, and other information that will better inform both Agencies about current and emerging practices by the private sector regarding sodium reduction in foods; current consumer understanding of the role of sodium in hypertension and other chronic illnesses; sodium consumption practices; motivation and barriers in reducing sodium in consumers' food intakes; and issues associated with the development of targets for sodium reduction in foods to promote reduction in excess sodium intake. FDA and FSIS are extending the comment period in response to a request from an industry association for additional time to allow interested persons to submit comments.

DATES: Submit either electronic or written comments and data and information by January 27, 2012.

ADDRESSES: *FDA:* Submit electronic comments and data and information to *http://www.regulations.gov*. Submit written comments and data and information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All submissions must include the Agency name and the docket number FDA–2011–N–0400.

FSIS: Submit electronic comments and data and information to *http://www.regulations.gov*. Submit written comments and data and information to the Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, FSIS Docket Room, 1400 Independence Ave., SW., Patriots Plaza III, Mailstop 3782, rm. 163A, Washington, DC 20250–3700. All submissions must include the Agency name and the docket number FSIS–2011–0014.

FOR FURTHER INFORMATION CONTACT:

FDA: Richard E. Bonnette, Center for Food Safety and Applied Nutrition (HFS–255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, (240) 402–1235.

FSIS: Rosalyn Murphy-Jenkins, Director, Labeling and Program Delivery Division, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, USDA, FSIS, OPPD, LPDD Stop Code 3784, Patriots Plaza III, 8–161A, 1400 Independence Ave., SW., Washington, DC 20250–3700.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 15, 2011 (76 FR 57050), FDA and FSIS published a notice entitled ''Approaches to Reducing Sodium Consumption; Establishment of Dockets; Request for Comments, Data, and Information.'' In this notice, FDA and FSIS requested comments, research, data, and other information that will better inform both Agencies about current and emerging practices by the private sector regarding sodium reduction; current consumer understanding of the role of sodium in hypertension and other chronic illnesses; sodium consumption practices; motivation and barriers in reducing sodium in consumers' food intakes; and issues associated with the development of targets for sodium reduction in foods to promote reduction in excess sodium intake. The notice provided a 75-day comment period, thereby establishing November 29, 2011, as the deadline for the submission of comments, data, and information.

On November 4, 2011, FDA and FSIS received a request from an industry association for an extension of the comment period until January 27, 2011. The request conveyed the concern that the current 75-day comment period does not allow sufficient time to collect responsive information and data and prepare it for submission to the Agencies.

FDA and FSIS have considered the request and are extending the comment period for the notice entitled ''Approaches to Reducing Sodium Consumption; Establishment of Dockets; Request for Comments, Data, and Information'' until January 27, 2012. FDA and FSIS believe that the extension provides adequate time for interested persons to submit comments.

II. Request for Comments

FDA: Interested persons may submit to FDA's 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.

FSIS: Interested persons may submit to FSIS's Docket Clerk (see **ADDRESSES**) either electronic or written comments regarding this document. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the FSIS Docket Room between 8:30 a.m. and 4:30 p.m., Monday through Friday.

Because two docket numbers are associated with this document, please include with your comments the docket number that corresponds with the appropriate Agency. Comments

submitted for inclusion in both dockets should be submitted separately to each identified docket number to ensure consideration by both Agencies.

Dated: November 22, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy, Food and Drug Administration.

Dated: November 23, 2011.

Alfred V. Almanza,

Administrator, Food Safety and Inspection Service.

[FR Doc. 2011–30865 Filed 11–28–11; 8:45 am]

BILLING CODE 4160–01–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Maine State 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 Maine Advisory Committee to the Commission (Committee) will convene by conference call at 9:30 a.m. (EST) on Wednesday, December 14, 2011. The purpose of the meeting is to plan future activities.

This meeting is available to the public through the following toll-free call-in number: (800) 399–0013; the conference call access code number 31521613. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–(800) 877–8339 and providing the Service with the conference call number and contact name Ivy Davis.

Members of the public are entitled to submit written comments; the comments must be received in the regional office by January 14, 2012. Comments may be mailed to the Eastern Regional Office (ERO), U.S. Commission on Civil Rights, 624 9th Street, NW., Washington, DC 20425 or emailed to *ero@usccr.gov*. Persons who desire additional information may contact ERO by email at *ero@usccr.gov* or by telephone at (202) 376–7533.

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 the Committee are directed to the Commission's Web site, *http://www.usccr.gov*, or may contact ERO at the above telephone number, email or street address.

The meeting will be conducted pursuant to the rules and regulations of the Commission and FACA.

Dated in Washington, DC, November 23, 2011.

Peter Minarik,

Acting Chief, Regional Programs Coordination Unit.

[FR Doc. 2011–30823 Filed 11–29–11; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Emerging Technology and Research Advisory Committee (ETRAC): Notice of Recruitment of Private-Sector Members

The Bureau of Industry and Security (BIS) is announcing a recruitment for new candidates to serve on the Emerging Technology and Research Advisory Committee (ETRAC) to advise the Department and other agency officials on: (i) The identification of emerging technologies and research and development activities that may be of interest from a dual-use perspective; (ii) the prioritization of new and existing controls to determine which are of greatest impact; (iii) the potential impact of dual-use export control requirements on research activities; and (iv) the threat to national security posed by unauthorized export technologies.

BIS will consider resumes from accomplished individuals with scientific and technical training actively engaged in research and technology development in industrial and university settings across all fields. Submissions are especially sought from persons with significant involvement in leading edge research and/or development-manufacturing activity in biological sciences (particularly bio electronics and synthetic biology), chemical engineering, directed energy, materials, space technologies (including satellite systems). The purpose of this recruitment is to fill current and future vacancies on the committee.

DATES: To respond to the recruitment notice, please send a copy of your resume to the individual identified under the **ADDRESSES** heading. This Notice of Recruitment expires on January 15, 2012.

ADDRESSES: Interested parties may submit their resume to Ms. Yvette Springer at yvette.springer@bis.doc.gov—or mail their resume to U.S. Department of Commerce, Bureau of Industry and Security, 14th Street and Constitution Ave., NW., Rm. 1093, Washington DC 20230.

FOR FURTHER INFORMATION CONTACT: Mark Crawford, Office of Technology Evaluation (OTE), Bureau of Industry and Security, telephone (202) 482–4933, or *email: mark.crawford@bis.doc.gov;* or

SUPPLEMENTARY INFORMATION: The Emerging Technology and Research Advisory Committee (ETRAC) serves as a technical advisory committee to the Bureau of Industry and Security (BIS) since September 2008. It operates under the terms of section 5(h) of the Export Administration Act of 1979, as amended (EAA), 50 U.S.C. 1701–1707 (2007), and the Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2 (2005. ETRAC is an important vehicle for gathering necessary data as part of the Department's efforts to ensure that export controls continue to apply to sensitive items and keep pace with technological and research innovation without stifling U.S. competitiveness.

BIS's decision to establish the ETRAC drew on three sources: Public comments submitted to BIS in 2007 regarding the Commerce Control List (CCL); the report issued by the Deemed Export Advisory Committee (DEAC), a Federal advisory committee charged with making recommendations to the Secretary regarding BIS's deemed export policy; and a Presidential directive calling for BIS to regularly reassess and update the CCL.

First, in response to a notice of inquiry, ''Request for Public Comments on a Systematic Review of the Commerce Control List,'' published in the **Federal Register** on July 17, 2007, BIS received public comments stating that the CCL was not keeping pace with technology and suggesting that university experts play a greater role in updating the list.

Second, on December 20, 2007, the DEAC submitted its final report, The Deemed Export Rule in the Era of Globalization, to the Secretary of Commerce. The DEAC recommended that BIS create a panel of outside experts in the field of science and engineering to conduct a ''zero-based'' annual review of the list of technologies on the CCL subject to deemed export licensing policy. The DEAC also suggested that the Department increase the focus on and ''build higher fences around those elements of technical knowledge that could have the greatest consequences in the national/homeland security sphere by systematically reviewing the Commerce Control List, with advice from independent experts, to eliminate those items and technologies that have little or no such consequences.''

The DEAC's recommendations contained in the report constitute a written request from representatives of a substantial segment of an industry that produces goods or technology subject to export controls, a requirement under section 5(h) of the EAA for the establishment of a technical advisory committee. Specifically, the DEAC's members were senior officials with significant experience in business, educational research, and national homeland security matters related to scientific and engineering knowledge. As such, there represented a substantial segment of an affected industry that produces items subject to export controls, namely, the U.S. technology community, which is engaged in producing technical data and providing technical assistance.

Finally, the President issued a Dual-Use Trade Reform directive on January 22, 2008, that called for export controls to be constantly reassessed to ensure that they control the export and reexport of sensitive items while minimizing their impact on U.S. economic competitiveness and innovation. In order to meet this objective, the President directed the Secretary of Commerce to develop a regularized process that would consider input by technical advisory committees in the review and updating of the CCL.

The ETRAC is charged with identifying emerging technologies and research and development activities that may be of interest from a dual-use perspective, prioritizing new and existing controls related to deemed exports to determine which are of greatest consequence to national security, and examining how research is performed to understand the impact that the Export Administration Regulations have on academia, federal laboratories, and industry.

Emerging Technology and Research Advisory Committee (ETRAC): Notice of Recruitment of Members. The membership is drawn from both private and public sectors, based on the description below as well as the charter.

BIS is recruiting members for the ETRAC. The ETRAC consists of a maximum of 28 members and will feature a balanced membership that will include diverse points of view. It will consist of experts drawn equally from academia, federal laboratories, and industry to ensure a comprehensive discussion of emerging technologies and research and development activities and their implications with regard to national and economic security. ETRAC members will be appointed by the Secretary of Commerce and serve a term of not more than four consecutive years. Each member must be able to qualify for a Secret clearance prior to appointment. These clearances are necessary so that members may be permitted access to sensitive intelligence and law enforcement information related to the ETRAC's mission. The ETRAC will also reach out to other government and non-government experts to ensure a broad and thorough review of the issues.

To respond to the recruitment notice, please send a copy of your resume to Ms. Yvette Springer at *Yvette.springer@bis.doc.gov*.

Dated: November 21, 2011.

Yvette Springer,

Committee Liaison Officer.

[FR Doc. 2011–30439 Filed 11–25–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (''the Department'') has received requests to conduct administrative reviews of various antidumping and countervailing duty orders and findings with October anniversary dates. In accordance with the Department's regulations, we are initiating those administrative reviews. The Department also received a request to revoke one antidumping duty order in part.

DATES: *Effective Date:* November 30, 2011.

FOR FURTHER INFORMATION CONTACT: Brenda Waters, Office of AD/CVD Operations, Customs Unit, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW, Washington, DC 20230, *telephone:* (202) 482–4735.

SUPPLEMENTARY INFORMATION:

Background

The Department has received timely requests, in accordance with 19 CFR 351.213(b), for administrative reviews of various antidumping and countervailing duty orders and findings with October anniversary dates. The Department also received a timely request to revoke in part the antidumping duty order on Steel Wire Garment Hangers from the People's Republic of China for one exporter.

All deadlines for the submission of various types of information, certifications, or comments or actions by the Department discussed below refer to the number of calendar days from the applicable starting time.

Notice of No Sales

If a producer or exporter named in this notice of initiation had no exports, sales, or entries during the period of review (''POR''), it must notify the Department within 60 days of publication of this notice in the **Federal Register**. All submissions must be filed electronically at *http://iaaccess.trade.gov* in accordance with 19 CFR 351.303. *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011). Such submissions are subject to verification in accordance with section 782(i) of the Tariff Act of 1930, as amended (''Act''). Further, in accordance with 19 CFR 351.303(f)(3)(ii), a copy of each request must be served on the petitioner and each exporter or producer specified in the request.

Respondent Selection

In the event the Department limits the number of respondents for individual examination for administrative reviews, the Department intends to select

respondents based on U.S. Customs and Border Protection (''CBP'') data for U.S. imports during the POR. We intend to release the CBP data under Administrative Protective Order (''APO'') to all parties having an APO within seven days of publication of this initiation notice and to make our decision regarding respondent selection within 21 days of publication of this **Federal Register** notice. The Department invites comments regarding the CBP data and respondent selection within five days of placement of the CBP data on the record of the applicable review.

In the event the Department decides it is necessary to limit individual examination of respondents and conduct respondent selection under section 777A(c)(2) of the Act:

In general, the Department has found that determinations concerning whether particular companies should be ''collapsed'' (i.e., treated as a single entity for purposes of calculating antidumping duty rates) require a substantial amount of detailed information and analysis, which often require follow-up questions and analysis. Accordingly, the Department will not conduct collapsing analyses at the respondent selection phase of this review and will not collapse companies at the respondent selection phase unless there has been a determination to collapse certain companies in a previous segment of this antidumping proceeding (*i.e.,* investigation, administrative review, new shipper review or changed circumstances review). For any company subject to this review, if the Department determined, or continued to treat, that company as collapsed with others, the Department will assume that such companies continue to operate in the same manner and will collapse them for respondent selection purposes. Otherwise, the Department will not-collapse companies for purposes of respondent selection. Parties are requested to (a) identify which companies subject to review previously were collapsed, and (b) provide a citation to the proceeding in which they were collapsed. Further, if companies are requested to complete the Quantity and Value Questionnaire for purposes of respondent selection, in general each company must report volume and value data separately for itself. Parties should not include data for any other party, even if they believe they should be treated as a single entity with that other party. If a company was collapsed with another company or companies in the most recently completed segment of this proceeding where the Department considered collapsing that entity, complete quantity and value data for that collapsed entity must be submitted.

Deadline for Withdrawal of Request for Administrative Review

Pursuant to 19 CFR 351.213(d)(1), a party that has requested a review may withdraw that request within 90 days of the date of publication of the notice of initiation of the requested review. The regulation provides that the Department may extend this time if it is reasonable to do so. In order to provide parties additional certainty with respect to when the Department will exercise its discretion to extend this 90-day deadline, interested parties are advised that, with regard to reviews requested on the basis of anniversary months on or after August 2011, the Department does not intend to extend the 90-day deadline unless the requestor demonstrates that an extraordinary circumstance has prevented it from submitting a timely withdrawal request. Determinations by the Department to extend the 90-day deadline will be made on a case-by-case basis.

Separate Rates

In proceedings involving non-market economy (''NME'') countries, the Department begins with a rebuttable presumption that all companies within the country are subject to government control and, thus, should be assigned a single antidumping duty deposit rate. It is the Department's policy to assign all exporters of merchandise subject to an administrative review in an NME country this single rate unless an exporter can demonstrate that it is sufficiently independent so as to be entitled to a separate rate.

To establish whether a firm is sufficiently independent from government control of its export activities to be entitled to a separate rate, the Department analyzes each entity exporting the subject merchandise under a test arising from the *Final Determination of Sales at Less Than Fair Value: Sparklers from the People's Republic of China,* 56 FR 20588 (May 6, 1991), as amplified by *Final Determination of Sales at Less Than Fair Value: Silicon Carbide from the People's Republic of China,* 59 FR 22585 (May 2, 1994). In accordance with the separate rates criteria, the Department assigns separate rates to companies in NME cases only if respondents can demonstrate the absence of both *de jure* and *de facto* government control over export activities.

All firms listed below that wish to qualify for separate rate status in the administrative reviews involving NME countries must complete, as appropriate, either a separate rate application or certification, as described below. For these administrative reviews, in order to demonstrate separate rate eligibility, the Department requires entities for whom a review was requested, that were assigned a separate rate in the most recent segment of this proceeding in which they participated, to certify that they continue to meet the criteria for obtaining a separate rate. The Separate Rate Certification form will be available on the Department's Web site at *http://www.trade.gov/ia* on the date of publication of this **Federal Register** notice. In responding to the certification, please follow the ''Instructions for Filing the Certification'' in the Separate Rate Certification. Separate Rate Certifications are due to the Department no later than 60 calendar days after publication of this **Federal Register** notice. The deadline and requirement for submitting a Certification applies equally to NME-owned firms, wholly foreign-owned firms, and foreign sellers who purchase and export subject merchandise to the United States.

Entities that currently do not have a separate rate from a completed segment of the proceeding [1] should timely file a Separate Rate Application to demonstrate eligibility for a separate rate in this proceeding. In addition, companies that received a separate rate in a completed segment of the proceeding that have subsequently made changes, including, but not limited to, changes to corporate structure, acquisitions of new companies or facilities, or changes to their official company name [2], should timely file a Separate Rate Application to demonstrate eligibility for a separate rate in this proceeding. The Separate Rate Status Application will be available on the Department's Web site at *http://www.trade.gov/ia* on the date of publication of this **Federal Register** notice. In responding to the Separate Rate Status Application, refer to the instructions contained in the application. Separate Rate Status Applications are due to the Department no later than 60 calendar days of

[1] Such entities include entities that have not participated in the proceeding, entities that were preliminarily granted a separate rate in any currently incomplete segment of the proceeding (*e.g.,* an ongoing administrative review, new shipper review, *etc.*) and entities that lost their separate rate in the most recently complete segment of the proceeding in which they participated.

[2] Only changes to the official company name, rather than trade names, need to be addressed via a Separate Rate Application. Information regarding new trade names may be submitted via a Separate Rate Certification.

publication of this **Federal Register** notice. The deadline and requirement for submitting a Separate Rate Status Application applies equally to NME-owned firms, wholly foreign-owned firms, and foreign sellers that purchase and export subject merchandise to the United States.

For exporters and producers who submit a separate-rate status application or certification and subsequently are selected as mandatory respondents, these exporters and producers will no longer be eligible for separate rate status unless they respond to all parts of the questionnaire as mandatory respondents.

Initiation of Reviews

In accordance with 19 CFR 351.221(c)(1)(i), we are initiating administrative reviews of the following antidumping and countervailing duty orders and findings. We intend to issue the final results of these reviews not later than October 31, 2012.

	Period to be reviewed
Antidumping Duty Proceedings	
MEXICO: Carbon and Certain Alloy Steel Wire Rod A–201–830	10/1/10–9/30/11
DeAcero S.A. de C.V.	
Certain Magnesia Carbon Bricks [3] A–201–837	3/11/10–9/6/10 & 9/16/10–8/31/11
THE PEOPLE'S REPUBLIC OF CHINA: Steel Wire Garment Hangers [4] A–570–918	10/1/10–9/30/11
Angang Clothes Rack Manufacture	
Angang Clothes Rack Manufacture Co.,	
Brightwell (Hong Kong) Enterprise Ltd.	
Delmar International (China) Inc.	
Hangzhou Chenyang Plastic Dipping Co., Ltd.	
Hezhou City Yaolong Trade Co Ltd.	
Jiaxing Boyi Medical Device Co. Ltd.	
Jingdezhen Honghe Im. & Ex. Trade Co. Ltd.	
Kingtex Imp & Exp Co., Ltd.	
Laidlaw Company LLC	
Mao's Clothes Hangers Co., Ltd.	
Ningbo Beilun Huafa Metal Products	
Ningbo Dasheng Hanger Ind. Co., Ltd.	
Pujiang County Command Metal Products Co., Ltd.	
Quanzhou Xiongxin Trade Co., Ltd.	
Quyky Yanglei International Co., Ltd.	
Shaan Xi Succeed Trading Co., Ltd.	
Shandong Autjinrong Found-Assemble Co., Ltd.	
Shanghai Almex Co., Ltd.	
Shanghai China Light Industry International	
Shanghai Jianhai International Trade Co., Ltd.	
Shanghai Jinda Imp & Exp Inc.	
Shanghai M2M Imp. Exp. Co., Ltd.	
Shanghai Mosta Wath & Clock Imp. Exp.	
Shanghai Ruishan Metal Products Co., Ltd.	
Shanghai Sagacity International	
Shanghai Sanmao Import & Export	
Shanghai Shengsing Enterprise Co.	
Shanghai Textile Raw Materials	
Shanghai Textile United Co., Ltd.	
Shanghai Wells Hanger Co., Ltd.	
Shanghai Yangfan Industrial Co., Ltd.	
Shanghai Zhonghui Intl Trade Co., Ltd.	
Shangyu Baoxiang Metal Manufactured Co., Ltd	
Shaoxing Andrew Metal Manufactured	
Shaoxing Dingli Metal Clotheshorse	
Shaoxing Gangyuan Metal Manufacture	
Shaoxing Guochao Metallic Products Co., Ltd.	
Shaoxing Kinglaw Metal Products Co., Ltd.	
Shaoxing Leiluo Metal Manufactured	
Shaoxing Liangbao Metal Manufactured Co., Ltd.	
Shaoxing Meideli Metal Hanger Co., Ltd.	
Shaoxing Shunji Metal Clotheshorse Co., Ltd.	
Shaoxing Tongzhou Metal Manufactured Co., Ltd.	
Shaoxing Yuan Metal Manufactured Co., Ltd.	
Shaoxing Zhongbao Metal Manufactured Co., Ltd.	
Shenzhen SED Industry Co., Ltd. a/k/a Shenzhen SED Electronics Co.	
Suzhou Daoyuan Import & Export Co., Ltd.	
Suzhou Hengsheng Import & Export Co., Ltd.	
Wesken International (Kunshan) Co., Ltd.	
Winwell Industrial Ltd.	
Yiwu An'Tai Imp. Exp. Co., Ltd.	
Yiwu Ao-Si Metal Products Co., Ltd.	
Zhejiang Jiashan Rigging Industry Co., Ltd.	
Zhejiang Lucky Cloud Hanger Co., Ltd.	
Zhejiang Perfect Arts & Crafts Co., Ltd.	
Zhejiang Taizhou Hongda Metal Products Co., Ltd. (a/k/a Taizhou Hongda Metal Material Co., Ltd.)	

	Period to be reviewed
Zhejiang Willing Foreign Trading Co. Ltd. Zhuocheng Plastic Co., Ltd.	
Countervailing Duty Proceedings	
None	
Suspension Agreements	
None	

Duringany administrative review covering all or part of a period falling between the first and second or third and fourth anniversary of the publication of an antidumping duty order under 19 CFR 351.211 or a determination under 19 CFR 351.218(f)(4) to continue an order or suspended investigation (after sunset review), the Secretary, if requested by a domestic interested party within 30 days of the date of publication of the notice of initiation of the review, will determine, consistent with *FAG Italia* v. *United States,* 291 F.3d 806 (Fed Cir. 2002), as appropriate, whether antidumping duties have been absorbed by an exporter or producer subject to the review if the subject merchandise is sold in the United States through an importer that is affiliated with such exporter or producer. The request must include the name(s) of the exporter or producer for which the inquiry is requested.

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant provisional-measures ''gap'' period, of the order, if such a gap period is applicable to the period of review.

Interested parties must submit applications for disclosure under administrative protective orders in accordance with 19 CFR 351.305. On January 22, 2008, the Department published *Antidumping and Countervailing Duty Proceedings: Documents Submission Procedures; APO Procedures,* 73 FR 3634 (January 22, 2008). Those procedures apply to administrative reviews included in this notice of initiation. Parties wishing to participate in any of these administrative reviews should ensure that the meet the requirements of these procedures (*e.g.,* the filing of separate letters of appearance as discussed at 19 CFR 351.103(d)).

Any party submitting factual information in an antidumping duty or countervailing duty proceeding must certify to the accuracy and completeness of that information. *See* section 782(b) of the Act. Parties are hereby reminded that revised certification requirements are in effect for company/government officials as well as their representatives in all segments of any antidumping duty or countervailing duty proceedings initiated on or after March 14, 2011. *See Certification of Factual Information to Import Administration During Antidumping and Countervailing Duty Proceedings: Interim Final Rule,* 76 FR 7491 (February 10, 2011) (*Interim Final Rule*), amending 19 CFR 351.303(g)(1) and (2). The formats for the revised certifications are provided at the end of the *Interim Final Rule.* The Department intends to reject factual submissions in any proceeding segments initiated on or after March 14, 2011 if the submitting party does not comply with the revised certification requirements.

These initiations and this notice are in accordance with section 751(a) of the Act (19 U.S.C. 1675(a)) and 19 CFR 351.221(c)(1)(i).

Dated: November 18, 2011.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2011–30857 Filed 11–29–11; 8:45 am]

BILLING CODE 3510–DS–P

[3] In the initiation notice that published on October 31, 2011 (76 FR 67133), the period of review for the above referenced case was incorrect. The period listed above is the correct period of review for this case.

[4] If one of the above named companies does not qualify for a separate rate, all other exporters of Steel Wire Garment Hangers from the People's Republic of China (''PRC'') who have not qualified for a separate rate are deemed to be covered by this review as part of the single PRC entity of which the named exporters are a part.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–357–812]

Honey From Argentina: Final Results of Antidumping Duty New Shipper Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On August 31, 2011, the Department of Commerce (the Department) published its preliminary results of the 2009–2010 new shipper review of the antidumping duty order on honey from Argentina.[1] This review covers one exporter, Villamora S.A. (Villamora).[2] The period of review (POR) is December 1, 2009 through November 30, 2010. We invited interested parties to comment on the *Preliminary Results* and received no comments. Therefore, our final results remain unchanged from our *Preliminary Results.*

DATES: *Effective Date:* November 30, 2011.

FOR FURTHER INFORMATION CONTACT: Patrick Edwards or Ericka Ukrow, Office 7, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; *telephone:* (202) 482–8029 or (202) 482–0405, respectively.

SUPPLEMENTARY INFORMATION:

Background

On August 31, 2011, the Department published in the **Federal Register** the preliminary results of the new shipper review of the antidumping duty order on honey from Argentina. *See Preliminary Results.* We invited parties to comment on the *Preliminary Results.* We received neither comments nor a request for a hearing.

Period of Review

The POR is December 1, 2009 through November 30, 2010.

Scope of the Order

The merchandise covered by the order is honey from Argentina. The products covered are natural honey, artificial honey containing more than 50 percent natural honey by weight, preparations of natural honey containing more than 50 percent natural honey by weight, and flavored honey. The subject merchandise includes all grades and colors of honey whether in liquid,

[1] *See Honey From Argentina: Preliminary Results of Antidumping Duty New Shipper Review,* 76 FR 54202 (August 31, 2011) (*Preliminary Results*).

[2] The Department determined in its preliminary results that it was appropriate to treat Enzo Juan Garaventa and Villamora as a single entity, pursuant to 19 CFR 351.401(f)(1) and (2). *See Preliminary Results.* For a more detailed discussion of our collapsing analysis, *see* Affiliation and Collapsing Memorandum dated August 31, 2011.

creamed, comb, cut comb, or chunk form, and whether packaged for retail or in bulk form. The merchandise is currently classifiable under subheadings 0409.00.00, 1702.90.90, and 2106.90.99 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and U.S. Customs and Border Protection (CBP) purposes, the Department's written description of the merchandise under the order is dispositive.

Final Results of Review

We determine that the following dumping margin exists for the period December 1, 2009, through November 30, 2010:

Manufacturer/exporter	Weighted-average margin (percentage)
Enzo Juan Garaventa or Villamora S.A./Enzo Juan Garaventa or Villamora S.A.	0.00

Assessment Rates

The Department shall determine, and CBP shall assess, antidumping duties on all appropriate entries, in accordance with 19 CFR 351.212(b). The Department intends to issue appropriate assessment instructions directly to CBP 15 days after publication of these final results of review. In accordance with 19 CFR 351.212(b)(1), we are calculating importer- (or customer-) specific assessment rates for the merchandise subject to this review.

The Department clarified its automatic assessment regulation on May 6, 2003. *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003). This clarification will apply to entries of subject merchandise during the POR produced by the company included in these final results of review for which the reviewed company did not know their merchandise was destined for the United States. In such instances, we will instruct CBP to liquidate un-reviewed entries at the all-others rate if there is no rate for the intermediate company involved in the transaction.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this new shipper review for all shipments of the subject merchandise by Enzo Juan Garaventa or Villamora entered, or withdrawn from warehouse, for consumption on or after the publication date of these final results, consistent with section 751(a)(2)(C) of the Act: (1) For subject merchandise manufactured by Enzo Juan Garaventa and exported by either Villamora or Enzo Juan Garaventa, or manufactured by Villamora and exported by either Enzo Juan Garaventa or Villamora, the cash deposit rate will be zero; (2) for subject merchandise exported by Villamora but not manufactured by Enzo Juan Garaventa or Villamora, or for subject merchandise exported by Enzo Juan Garaventa, but not manufactured by Villamora or Enzo Juan Garaventa, the cash deposit will continue to be the all-others rate (*i.e.,* 30.24 percent); and (4) for subject merchandise manufactured by Villamora or Enzo Juan Garaventa, but exported by any party other than Villamora or Enzo Juan Garaventa, the cash deposit rate will be the rate applicable to the exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notifications to Interested Parties

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

This notice also serves as a reminder to parties subject to administrative protective orders (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/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 violation, which is subject to sanction.

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Tariff Act of 1930, as amended.

Dated: November 22, 2011.

Paul Piquado,

Assistant Secretary for Import Administration.

[FR Doc. 2011–30859 Filed 11–29–11; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Application(s) for Duty-Free Entry of Scientific Instruments

Pursuant to Section 6(c) of the Educational, Scientific and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, as amended by Pub. L. 106–36; 80 Stat. 897; 15 CFR part 301), we invite comments on the question of whether instruments of equivalent scientific value, for the purposes for which the instruments shown below are intended to be used, are being manufactured in the United States.

Comments must comply with 15 CFR 301.5(a)(3) and (4) of the regulations and be postmarked on or before December 20, 2011. Address written comments to Statutory Import Programs Staff, Room 3720, U.S. Department of Commerce, Washington, DC 20230. Applications may be examined between 8:30 a.m. and 5 p.m. at the U.S. Department of Commerce in Room 3720.

Docket Number: 11–067. *Applicant:* Oregon State University, 640 Kerr Administration Building, Corvallis, OR 97331. *Instrument:* Electron Microscope. *Manufacturer:* FEI Co., the Netherlands. *Intended Use:* The instrument will be used to introduce students to the topics, methods, applications and data interpretation associated with the use of electron microscopy. It will also be used to study tissue samples, newly synthesized materials samples, metals and alloys, as well as to characterize thin films of photosensitive materials that may have use in next-generation photovoltaic devices. *Justification for Duty-Free Entry:* There are no instruments of the same general category manufactured in the United States. *Application accepted by Commissioner of Customs:* October 31, 2011.

Docket Number: 11–068. *Applicant:* Regents of the University of California at Riverside, Campus Purchasing, 4301 Watkins Dr., Riverside, CA 92521–0411. *Instrument:* Electron Microscope. *Manufacturer:* FEI Co., the Netherlands. *Intended Use:* The instrument will be used for research on synthetic and natural materials, live tissue, organelles, minerals, insects, microorganisms and bacteria. Specific research topics will include solar hydrogen generation, storage and conversion, fundamental flow and fracture processes in materials of Earth's crust, and studies on the developmental biology of mucosal tissues. This research relies on the characterization of morphology and structure at microscopic down to

nanometer scale of materials and biological tissues, which can be achieved successfully by utilizing the instrument with spatial resolution down to 1 nm. *Justification for Duty-Free Entry:* There are no instruments of the same general category manufactured in the United States. *Application accepted by Commissioner of Customs:* November 3, 2011.

Docket Number: 11–069. *Applicant:* U.S. Food and Drug Administration, WO62 RM 3204, 10903 New Hampshire Ave., Bldg WO 62, Room G248, Silver Spring, MD 20903. *Instrument:* Electron Microscope. *Manufacturer:* JEOL Ltd., Japan. *Intended Use:* The instrument will be used in the characterization of nanotechnology materials contained in pharmaceuticals, medical devices, biological products, foods and cosmetics. The research will determine the properties of these materials, their interaction with blood, tissue, and other biological products. *Justification for Duty-Free Entry:* There are no instruments of the same general category manufactured in the United States. *Application accepted by Commissioner of Customs:* November 7, 2011.

Dated: November 23, 2011.

Gregory Campbell,

Director, IA Subsidies Enforcement Office.

[FR Doc. 2011–30858 Filed 11–29–11; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XA849

Snapper-Grouper Fishery off the Southern Atlantic States; Amendments 18A, 18B, 18C, 20A, and 20B

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

ACTION: Supplemental Notice of intent (NOI) to prepare draft environmental impact statements (DEISs); request for comments.

SUMMARY: The South Atlantic Fishery Management Council (Council) previously published a NOI for Amendment 18 to the Fishery Management Plan (FMP) for the Snapper-Grouper Fishery of the South Atlantic Region (Amendment 18), on January 28, 2009, which has subsequently been divided into five separate amendments to the FMP for the Snapper-Grouper Fishery of the South Atlantic Region (Snapper-Grouper FMP). The new amendments to the Snapper-Grouper FMP are: Amendment 18A, which is supported by an Environmental Impact Statement (EIS); Amendment 18B, which is supported by an Environmental Assessment (EA); Amendment 18C, for which the specific National Environmental Policy Act (NEPA) document type (EIS or EA) has not yet been determined; Amendment 20A, which is supported by an EA; and Amendment 20B, for which the specific NEPA document has also not yet been determined. If Amendments 18C and 20B to the Snapper-Grouper FMP subsequently require the development of DEISs, NOIs for those amendments will be published in the **Federal Register** at a later date.

This supplemental NOI is intended to inform the public of the Council's decision to divide the actions in Amendment 18 into five separate amendments and subsequently prepare separate supporting NEPA documents for the new amendments. Comments are being solicited on each of the Amendments, regardless of the specific NEPA document being prepared.

DATES: Written comments on the scope of the issues to be addressed in these amendments will be accepted until December 30, 2011, at 5 p.m.

ADDRESSES: You may submit comments on the supplemental NOI identified by NOAA–NMFS–2011–0242 by any of the following methods:

- *Electronic submissions:* Submit electronic comments via the Federal e-Rulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Kate Michie, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

Instructions: All comments received are a part of the public record and will generally be posted to *http://www.regulations.gov* without change. All Personal Identifying 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.

To submit comments through the Federal e-Rulemaking Portal: *http://www.regulations.gov,* click on ''submit a comment'', then enter ''NOAA–NMFS–2011–0242'' in the keyword search and click on ''search''. To view posted comments during the comment period, enter ''NOAA–NMFS–2011–0242'' in the keyword search and click on ''search''. NMFS will accept anonymous comments (enter N/A in the required field if you wish to remain anonymous). You may submit attachments to electronic comments in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only. Comments received through means not specified in this rule will not be considered. Electronic copies of the draft documents may be obtained from the Southeast Regional Office Web site at *http://sero.nmfs.noaa.gov/sf/SASnapperGrouperHomepage.htm.*

FOR FURTHER INFORMATION CONTACT: Kate Michie, *telephone:* (727) 824–5305, *email: Kate.Michie@noaa.gov* or the South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405; *telephone:* (843) 571–4366; *fax:* (843) 769–4520; *email: safmc@safmc.net.*

SUPPLEMENTARY INFORMATION:

Background

The snapper-grouper fishery of the South Atlantic region in the exclusive economic zone is managed under the Snapper-Grouper FMP. The Snapper-Grouper FMP was prepared by the Council and implemented by NMFS under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622. Of the 98 species managed by the Council, 73 of these are included in the snapper-grouper management complex.

A NOI for Amendment 18 was published on January 22, 2008 (73 FR 3701), and contained a notice of consideration of developing a limited-access privilege (LAP) program for the commercial snapper-grouper fishery in the South Atlantic. However, the Council has postponed consideration of a LAP program for the entire snapper-grouper fishery. A second NOI for Amendment 18 was published on April 7, 2008 (73 FR 18782) to announce the development of an amendment to establish a rebuilding plan for the red snapper stock and various management measures to end its overfishing. The Council subsequently moved these management actions to Amendment 17A to the FMP (December 9, 2010, 75 FR 76874).

A third NOI for Amendment 18 was published on January 28, 2009 (74 FR 4944) to inform the public of the preparation of a DEIS in support of the new Amendment 18 to the FMP, which at that time, contained actions to extend the management range of snapper-grouper north of the Council's current jurisdiction; designate essential fish habitat for snapper-grouper species in the extended management range (New England and Mid-Atlantic); change the

golden tilefish fishing year; separate the snowy grouper quota into regions; improve data reporting; limit participation and effort in the golden tilefish and black sea bass fisheries; establish state or regional Annual Catch Limits (ACLs) and Annual Catch Targets for the recreational harvest of gag; and modify the Individual Transfer Quota (ITQ) program for wreckfish.

This supplemental NOI is intended to inform the public of the Council's decision to divide the actions in Amendment 18 into five separate amendments, not all of which require the development of DEISs, to reduce the number of actions contained in each amendment.

Amendment 18A

The Council will prepare an EIS for Amendment 18A. The Council is concerned that increased harvest restrictions imposed through the implementation of Amendment 13C (September 21, 2006, 71 FR 55096) and Amendment 16 (July 29, 2009, 74 FR 30964) will increase the incentive to harvest black sea bass, for which the fishing seasons have progressively been shortened due to meeting the commercial and recreational ACLs early in the fishing season and subsequently implementing their respective accountability measures (AMs) to close those segments of the fishery. Currently, there is no limit to the number of pot tags issued to fishermen to harvest black sea bass or the number of pots that may be fished. The Council and NMFS are looking into how increasing or decreasing black sea bass fishing effort may affect migrating endangered right whales during the calving season of November 15 through April 15. Additionally, to avoid increases in effort that could lead to the continuation of early commercial quota closures, the Council is considering the implementation of a black sea bass pot endorsement program, a limitation on the number of pots on board a vessel to reduce fishing effort in the black sea bass pot component of the snapper-grouper fishery, and the implementation of bycatch mitigation measures for the pot component of the fishery.

To further control effort in the black sea bass fishery and reduce the likelihood of protected species interactions, the Council is considering modifying or adding new management measures such as seasonal closures, trip limits, and size limits. Amendment 18A also includes actions to modify the recreational AMs for black sea bass, improve data reporting in the commercial sector and for-hire component of the snapper-grouper fishery, and actions to update management reference points for black sea bass. Additionally, Amendment 18A would update the current rebuilding strategy for black sea bass to take into account results from the most recent stock assessment (South East Data, Assessment, and Review, SEDAR 25). As part of the rebuilding strategy, Amendment 18A would modify current management reference points including sector ACLs, allowable biological catch, and optimum yield.

Amendment 18B

Amendment 18B is being developed to address management actions for golden tilefish. Amendment 18B will consider possible effort shifting into the longline and hook-and-line components of the commercial sector for golden tilefish due to harvest restrictions on other snapper-grouper species. Amendment 18B would also address potential modifications to the golden tilefish fishing year to ensure that the regulations for golden tilefish do not impact select fishermen disproportionately. Additionally, Amendment 18B would address the establishment of an endorsement program for the longline and hook-and-line components of the golden tilefish commercial sector of the snapper-grouper fishery to control commercial fishing effort on golden tilefish. The actions in Amendment 18B are not likely to result in significant impacts on the human environment. Therefore an EA is being prepared to support the actions contained therein.

Amendment 18C

Amendment 18C would contain actions to potentially extend the range of selected snapper-grouper species in the FMP northward into the mid-Atlantic in order to better conserve and manage these species. The current regional jurisdictional boundaries between the South Atlantic and Mid-Atlantic fishery management councils would not be addressed in Amendment 18C for golden tilefish, black sea bass, and scup. Additionally, Amendment 18C would address the establishment of essential fish habitat for snapper-grouper species in the extended management area. At this time, the determination on whether either an EIS or EA will be prepared has not been made.

Amendment 20A

In Amendment 20A the Council is considering reverting inactive wreckfish ITQ shares and redistributing those shares to active fishery participants. Amendment 20A would also consider actions to establish an ITQ share cap in accordance with the Magnuson-Stevens Act requirement to limit excessive share holdings by any one entity. The amendment would also include an appeals process by which participants may contest the wreckfish share redistribution.

Amendment 20A was initially part of Amendment 20 to the FMP for the Snapper-Grouper Fishery of the South Atlantic Region (Amendment 20), which was determined to require development a DEIS. Subsequent to that determination, the actions to revert and redistribute inactive wreckfish shares were separated out of Amendment 20 in order to prevent unnecessary economic impacts on the fishery caused by the combination of a pending reduction in ACL and a large percentage of inactive shares. The actions in Amendment 20A will not have significant impacts on the human environment. Therefore, an EA is being developed for Amendment 20A rather than a DEIS.

Amendment 20B

Amendment 20B would address Magnuson-Stevens Act requirements associated with the wreckfish ITQ system. Amendment 20B would update and possibly modify various aspects of the current wreckfish ITQ system as needed in order to better manage the wreckfish commercial sector according the Magnuson-Stevens Act requirements for LAP programs such as cost recovery and overall efficiency. At this time, the determination on whether either an EIS or EA will be prepared has not been made.

Public Hearings, Times, and Locations

Public hearings for Amendments 18A, 18B, and 20A were held in November 2011. Additional public hearings for these amendments may be held in the future. Exact dates, times, and locations will be announced by the Council. The public will be informed, via a notification in the **Federal Register,** of future scoping meetings and public hearings for Amendments 18C and 20B when they are scheduled to occur. The meetings will be physically accessible to people with disabilities. Requests for information packets or for sign language interpretation or other auxiliary equipment should be directed to the Council (see **FOR FURTHER INFORMATION CONTACT**).

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

Dated: November 23, 2011.

Alan D. Risenhoover,

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

[FR Doc. 2011–30853 Filed 11–29–11; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XA839

Fishing Capacity Reduction Program for the Longline Catcher Processor Subsector of the Bering Sea and Aleutian Islands Non Pollock Groundfish Fishery

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

ACTION: Notice of fee rate adjustment.

SUMMARY: NMFS issues this notice to decrease the fee rate for the non-pollock groundfish fishery to repay the $35,000,000 reduction loan to finance the non-pollock groundfish fishing capacity reduction program.

DATES: The non-pollock groundfish program fee rate decrease will begin on January 1, 2012.

ADDRESSES: Send questions about this notice to Paul Marx, Chief, Financial Services Division, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910–3282.

FOR FURTHER INFORMATION CONTACT: Paul Marx, (301) 427–8799.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 312(b)–(e) of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1861a(b) through (e)) generally authorizes fishing capacity reduction programs. In particular, section 312(d) authorizes industry fee systems for repaying reduction loans which finance reduction program costs.

Subpart L of 50 CFR part 600 is the framework rule generally implementing section 312(b)–(e).

Sections 1111 and 1112 of the Merchant Marine Act, 1936 (46 App. U.S.C. 1279f and 1279g) generally authorizes reduction loans.

Enacted on December 8, 2004, section 219, Title II, of FY 2005 Appropriations Act, Public Law 104–447 (Act) authorizes a fishing capacity reduction program implementing capacity reduction plans submitted to NMFS by catcher processor subsectors of the Bering Sea and Aleutian Islands (''BSAI'') non-pollock groundfish fishery (''reduction fishery'') as set forth in the Act.

The longline catcher processor subsector (the ''Longline Subsector'') is among the catcher processor subsectors eligible to submit to NMFS a capacity reduction plan under the terms of the Act.

The longline subsector non-pollock groundfish reduction program's objective was to reduce the number of vessels and permits endorsed for longline subsector of the non-pollock groundfish fishery.

All post-reduction fish landings from the reduction fishery are subject to the longline subsector non-pollock groundfish program's fee.

NMFS proposed the implementing notice on August 11, 2006 (71 FR 46364), and published the final notice on September 29, 2006 (71 FR 57696).

NMFS allocated the $35,000,000 reduction loan to the reduction fishery and is repayable by fees from the fishery.

NMFS published in the **Federal Register** on September 24, 2007 (72 FR 54219), the final rule to implement the industry fee system for repaying the non-pollock groundfish program's reduction loan and established October 24, 2007, as the effective date when fee collection and loan repayment began. The regulations implementing the program are located at § 600.1012 of 50 CFR part 600's subpart M.

NMFS published in the **Federal Register** on November 2, 2009 (74 FR 56592), a notice to decrease the fee rate to .016 per pound effective January 1, 2010. Then, on November 12, 2010 (75 FR 69401), a notice to decrease the fee rate to $0.015 per pound, effective January 1, 2011.

II. Purpose

The purpose of this notice is to adjust, in accordance with the framework rule's § 600.1013(b), the fee rate for the reduction fishery. Section 600.1013(b) directs NMFS to recalculate the fee rate that will be reasonably necessary to ensure reduction loan repayment within the specified 30 year term.

NMFS has determined for the reduction fishery that the current fee rate of $0.015 per pound is more than needed to service the loan. Therefore, NMFS is decreasing the fee rate to $0.0145 per pound which NMFS has determined is sufficient to ensure timely loan repayment.

Subsector members may continue to use *Pay.gov* to disburse collected fee deposits at: *http://www.pay.gov/paygov/.*

Please visit the NMFS Web site for additional information at: *http://www.nmfs.noaa.gov/mb/financial_services/buyback.htm.*

III. Notice

The new fee rate for the non-pollock Groundfish fishery will begin on January 1, 2012.

From and after this date, all subsector members paying fees on the non-pollock groundfish fishery shall begin paying non-pollock groundfish fishery program fees at the revised rate.

Fee collection and submission shall follow previously established methods in § 600.1013 of the framework rule and in the final fee rule published in the **Federal Register** on September 24, 2007 (72 FR 54219).

Authority

The authority for this action is Public Law 108–447, 16 U.S.C. 1861a (b–e), and 50 CFR 600.1000 *et seq.*

Dated: November 23, 2011.

Gary C. Reisner,

Director, Office of Management and Budget, National Marine Fisheries Service.

[FR Doc. 2011–30851 Filed 11–29–11; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF EDUCATION

Notice of Submission for OMB Review

AGENCY: Department of Education.

ACTION: Comment request.

SUMMARY: The Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management, invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13).

DATES: Interested persons are invited to submit comments on or before December 30, 2011.

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.* Please note that written comments received in response to this notice will be considered public records.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of

1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. The OMB is particularly interested in comments which: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Dated: November 25, 2011.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.

Institute of Education Sciences

Type of Review: New.

Title of Collection: College Affordability and Transparency Explanation Form (CATEF) 2011–2014.

OMB Control Number: Pending.

Agency Form Number(s): N/A.

Frequency of Responses: Annually.

Affected Public: State, Local and Tribal Government.

Total Estimated Number of Annual Responses: 532.

Total Estimated Annual Burden Hours: 1,596.

Abstract: The National Center for Education Statistics (NCES) is seeking a three-year clearance for a new survey data collection for the College Affordability and Transparency List Explanation Form (CATEF). The collection of this information is necessary pursuant to the Higher Education Opportunity Act (HEOA) Section 111, Part C (20 U.S.C. 1015a) with the goal of increasing transparency of college tuition prices for consumers. The clearance should start with the 2011–12 collection year and extend through the 2012–13 and 2013–14 collections. Part C of Section 111 of HEOA included provisions for improved transparency in college tuition for consumers. In response to these provisions, the Department of Education created The College Affordability and Transparency Center (CATC) which can be accessed through College Navigator. The CATC includes information for students, parents, and policymakers about college costs at America's colleges and universities. The CATC also includes several lists of institutions based on the tuition and fees and/or net prices (the price of attendance after considering all grant and scholarship aid) charged to students, including a list of institutions that are in the five percent of institutions in their institutional sector that have the highest increases, expressed as a percentage change, over the three-year time period for which the most recent data are available. The clearance being requested is to survey the institutions on this list using the College Affordability and Transparency Explanation Form to collect follow-up information. The lists appearing in CATC are generated using data collected by NCES through the Integrated Postsecondary Education Data System (IPEDS). IPEDS is a mandatory data collection for institutions that participate in or are applicants for participation in any federal student financial aid program authorized by Title IV of the Higher Education Act of 1965, as amended (20 USC 1094, Section 487(a)(17) and 34 CFR 668.14(b)(19)). The additional information to be collected will be used to write a summary report for Congress which will also be posted on the College Navigator Web site. The report will summarize the general and sector specific findings from the CATEF using descriptive statistics. The main cost areas showing the highest increases will be identified using the percent change information provided by institutions. The most commonly reported plans to reduce the increases in those cost increases will also be indicated. Finally, the extent to which institutions participate in setting tuition and fees and net prices for students will be described and the agencies outside of the institutions that decide those student charges will be identified.

Copies of the information collection submission for OMB review may be accessed from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAMain* or from the Department's Web site at *http://edicsweb.ed.gov,* by selecting the ''Browse Pending Collections'' link and by clicking on link number 4729. 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 and OMB Control Number 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. 2011–30847 Filed 11–29–11; 8:45 a.m.]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

National Coal Council

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of renewal.

SUMMARY: Pursuant to section 14(a)(2)(A) of the Federal Advisory Committee Act (Pub. L. 92–463) and in accordance with Title 41 of the Code of Federal Regulations, Section 102–3.65(a), and following consultation with the Committee Management Secretariat, General Services Administration, notice is hereby given that the National Coal Council will be renewed for a two-year period beginning November 23, 2011. The Council will provide advice and recommendations to the Secretary of Energy on general policy matters relating to coal issues.

Additionally, the renewal of the Council has been determined to be essential to the conduct of the Department's business and to be in the public interest in connection with the performance of duties imposed upon the Department of Energy by law and agreement. The Council will continue to operate in accordance with the provisions of the Federal Advisory Committee Act and the rules and regulations in implementation of that Act.

FOR FURTHER INFORMATION CONTACT: Michael Ducker at (202) 586–7810.

Issued at Washington, DC, on November 23, 2011.

Carol A. Matthews,

Committee Management Officer.

[FR Doc. 2011–30836 Filed 11–29–11; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

[Docket Number EERE–2011–BT–NOA–0064]

Measured Building Energy Performance Data Taxonomy

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

ACTION: Notice of request for information (RFI).

SUMMARY: The U.S. Department of Energy (DOE) seeks comments and information related to a measured building energy performance data taxonomy. DOE has created this measured building energy performance data taxonomy as part of its DOE Buildings Performance Database project. This information is focused on data related to the energy performance of buildings and is not intended to be a general taxonomy for other building information and applications (i.e., non-energy applications such as structural analysis, space planning, et cetera).

DATES: Written comments and information are requested on or before December 30, 2011.

ADDRESSES: Interested persons may submit comments, identified by docket number EERE–2011–BT–NOA–0064, by any of the following methods. Your response should be in the form of either a word document, or a compatible format. Questions relative to responding to this RFI may be sent to the same mailbox in advance of your response, and will be answered via email.

- *Email:* to *TaxonomyRFI123–0064@ee.doe.gov*. Include EERE–2011–BT–NOA–0064 in the subject line of the message.
- *Mail:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, Mailstop EE–2J, Revisions to Energy Efficiency Enforcement Regulations, EERE–2011–BT–NOA–0064, 1000 Independence Avenue SW., Washington, DC 20585–0121. Phone: (202) 586–2945. Please submit one signed paper original.
- *Hand Delivery/Courier:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, 6th Floor, 950 L'Enfant Plaza SW., Washington, DC 20024. *Phone:* (202) 586–2945. Please submit one signed paper original.

Instructions: All submissions received must include the agency name and docket number.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information may be sent to Cody Taylor, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Program, EE–2J, 1000 Independence Avenue SW., Washington, DC 20585–0121. *Telephone:* (202) 287–5842. *Email: TaxonomyRFI123–0064@ee.doe.gov.*

SUPPLEMENTARY INFORMATION:

Overview

The U.S. Department of Energy (DOE) seeks comments and information related to a measured building energy performance data taxonomy. DOE has created this measured building energy performance data taxonomy as part of its DOE Buildings Performance Database project. This information is focused on data related to the energy performance of buildings and is not intended to be a general taxonomy for other building information and applications (i.e., non-energy applications such as structural analysis, space planning, et cetera). A copy of the information on which DOE seeks comment can be downloaded from this web address: *http://buildingsperformance.net/taxonomyrfi*. Stakeholders should download the taxonomy file from the provided Web site, as the information is not duplicated in this RFI.

Detailed Description

The data taxonomy described in this RFI provides guidance on how measured building energy performance data and building characteristics are defined, organized and classified in the DOE Buildings Performance Database. The full taxonomy description can be downloaded at this site: *http://buildingsperformance.net/taxonomyrfi*. Please use this web address to access and download the information on which DOE is seeking comment.

The taxonomy was developed with several goals in mind. The taxonomy is intended to be general and flexible enough to accommodate a wide set of current and anticipated use cases to analyze the measured energy performance of both commercial and residential buildings. The taxonomy should be general enough to support use cases for multiple stakeholders including financiers, utilities, service providers, and policy makers, and flexible enough to accommodate use cases that have not yet been fully specified. The taxonomy should support a wide range of existing data sources while also anticipating future data collection efforts that may provide more detailed datasets. The taxonomy focuses on measured building energy performance data and related building characteristics, and does not include modeled or derived data. Finally, it does not include any fields for personally identifiable information or the identity of the data source.

The taxonomy presented was developed after reviewing and considering related efforts, such as the Industry Foundation Classes, OmniClass systems, ASTM Building Energy Performance Assessment checklist, and ASHRAE Audit Procedures Checklist. To date, the taxonomy has mapped five data sources, including the Commercial Building Energy Consumption Survey, the Residential Energy Consumption Survey, University of Dayton, ENERGY STAR, and the General Services Administration data. The taxonomy will continue to evolve as new data sources are mapped.

Overview of the Taxonomy

The taxonomy consists of entities and data fields. Each entity is a logical grouping of data fields. The entities and their inter-relationships generally reflect the hierarchical nature of building characteristics (site, facility, activity area, building systems). This scheme was developed using a ''top-down'' approach, based on a logical understanding of building performance information, and is intended to be flexible and stable enough to accommodate a broad array of use cases. For example, the entity ''Facility'' is used to describe the major characteristics of a building and has data fields for gross floor area, net floor area, number of stories, etc. There are currently sixteen entities within the taxonomy scheme.

The data field descriptions in the taxonomy contain a list of the data fields under each entity, along with the units of measurement and a description of each field. The data fields were developed using a ''bottom-up'' approach, by compiling and editing lists of fields from existing data sources and taxonomies. Certain data fields have enumerated types that provide a discrete set of named responses specific to the data field. An example of an enumerated type would be for the data field ''Fuel.'' Responses include Electricity, Renewable Electricity, Natural Gas, Fuel Oil, Fuel Oil No. 4, Solar Hot Water, Kerosene, and Coal, among several other choices. Note that most constrained lists include items at different levels of specificity (e.g. Fuel Oil versus Fuel Oil No. 1), in order to accommodate a range of data sources and use cases. Therefore, the items in a constrained list are not mutually exclusive.

The data fields have been organized into three priority levels. The

prioritization is based on the relative importance for analysis use cases, as well as relative ease of obtaining data. Priority 3 data fields connote unusual fields or those that are unique to a particular data source. For example, within the ''Energy Use'' entity, the Priority 1 data fields include elements such as Fuel (type), End Use Type, and Units. The Priority 2 data fields include elements such as Electric Utility, Electric Rate Structure, and Electricity Summer Peak Power. The Priority 3 data fields include elements such as Bottled Gas Amount, Amount Wood Burned, and Natural Gas Peak Power.

Issues on Which DOE Seeks Comment and Information.

DOE invites comments from respondents on all the specific elements discussed above, as well as any additional issues the respondent deems important. Specifically, DOE is requesting comment as to (a) The overall taxonomy schema i.e. the entities and their relationships; (b) definitions of the data fields contained within this taxonomy; (c) new data fields needed to accommodate existing or anticipated future data sources. The full taxonomy can be accessed at *http://buildingsperformance.net/taxonomyrfi*.

Disclaimer and Important Notes

This is an RFI issued solely for information and program planning purposes; this RFI does not constitute a formal solicitation for proposals or abstracts. Your response to this notice will be treated as information only. DOE will not provide reimbursement for costs incurred in responding to this RFI. Respondents are advised that DOE is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted under this RFI. Responses to this RFI do not bind DOE to any further actions related to this topic.

Confidential Business Information

According to 10 CFR 1004.11, any person submitting information he or she believes to be confidential and exempt by law from public disclosure should submit via email, postal mail, or hand delivery/courier two well-marked copies: One copy of the document marked confidential including all the information believed to be confidential, and one copy of the document marked non-confidential with the information believed to be confidential deleted. Submit these documents via email or on a CD, if feasible. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

Factors of interest to DOE when evaluating requests to treat submitted information as confidential include: (1) A description of the items; (2) whether and why such items are customarily treated as confidential within the industry; (3) whether the information is generally known by or available from other sources; (4) whether the information has previously been made available to others without obligation concerning its confidentiality; (5) an explanation of the competitive injury to the submitting person which would result from public disclosure; (6) when such information might lose its confidential character due to the passage of time; and (7) why disclosure of the information would be contrary to the public interest.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

Issued in Washington, DC, on November 22, 2011.

Kathleen B. Hogan,

Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

[FR Doc. 2011–30837 Filed 11–29–11; 8:45 a.m.]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2011–0766; FRL–8890–3]

Agency Information Collection Activities; Proposed Collection; Comment Request

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 EPA is planning to submit a request to renew an existing approved Information Collection Request (ICR) to the Office of Management and Budget (OMB). This ICR, entitled: ''Foreign Purchaser Acknowledgement Statement of Unregistered Pesticides'' and identified by EPA ICR No. 0161.12 and OMB Control No. 2070–0027, is scheduled to expire on July 31, 2012. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection.

DATES: Comments must be received on or before January 30, 2012.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2011–0766, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

Instructions: Direct your comments to docket ID number EPA–HQ–OPP–2011–0766. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or email. The 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 regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Scott Drewes, Field and External Affairs Division (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; *telephone number:* (703) 347–0107; *fax number:* (703) 305–5884; *email address: drewes.scott@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. What information is EPA particularly interested in?

Pursuant to section 3506(c)(2)(A) of PRA, EPA specifically solicits comments and information to enable it to:

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 estimates 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.

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. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

II. What should I consider when I prepare my comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible and provide specific examples.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Offer alternative ways to improve the collection activity.

7. Make sure to submit your comments by the deadline identified under **DATES**.

8. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

III. What information collection activity or ICR does this action apply to?

Affected entities: Entities potentially affected by this ICR are individuals or entities that either manufacture and export or that reformulate or repackage and export unregistered pesticides. The North American Industrial Classification System (NAICS) code assigned to the parties responding to this information is 325320.

Title: Foreign Purchaser Acknowledgement Statement of Unregistered Pesticides.

ICR numbers: EPA ICR No. 0161.12, OMB Control No. 2070–0027.

ICR status: This ICR is currently scheduled to expire on July 31, 2012. 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 Code of Federal Regulations (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 for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: This information collection program is designed to enable EPA to provide notice to foreign purchasers of unregistered pesticides exported from the United States that the pesticide product cannot be sold in the United States. Section 17(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires an exporter of any pesticide not registered under FIFRA section 3 or sold under FIFRA section 6(a)(1) to obtain a signed statement from the foreign purchaser acknowledging that the purchaser is aware that the pesticide is not registered for use in, and cannot be sold in, the United States. A copy of this statement, which is known as the Foreign Purchaser Acknowledgement Statement, or FPAS, must be transmitted to an appropriate official of the government in the importing country. This information is submitted in the form of annual or per-shipment statements to EPA, which maintains original records and transmits copies, along with an explanatory letter, to appropriate government officials of the countries which are importing the pesticide.

In addition to the export notification for unregistered pesticides, FIFRA requires that all exported pesticides include appropriate labeling. There are different requirements for registered and unregistered products. Export labeling requirements meet the definition of third-party notification. In the interests of consolidating various related information collection requests, this ICR includes burden estimates for the FPAS requirement for unregistered pesticides, as well as the labeling requirement for all exported pesticides, both registered and unregistered. These burdens have been consolidated in this information collection since the implementation of the 1993 pesticide export policy governing the export of pesticides, devices, and active ingredients used in producing pesticides.

Burden statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average from one to eight hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources;

complete and review the collection of information; and transmit or otherwise disclose the information.

The ICR provides a detailed explanation of this estimate, which is only briefly summarized here:

Estimated total number of potential respondents: 50.

Frequency of response: On occasion.

Estimated total average number of responses for each respondent: 18–50.

Estimated total annual burden hours: 24,470 hours.

Estimated total annual costs: $1,461,658. This is the estimated burden cost; there is no cost for capital investment or maintenance and operational costs in this information collection.

IV. Are there changes in the estimates from the last approval?

There is a decrease of 22 hours in the total estimated respondent burden compared with that identified in the ICR currently approved by OMB. This decrease reflects EPA's updating of burden estimates for this collection based upon historical information on the number of foreign purchaser acknowledgement statements. Based upon revised estimates, the number of foreign purchaser acknowledgement statements has decreased from 2,304 to 2,283, with a corresponding decrease in the associated burden from 2,442 hours in the previous renewal to 2,420 hours in the current renewal. This change is an adjustment.

V. What is the next step in the process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another **Federal Register** notice pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

List of Subjects

Environmental protection, Reporting and recordkeeping requirements.

Dated: November 21, 2011.

Stephen A. Owens,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2011–30862 Filed 11–29–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2011–0940; FRL–9497–9]

Agency Information Collection Activities; Proposed Collection; Comment Request; Reporting Requirements Under EPA's Climate Leaders Partnership (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 EPA is planning to submit a request to renew an existing approved Information Collection Request (ICR) (EPA ICR No. 2100.05) to the Office of Management and Budget (OMB) (OMB Control No. 2060–0532). This ICR is scheduled to expire on April 30, 2012. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection as described below.

DATES: Comments must be submitted on or before January 30, 2012.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2011–0940 by one of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Email: a-and-r-docket@epa.gov.*
- *Fax:* (202) 566–9744.
- *Mail:* Environmental Protection Agency, EPA Docket Center, Air and Radiation Docket, Mailcode: 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460.
- *Hand Delivery:* EPA Docket—Public Reading Room, EPA West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. Such deliveries are accepted only during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OAR–2011–0940. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or email. 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 www.regulations.gov your email address will be captured automatically and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

FOR FURTHER INFORMATION CONTACT: John Sottong, Climate Protection Partnerships Division, Office of Atmospheric Programs, (6202J), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; *telephone number:* (202) 343–9397; *fax number:* (202) 343–2208; *email address: sottong.john@epa.gov.*

SUPPLEMENTARY INFORMATION:

How can I access the docket and/or submit comments?

EPA has established a public docket for this ICR under Docket ID No. EPA–HQ–OAR–2011–0940, which is available for online viewing at *http://www.regulations.gov,* or in person viewing at the Air and Radiation Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The EPA/DC Public Reading Room is open from 8:30 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 Air and Radiation Docket is (202) 566–1742.

Use *http://www.regulations.gov* to obtain a copy of the draft collection of information, submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the docket ID number identified in this document.

What information is EPA particularly interested in?

Pursuant to section 3506(c)(2)(A) of the PRA, EPA specifically solicits comments and information to enable it to:

(i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(ii) Evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) Enhance the quality, utility, and clarity of the information to be collected; and

(iv) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

What should I consider when I prepare my comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible and provide specific examples.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Offer alternative ways to improve the collection activity.

6. Make sure to submit your comments by the deadline identified under **DATES**.

7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You also may provide the name, date, and **Federal Register** citation.

To what information collection activity or ICR does this apply?

Affected entities: Entities potentially affected by this action are participants in the U.S. EPA and U.S. GSA Federal Supplier Greenhouse Gas Emissions Inventory Pilot started during EPA's Climate Leaders Program.

Title: Reporting Requirements Under EPA's Climate Leaders Partnership (Renewal).

ICR numbers: EPA ICR No. 2100.05, OMB Control No. 2060–0532.

ICR status: This ICR is currently scheduled to expire on April 30, 2012. 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: On September 30, 2011, the U.S. Environmental Protection Agency officially ended its Climate Leaders program. One element of the Climate Leaders program was the Small Business Network (SBN) which offered small businesses tools and resources to assist them with managing and reducing their GHG emissions. In direct response to E.O. 13514, EPA and the U.S. General Services Administration (GSA) utilized the Climate Leaders SBN as the foundation to launch the Federal Supplier Greenhouse Gas Emissions Inventory Pilot (''the Pilot'') in August 2010 to assess the benefits and challenges experienced by small businesses in completing and reporting a GHG emissions inventory. The Pilot is a voluntary, three-year program in which small businesses are required to develop annual GHG emissions inventories through September 2013. The small businesses are also required to develop and implement GHG emissions reductions strategies and review their progress towards meeting their reduction goals and the associated benefits. Through this interagency agreement, EPA continues to support the Pilot with education and technical assistance. EPA has developed this renewal ICR to ensure that the Pilot remains credible by obtaining continued authorization to collect information from its participants to ensure that they are meeting their GHG goals. Companies that joined the Pilot voluntarily agree to the following: Setting a corporate GHG reduction goal; submitting a GHG inventory management plan; reporting to EPA, on an annual basis, the company's GHG emissions inventory, and progress toward their GHG reduction goal via the Annual GHG Inventory Summary and Goal Tracking Form. The information contained in the inventories of the companies that participate in the Pilot may be considered confidential business information and is maintained as such. EPA uses the data obtained from the companies to assess the success of the Pilot in achieving its goals and to identify the type of outreach, training, and other direct assistance and incentives that will help small business federal suppliers meet the objectives of E.O. 13514. Responses to the information collection are voluntary.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 40 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

The ICR provides a detailed explanation of the Agency's estimate, which is only briefly summarized here:

Estimated total number of potential respondents: Responses are expected from the 46 small businesses participating in the joint EPA–GSA Federal Supplier Greenhouse Gas Emissions Inventory Pilot.

Frequency of response: The companies will be required to submit one response annually.

Estimated total average number of responses for each respondent: One response will be received from each respondent per year.

Estimated total annual burden hours: 1,840 hours.

Estimated total annual costs: $171,810. This includes an estimated burden cost of $171,810 and an estimated cost of $0.00 for capital investment or maintenance and operational costs.

Are there changes in the estimates from the last approval?

There is a decrease of 17,796 hours in the total estimated respondent burden compared with that identified in the ICR currently approved by OMB. This decrease reflects EPA's phase down of the Climate Leaders program on September 30, 2011. As a result, the number of respondents to this ICR decreased to include only those 46 small businesses participating in the joint EPA–GSA Federal Supplier Greenhouse Gas Emissions Inventory Pilot.

What is the next step in the process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. At that time, EPA will issue another **Federal Register** notice pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

Dated: November 21, 2011.

Elizabeth Craig,

Director, Climate Protection Partnerships Division.

[FR Doc. 2011–30850 Filed 11–29–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2011–0891; FRL–9498–3]

Agency Information Collection Activities; Proposed Collection; Comment Request; Protection of Stratospheric Ozone: Recordkeeping and Periodic Reporting of the Production, Import, Recycling, Destruction, Transhipment, and Feedstock Use of Ozone-Depleting Substances (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 EPA is planning to submit a request to renew an existing approved Information Collection Request (ICR) to the Office of Management and Budget (OMB). This ICR, 1432.29, is scheduled to expire on April 30, 2012. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection as described below.

DATES: Comments must be submitted on or before January 30, 2012.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2011–0891 by one of the following methods:

- *http://www.regulations.gov*: Follow the on-line instructions for submitting comments.
- *Email: a-and-r-Docket@epa.gov.*
- *Fax:* (202) 566–1741
- *Mail:* EPA–HQ–OAR–2011–0891, Environmental Protection Agency, Mailcode: 6205J, 1200 Pennsylvania Ave. NW., Washington, DC 20460.
- *Hand Delivery:* EPA–HQ–OAR–2011–0891, Air and Radiation Docket at EPA West, 1301 Constitution Avenue NW., Room B108, Mail Code 6102T, Washington, DC 20460. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OAR–2011–0891. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *www.regulations.gov* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

FOR FURTHER INFORMATION CONTACT: Staci Gatica, Stratospheric Protection Division, Office of Atmospheric Programs, (6205J), Environmental Protection Agency, 1200 Pennsylvania Ave., NW. Washington, DC 20460; *telephone number:* (202) 343–9469; *fax number:* (202) 343–2338; *email address: gatica.staci@epa.gov*. You may also visit the Ozone Depletion Web site of EPA's Stratospheric Protection Division at *www.epa.gov/ozone/strathome.html* for further information about EPA's Stratospheric Ozone Protection regulations, the science of ozone layer depletion, and related topics.

SUPPLEMENTARY INFORMATION:

How can I access the docket and/or submit comments?

EPA has established a public docket for this ICR under Docket ID No. EPA–HQ–OAR–2011–0891, which is available for online viewing at *www.regulations.gov*, or in person viewing at the Air and Radiation Docket in the EPA Docket Center (EPA/DC), EPA West Room 3334, 1301 Constitution Ave. NW., Washington, DC. The EPA/DC Public Reading Room is open from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for Air and Radiation Docket is (202) 566–1742.

Use *www.regulations.gov* to obtain a copy of the draft collection of information, submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the docket ID number identified in this document.

What information is EPA particularly interested in?

Pursuant to section 3506(c)(2)(A) of the PRA, EPA specifically solicits comments and information to enable it to:

(i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(ii) Evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) Enhance the quality, utility, and clarity of the information to be collected; and

(iv) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

What should I consider when I prepare my comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible and provide specific examples.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Offer alternative ways to improve the collection activity.
6. Make sure to submit your comments by the deadline identified under **DATES**.
7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

What information collection activity or ICR does this apply to?

Affected entities: Entities potentially affected by this action are producers, importers, and distributors of Class I ozone-depleting substances, including chlorofluorocarbons, halons, and quarantine and preshipment methyl bromide, as well as research institutions using such substances.

Title: Agency Information Collection Activities; Proposed Collection; Comment Request; Protection of Stratospheric Ozone: Recordkeeping and Periodic Reporting of the Production, Import, Recycling, Destruction, Transhipment, and Feedstock Use of Ozone-Depleting Substances (Renewal).

ICR numbers: EPA ICR No. 1432.30, OMB Control No. 2060–0170.

ICR status: EPA ICR 1432.29 is currently scheduled to expire on April 30, 2012. 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: EPA is seeking to renew EPA ICR 1432.29 which authorizes the recordkeeping and reporting requirements established in the regulations stated in 40 CFR part 82, subpart A and as required by the United States' commitments under the international treaty *The Montreal Protocol on Substances that Deplete the Ozone Layer* (Protocol). This information collection allows EPA to monitor the United States' compliance with the Protocol and Title VI of the Clean Air Act Amendments of 1990 (CAA).

Under its Protocol commitments, the United States is obligated to cease production and import of Class I controlled substances excluding chlorofluorocarbons (CFCs) that are subject to essential use exemptions, methyl bromide that is subject to critical use exemptions or exemptions for quarantine and preshipment uses, previously used material, and material that will be transformed, destroyed, or exported to developing countries. The Protocol also establishes limits and reduction schedules leading to the eventual phaseout of Class II controlled substances with similar exemptions beyond the phaseout. In addition to the Montreal Protocol, the CAA has its own limits on production and consumption of controlled substances that EPA must adhere to and enforce.

Under 40 CFR 82.13, producers, importers, exporters, and distributors of Class I ozone-depleting substances (ODS) must meet quarterly, annual, and/or transactional recordkeeping and reporting requirements. This information collection is conducted to meet U.S. obligations under the Montreal Protocol. The information collection request is required to obtain a benefit under Title VI of the CAA, added by Section 764 of the 1999 Omnibus Consolidated and Emergency Supplemental Appropriations Act (Pub. L. 105–277; October 21, 1998).

The reporting and recordkeeping requirements for Class I ODS will enable EPA to:

1. Ensure compliance with the restrictions on production, import, and export of Class I controlled substances;
2. Allow exempted production and import for certain uses and the consequent tracking of that production and import;
3. Address industry and Federal concerns regarding the illegal import of mislabeled used controlled substances;
4. Satisfy the United States' obligations to report data under Article 7 of the Montreal Protocol;
5. Fulfill statutory obligations under Section 603(b) of the CAA for reporting and monitoring;
6. Provide information to report to the U.S. Congress on the production, use, and consumption of Class I controlled substances as statutorily required in Section 603(d) of Title VI of the CAA.

The reported data will enable EPA to:

1. Maintain compliance with the Protocol requirements for annual data submission on the production of ODS; and
2. Analyze technical use data to ensure that exemptions are used in accordance with requirements included in the annual authorization rulemakings.

EPA informs respondents that they may assert claims of business confidentiality for any of the information they submit. Information claimed confidential will be treated in accordance with the procedures for handling information claimed as confidential under 40 CFR Part 2, Subpart B, and will be disclosed only to the extent, and by means of the procedures, set forth in Subpart B. If no claim of confidentiality is asserted when the information is received by EPA, it may be made available to the public without further notice to the respondents (40 CFR 2.203).

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 2.3 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently

changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

The ICR draft supporting statement available in the public docket provides a detailed explanation of the Agency's estimate, which is only briefly summarized here:

• Estimated total number of potential respondents: 1143.

• Frequency of response:

—Producers, importers, exporters of methyl bromide, laboratory suppliers, and distributors of QPS methyl bromide (Class I, Group VI substances) are to report to EPA quarterly (45 days after the end of each quarter).

—Exporters (of non-methyl bromide Class I substances), and persons that destroy and transform Class I controlled ODS are to report to EPA annually (45 days after the end of the control period).

—Persons wanting to transfer CFCs or who petition to import used Class I controlled substances are to submit reports to EPA on a transactional basis.

—All entities may be required to provide other such information that the Administrator may reasonably require to comply with requests from the Ozone Secretariat seeking information required by decisions taken by the Parties to the Montreal Protocol.

• Estimated total annual burden hours: 2583 hours.

• Estimated total annual costs: $277,130. This includes an estimated burden cost of $71,550 and an estimated cost of $5,580 for capital investment or maintenance and operational costs.

Are there changes in the estimates from the last approval?

There is a decrease of 227 hours in the total estimated respondent burden compared with that identified in the EPA ICR 1432.29 which is currently approved by OMB. This decrease is due to the continued phaseout and decreased use of Class I controlled substances which subsequently reduces reporting obligations. For example, the exemption under the Montreal Protocol allowing for production and export of Class I controlled substances to developing countries for basic domestic needs expired in 2010. The burden and cost estimates for the Agency decreased due to revisions to the managerial review of reporting forms. Most reviews are done at the technical staff level. EPA also now offers electronic reporting via the Agency's central data exchange (CDX) to the regulated community which has contributed to the reduction in burden for both the Agency as well as the regulated community.

What is the next step in the process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. At that time, EPA will issue another **Federal Register** notice pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

Dated: November 20, 2011.

Drusilla Hufford,

Director, Stratospheric Protection Division.

[FR Doc. 2011–30855 Filed 11–29–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9498–4]

Clean Water Act Section 303(d): Availability of List Decisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: This notice announces the availability of EPA's action identifying water quality limited segments and associated pollutants in Louisiana to be listed pursuant to Clean Water Act Section 303(d), and request for public comment. Section 303(d) requires that States submit and EPA approve or disapprove lists of waters for which existing technology-based pollution controls are not stringent enough to attain or maintain State water quality standards and for which total maximum daily loads (TMDLs) must be prepared.

On November 17, 2011, EPA partially approved and proposed to partially disapprove Louisiana's 2010 Section 303(d) submittal. Specifically, EPA approved Louisiana's listing of 410 waterbody pollutant combinations, and associated priority rankings. EPA proposed to disapprove Louisiana's decisions not to list three waterbodies. These three waterbodies were added by EPA because the applicable numeric water quality standards marine criterion for dissolved oxygen was not attained in these segments.

EPA is providing the public the opportunity to review its proposed decisions to add the three waters to Louisiana's 2010 Section 303(d) List. EPA will consider public comments and if necessary amend its proposed action on the additional waterbodies identified for inclusion on Louisiana's Final 2010 Section 303(d) List.

DATES: Comments must be submitted in writing to EPA on or before December 30, 2011.

ADDRESSES: Comments on the decisions should be sent to Diane Smith, Environmental Protection Specialist, Water Quality Protection Division, U.S. Environmental Protection Agency Region 6, 1445 Ross Ave., Dallas, TX 75202–2733, telephone (214) 665–2145, facsimile (214) 665–6490, or email: *smith.diane@epa.gov*. Oral comments will not be considered. Copies of the documents which explain the rationale for EPA's decisions and a list of the 3 water quality limited segments for which EPA proposed disapproval of Louisiana's decisions not to list can be obtained at EPA Region 6's web site at *http://www.epa.gov/region6/water/npdes/tmdl/index.htm*, or by writing or calling Ms. Smith at the above address. Underlying documents from the administrative record for these decisions are available for public inspection at the above address. Please contact Ms. Smith to schedule an inspection.

FOR FURTHER INFORMATION CONTACT: Diane Smith at (214) 665–2145.

SUPPLEMENTARY INFORMATION: Section 303(d) of the Clean Water Act (CWA) requires that each State identify those waters for which existing technology-based pollution controls are not stringent enough to attain or maintain State water quality standards. For those waters, States are required to establish Total Maximum Daily Loads (TMDLs) according to a priority ranking. EPA's Water Quality Planning and Management regulations include requirements related to the implementation of Section 303(d) of the CWA (40 CFR 130.7). The regulations require States to identify water quality limited waters still requiring TMDLs every two years. The list of waters still needing TMDLs must also include priority rankings and must identify the waters targeted for TMDL development during the next two years (40 CFR 130.7). On March 31, 2000, EPA promulgated a revision to this regulation that waived the requirement for States to submit Section 303(d) lists in 2000 except in cases where a court

order, consent decree, or settlement agreement required EPA to take action on a list in 2000 (65 FR 17170).

Consistent with EPA's regulations, Louisiana submitted to EPA its listing decisions under Section 303(d) on January 13, 2011. On November 17, 2011, EPA approved Louisiana's listing of 410 water body-pollutant combinations and associated priority rankings. EPA proposed to disapprove Louisiana's decisions not to list three waterbodies. These three waterbodies were proposed for addition by EPA because the applicable numeric water quality standards marine criterion for dissolved oxygen was not attained in these segments. EPA solicits public comment on its identification of three additional waters for inclusion on Louisiana's 2010 Section 303(d) List.

Dated: November 17, 2011.

William K. (Bill) Honker,

Acting Director, Water Quality Protection Division.

[FR Doc. 2011–30848 Filed 11–29–11; 8:45 am]

BILLING CODE 6560–50–P

EXPORT-IMPORT BANK OF THE UNITED STATES

Notice of Open Meeting of the Advisory Committee of the Export-Import Bank of the United States (Ex-Im Bank)

SUMMARY: The Advisory Committee was established by Public Law 98–181, November 30, 1983, to advise the Export-Import Bank on its programs and to provide comments for inclusion in the reports of the Export-Import Bank of the United States to Congress.

Time and Place: Tuesday, December 13, 2011 from 11 a.m. to 3 p.m. A break for lunch will be at the expense of the attendee. Security processing will be necessary for reentry into the building. The meeting will be held at Ex-Im Bank in the Main Conference Room 1143, 811 Vermont Avenue NW, Washington, DC 20571.

Agenda: Agenda items include a briefing of the Advisory Committee members on challenges for 2012, their roles and responsibilities and an ethics briefing.

Public Participation: The meeting will be open to public participation, and the last 10 minutes will be set aside for oral questions or comments. Members of the public may also file written statement(s) before or after the meeting. If you plan to attend, a photo ID must be presented at the guard's desk as part of the clearance process into the building, and you may contact Susan Houser to be placed on an attendee list. If any person wishes auxiliary aids (such as a sign language interpreter) or other special accommodations, please contact, prior to December 6, 2011, Susan Houser, Room 1273, 811 Vermont Avenue NW, Washington, DC 20571, Voice: (202) 565–3232.

FOR FURTHER INFORMATION CONTACT: For further information, contact Susan Houser, Room 1273, 811 Vermont Ave., NW., Washington, DC 20571, (202) 565–3232.

Lisa Terry,

Assistant General Counsel for Administration (Acting).

[FR Doc. 2011–30669 Filed 11–29–11; 8:45 am]

BILLING CODE 6690–01–M

FEDERAL COMMUNICATIONS COMMISSION

[DA 11–1912]

Notice of Suspension and Initiation of Debarment Proceedings

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In this document, the Commission gives notice of Dr. Dennis L. Bruno's suspension from the schools and libraries universal service support mechanism (or ''E–Rate Program''). Additionally, the Bureau gives notice that debarment proceedings are commencing against him. Dr. Bruno, or any person who has an existing contract with or intends to contract with him to provide or receive services in matters arising out of activities associated with or related to the schools and libraries support, may respond by filing an opposition request, supported by documentation.

DATES: Opposition requests must be received by December 30, 2011. However, an opposition request by the party to be suspended must be received 30 days from the receipt of the suspension letter or December 30, 2011, whichever comes first. The Bureau will decide any opposition request for reversal or modification of suspension or debarment within 90 days of its receipt of such requests.

ADDRESS: Federal Communications Commission, Enforcement Bureau, Investigations and Hearings Division, Room 4–A236, 445 12th Street SW., Washington, DC 20554. However, an opposition request by the party to be suspended must be received 30 days from the receipt of the suspension letter or December 30, 2011, whichever comes first. The Bureau will decide any opposition request for reversal or modification of suspension or debarment within 90 days of its receipt of such requests.

FOR FURTHER INFORMATION CONTACT: Joy Ragsdale, Federal Communications Commission, Enforcement Bureau, Investigations and Hearings Division, Room 4–C330, 445 12th Street SW., Washington, DC 20554. Joy Ragsdale may be contacted by phone at (202) 418–1697 or email at *Joy.Ragsdale@fcc.gov*. If Ms. Ragsdale is unavailable, you may contact Ms. Terry Cavanaugh, Acting Chief, Investigations and Hearings Division, by telephone at (202) 418–1420 and by email at *Theresa.Cavanaugh@fcc.gov*.

SUPPLEMENTARY INFORMATION: The Bureau has suspension and debarment authority pursuant to 47 CFR 54.8. Suspension will help to ensure that the party to be suspended cannot continue to benefit from the schools and libraries mechanism pending resolution of the debarment process. Attached is the suspension letter, DA 11–1912, which was mailed to Dr. Bruno and released on November 18, 2011. The complete text of the notice of suspension and initiation of debarment proceedings is available for public inspection and copying during regular business hours at the FCC Reference Information Center, Portal II, 445 12th Street SW., Room CY–A257, Washington, DC 20554, In addition, the complete text is available on the FCC's Web site at *http://www.fcc.gov*. The text may also be purchased from the Commission's duplicating inspection and copying during regular business hours at the contractor, Best Copy and Printing, Inc., Portal II, 445 12th Street SW., Room CY–B420, Washington, DC 20554, telephone (202) 488–5300 or (800) 378–3160, facsimile (202) 488–5563, or via email *http://www.bcpiweb.com*.

Federal Communications Commission.

Theresa Z. Cavanaugh,

Acting Chief, Investigations and Hearings Division, Enforcement Bureau.

The suspension letter follows:

November 18, 2011

DA 11–1912

SENT VIA CERTIFIED MAIL, RETURN RECEIPT REQUESTED AND EMAIL

Dr. Dennis L. Bruno
c/o Mr. Arthur T. McQuillan
McQuillan Law Offices
206 Main Street
Johnstown, PA 15901

Re: Notice of Suspension and Initiation of Debarment Proceedings FCC File No. EB–11–IH–1582

Dear Dr. Bruno:

The Federal Communications Commission (''Commission'') has received notice of your conviction of misappropriating federal education funds in violation of 18 U.S.C § 666(a)(1)(A), as well as your admission to committing an offense related to the federal schools and libraries universal service support mechanism (''E–Rate program'').[1] Consequently, pursuant to 47 C.F.R. § 54.8, this letter constitutes official notice of your suspension from the E–Rate program. In addition, the Enforcement Bureau (''Bureau'') hereby notifies you that the Bureau will commence debarment proceedings against you.[2]

I. Notice of Suspension

The Commission established procedures to prevent persons who have ''defrauded the government or engaged in similar acts through activities associated with or related to the schools and libraries support mechanism'' from receiving the benefits associated with that program.[3] On May 9, 2011, you pled guilty to intentionally misappropriating $49,600 from the Department of Education's Fund for the Improvement of Education program from October 2005 to July 2006 in your capacity as Superintendent of the Glendale School District.[4] In connection with your guilty plea, you admitted and stipulated in a plea agreement that you were involved in a conspiracy to commit an offense against the United States related to the E–Rate program.[5] Specifically, you conspired with others to obtain $414,421.92 from the E–Rate program.[6] Your stipulation to conspiring to commit an offense related to the E–Rate program constitutes the conduct or transaction upon which this suspension notice and debarment proceeding are based.[7]

Pursuant to section 54.8(b) of the Commission's rules,[8] the Bureau is required to suspend you from participating in any activities associated with or related to the schools and libraries support mechanism, including the receipt of funds or discounted services through the schools and libraries support mechanism, or consulting with, assisting, or advising applicants or service providers regarding the schools and libraries support mechanism.[9] Your suspension becomes effective upon either the date of your receipt of this notice or of its publication in the **Federal Register**, whichever date occurs first.[10]

In accordance with the Commission's debarment rules, you may contest this suspension or the scope of this suspension by filing arguments, with any relevant documents, within 30 calendar days after receipt of this letter or after a notice is published in the **Federal Register**, whichever comes first.[11] Such requests, however, will not ordinarily be granted.[12] The Bureau may reverse or limit the scope of suspension only upon a finding of extraordinary circumstances.[13] Absent extraordinary circumstances, the Bureau will decide any request to reverse or modify a suspension within 90 calendar days of its receipt of such request.[14]

II. Initiation of Debarment Proceedings

As discussed above, your guilty plea and stipulation to participating in a conspiracy in connection with the E-Rate program serves as a basis for immediate suspension from the program, as well as a basis to commence debarment proceedings against you. Your stipulation to conspiracy is cause for debarment as defined in section 54.8(c) of the Commission's rules.[15] Therefore, pursuant to section 54.8(b) of the rules, the Bureau is required to commence debarment proceedings against you.[16]

As with the suspension process, you may contest the proposed debarment or the scope of the proposed debarment by filing arguments and any relevant documentation within 30 calendar days of receipt of this letter or publication in the **Federal Register**, whichever comes first.[17] The Bureau, in the absence of extraordinary circumstances, will notify you of its decision to debar within 90 calendar days of receiving any information you may have filed.[18] If the Bureau decides to debar you, its decision will become effective upon either your receipt of a debarment notice or publication of the decision in the **Federal Register**, whichever comes first.[19]

If and when your debarment becomes effective, you will be prohibited from participating in activities associated with or related to the schools and libraries support mechanism for three years from the date of debarment.[20] The Bureau may set a longer debarment period or extend an existing debarment

[1] Any further reference in this letter to ''your conviction'' refers to your conviction in United States v. Dennis L. Bruno, Criminal Docket No. 11–15 J, Information (W.D. Pa. 2011).

[2] 47 C.F.R. 54.8; 47 C.F.R. § 0.111 (delegating to the Enforcement Bureau authority to resolve universal service suspension and debarment proceedings). The Commission adopted debarment rules for the schools and libraries universal service support mechanism in 2003. See Schools and Libraries Universal Service Support Mechanism, Second Report and Order and Further Notice of Proposed Rulemaking, 18 FCC Rcd 9202 (2003) (''Second Report and Order'') (adopting section 54.521 to suspend and debar parties from the E-rate program). In 2007 the Commission extended the debarment rules to apply to all Federal universal service support mechanisms. Comprehensive Review of the Universal Service Fund Management, Administration, and Oversight; Federal-State Joint Board on Universal Service; Schools and Libraries Universal Service Support Mechanism; Rural Health Care Support Mechanism; Lifeline and Link Up; Changes to the Board of Directors for the National Exchange Carrier Association, Inc., Report and Order, 22 FCC Rcd 16372 App. C at 16410–12 (2007) (Program Management Order) (section 54.521 of the universal service debarment rules was renumbered as section 54.8 and subsections (a)(1), (5), (c), (d), (e)(2)(i), (3), (e)(4), and (g) were amended.)

[3] Second Report and Order, 18 FCC Rcd at 9225, ¶ 66; Program Management Order, 22 FCC Rcd at 16387, ¶ 32. The Commission's debarment rules define a ''person'' as ''[a]ny individual, group of individuals, corporation, partnership, association, unit of government or legal entity, however organized.'' 47 C.F.R. 54.8(a)(6).

[4] United States v. Dennis L. Bruno, Criminal Docket No. 11–15 J, Arraignment Plea. *See* also United States Attorney's Office, Western District of Pennsylvania, News, Former Superintendent Pleads Guilty to Federal Program Theft, May 9, 2011, at *http://www.justice.gov/usao/paw/news/2011/2011_may/2011_05_09_05.html* (''Press Release'').

[5] Press Release at 1.

[6] Id.

[7] Second Report and Order, 18 FCC Rcd at 9226, ¶ 70; 47 C.F.R. 54.8(e)(2)(i).

[8] 47 C.F.R. 54.8(a)(4). See Second Report and Order, 18 FCC Rcd at 9225–9227, ¶¶ 67–74.

[9] 47 C.F.R. 54.8(a)(1), (d).

[10] Second Report and Order, 18 FCC Rcd at 9226, ¶ 69; 47 C.F.R. 54.8(e)(1).

[11] 47 C.F.R. 54.8(e)(4).

[12] Id.

[13] 47 C.F.R. 54.8(f).

[14] Second Report and Order, 18 FCC Rcd at 9226, ¶ 70; 47 C.F.R. 54.8(e)(5), (f).

[15] ''Causes for suspension and debarment are conviction of or civil judgment for attempt or commission of criminal fraud, theft, embezzlement, forgery, bribery, falsification or destruction of records, making false statements, receiving stolen property, making false claims, obstruction of justice and other fraud or criminal offense arising out of activities associated with or related to the schools and libraries support mechanism, the high-cost support mechanism, the rural healthcare support mechanism, and the low-income support mechanism.'' 47 C.F.R. 54.8(c). Associated activities ''include the receipt of funds or discounted services through [the Federal universal service] support mechanisms, or consulting with, assisting, or advising applicants or service providers regarding [the Federal universal service] support mechanisms.'' 47 C.F.R. 54.8(a)(1).

[16] 47 C.F.R. 54.8(b).

[17] Second Report and Order, 18 FCC Rcd at 9226, ¶ 70; 47 C.F.R. 54.8(e)(3).

[18] Id., 18 FCC Rcd at 9226, ¶ 70; 47 C.F.R. 54.8(e)(5).

[19] Id. The Commission may reverse a debarment, or may limit the scope or period of debarment upon a finding of extraordinary circumstances, following the filing of a petition by you or an interested party or upon motion by the Commission. 47 C.F.R. 54.8(f).

[20] Second Report and Order, 18 FCC Rcd at 9225, ¶ 67; 47 C.F.R. 54.8(d), (g).

period if necessary to protect the public interest.[21]

Please direct any response, if sent by messenger or hand delivery, to Marlene H. Dortch, Secretary, Federal Communications Commission, 445 12th Street SW., Room TW–A325, Washington, DC 20554, to the attention of Joy M. Ragsdale, Attorney Advisor, Investigations and Hearings Division, Enforcement Bureau, Room 4–A236, with a copy to Theresa Z. Cavanaugh, Acting Division Chief, Investigations and Hearings Division, Enforcement Bureau, Room 4–C322, Federal Communications Commission. All messenger or hand delivery filings must be submitted without envelopes.[22] If sent by commercial overnight mail (other than U.S. Postal Service (USPS) Express Mail and Priority Mail), the response must be sent to the Federal Communications Commission, 9300 East Hampton Drive, Capitol Heights, Maryland 20743. If sent by USPS First Class, Express Mail, or Priority Mail, the response should be addressed to Joy Ragsdale, Attorney Advisor, Investigations and Hearings Division, Enforcement Bureau, Federal Communications Commission, 445 12th Street SW., Room 4–A236, Washington, DC 20554, with a copy to Theresa Z. Cavanaugh, Acting Division Chief, Investigations and Hearings Division, Enforcement Bureau, Federal Communications Commission, 445 12th Street SW., Room 4–C322, Washington, DC 20554. You shall also transmit a copy of your response via email to Joy M. Ragsdale, *joy.ragsdale@fcc.gov* and to Theresa Z. Cavanaugh, *Terry.Cavanaugh@fcc.gov.*

If you have any questions, please contact Ms. Ragsdale via U.S. postal mail, email, or by telephone at (202) 418–1697. You may contact me at (202) 418–1553 or at the email address noted above if Ms. Ragsdale is unavailable.

Sincerely yours,

Theresa Z. Cavanaugh
Acting Chief
Investigations and Hearings Division
Enforcement Bureau

cc: Johnnay Schrieber, Universal Service Administrative Company (via email)
Rashann Duvall, Universal Service Administrative Company (via email)
Stephanie L. Haines, United States Attorney's Office, Western Pennsylvania (via email)

[FR Doc. 2011–30784 Filed 11–29–11; 8:45 am]

BILLING CODE 6712–01–P

[21] Id.

[22] See FCC Public Notice, DA 09–2529 for further filing instructions (rel. Dec. 3, 2009).

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary, Federal Maritime Commission, Washington, DC 20573, within ten days of the date this notice appears in the **Federal Register**. Copies of the agreements are available through the Commission's Web site (*http://www.fmc.gov*) or by contacting the Office of Agreements at (202) 523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 010099–054.

Title: International Council of Containership Operators.

Parties: APL Co. Pte Ltd.; American President Lines, Ltd.; A.P. Moller-Maersk A/S; ANL Singapore Pte Ltd.; China Shipping Container Lines Co., Ltd.; CMA CGM, S.A.; Companhia Libra de Navegacao; Compañía Chilena de Navegación Interoceánica S.A.; Compania Libra de Navegacion Uruguay S.A.; Compania Sud Americana de Vapores S.A.; COSCO Container Lines Co. Ltd; Crowley Maritime Corporation; Delmas SAS; Evergreen Marine Corporation (Taiwan), Ltd.; Hamburg-Süd KG; Hapag-Lloyd USA LLC; Hanjin Shipping Co., Ltd.; Hapag-Lloyd AG; Hyundai Merchant Marine Co., Ltd.; Kawasaki Kisen Kaisha, Ltd.; MISC Berhad; MSC Mediterranean Shipping Co. S.A.; Mitsui O.S.K. Lines, Ltd.; Nippon Yusen Kaisha; Norasia Container Lines Limited; Orient Overseas Container Line, Ltd.; Pacific International Lines (Pte) Ltd.; Regional Container Lines Public Company Ltd.; Safmarine Container Lines NV; United Arab Shipping Company (S.A.G.); Wan Hai Lines Ltd.; Yang Ming Transport Marine Corp.; and Zim Integrated Shipping Services Ltd.

Filing Party: John Longstreth, Esq.; K & L Gates LLP; 1601 K Street NW.; Washington, DC 20006–1600.

Synopsis: The amendment would remove Neptune Orient Lines, Ltd. and APL Limited as parties to the agreement.

Agreement No.: 012057–006.

Title: CMA CGM/Maersk Line Space Charter, Sailing and Cooperative Working Agreement Asia to USEC and PNW–Suez/PNW & Panama Loops.

Parties: A.P. Moller-Maersk A/S and CMA CGM S.A.

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Connor; 1627 I Street, NW., Suite 1100; Washington, DC 20006.

Synopsis: The amendment increases the operational capacities of the vessels deployed under the agreement, authorizes an additional vessel, revises space allocations, and extends the duration of the agreement.

Agreement No.: 012092–002.

Title: MOL/''K'' Line Space Charter and Sailing Agreement.

Parties: Kawasaki Kisen Kaisha, Ltd. and Mitsui O.S.K. Lines, Ltd.

Filing Parties: Robert B. Yoshitomi, Esq.; Nixon Peabody LLP; 444 West Fifth Street, 46th Floor; Los Angeles, CA 90013.

Synopsis: The amendment expands the geographic scope to include Sri Lanka, the United Arab Emirates, Indonesia, Korea, and Australia.

Agreement No.: 012147.

Title: GWF/AGRIEX Space Charter Agreement.

Parties: Great White Fleet (US) Ltd. and Agriculture Investment Export, Inc.

Filing Party: Wade S. Hooker, Esquire, 21 Central Park W.; New York, NY 10024.

Synopsis: The agreement authorizes Great White Fleet to charter space to Agriculture Investment in the trade between U.S. Atlantic and Gulf ports and ports in Guatemala and Honduras.

By Order of the Federal Maritime Commission.

Dated: November 23, 2011.

Karen V. Gregory,

Secretary.

[FR Doc. 2011–30804 Filed 11–29–11; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission an application for a license as a Non-Vessel-Operating Common Carrier (NVO) and/or Ocean Freight Forwarder (OFF)—Ocean Transportation Intermediary (OTI) pursuant to section 19 of the Shipping Act of 1984 as amended (46 U.S.C. Chapter 409 and 46 CFR 515). Notice is also hereby given of the filing of applications to amend an existing OTI license or the Qualifying Individual (QI) for a license.

Interested persons may contact the Office of Transportation Intermediaries, Federal Maritime Commission, Washington, DC 20573, by telephone at (202) 523–5843 or by email at *OTI@fmc.gov.*

Ameri Ocean Worldwide Lines, Limited Liability Company (NVO), 1040 North Avenue, Elizabeth, NJ 07201; Officer: Fahmi Eriba, Sole Member; (Qualifying Individual), Application Type: New NVO License.

Alliance Logistics Group Corp. (NVO), 17823 Evelyn Avenue, Gardena, CA 90248; Officers: Christian D. Ortiz, Dir/Pres/CEO/Treas/CFO; (Qualifying Individual), Iris Ortiz, Director/Secretary, Application Type: New NVO License.

ASF Advantage, L.L.C. (NVO & OFF), 330 Marshall Street, #400, Shreveport, LA 71101; Officers: Ron Stalvey, Operations Officer, (Qualifying Individual); Brian P. Barker, Member, Application Type: QI Change.

Encargo Export Corporation dba Encargo Logistics, dba Encargo Lines (NVO & OFF), 10800 NW 103 Street, Suite 5–E, Medley, FL 33178; Officers: Alberto Paniagua, President, (Qualifying Individual); Carlos J. Nadal, Vice President; Application Type: New NVO & OFF License.

Global Relogistics, Inc. dba Yacht Exports (NVO), 5337 Orange Drive, Davie, FL 33314; Officer: Alon Ezra, President/Secretary, (Qualifying Individual); Application Type: Trade Name Change.

Global Tradewind NVOCC, Inc. (NVO), 3532 Katela Avenue, Suite 227, Los Alamitos, CA 90720; Officer: Fiona M. Hooks, President/CFO, (Qualifying Individual); Ronald Mundwiller, Secretary, Application Type: New NVO License.

IJS Global Inc. (NVO & OFF), 2600 Main St. Extension, 2nd Floor, Sayreville, NJ 08872; Officers: Tina J. Okragly, President, (Qualifying Individual); Kevin C. Hartnett, Director, Application Type: QI Change.

King Solutions, Inc. (NVO & OFF), 11011 Holly Lane North, Dayton, MN 55369, Officers: William S. Panzarella, VP of International Development, (Qualifying Individual); Michael Patterson, CEO/CFO/Secretary, Application Type: New NVO & OFF.

Mira Transport USA, Inc. dba Mira Express (NVO & OFF), 16 Pershing Street, Staten Island, NY 10305; Officers: Veronica Cairns, President/Secretary/Treasurer, (Qualifying Individual); Serhat Dagtas, Vice President, Application Type: Add NVO Service.

NGL International, LLC (OFF), 2121 Abbott Road, Anchorage, AK 99507; Officers: Raymond P. Donahue, Executive Vice President, (Qualifying Individual); John Witte, Member, Application Type: New OFF License.

Royal International Shipping, Inc. (OFF), 5900 Roche Drive, Columbus, OH 43229; Officers: Klyde R. Edor, President/Treasurer, (Qualifying Individual); Lora S. Edor, Vice President/Secretary, Application Type: New OFF License.

Sea Freight Logistics, Inc. (NVO), Lote 5 B1 Calle Gildita, La Ceramica Ind. Park, Carolina, PR 00984; Officers: Carlos E. Urrutia, President, (Qualifying Individual); Ramon F. Sanabria, Treasurer, Application Type: New NVO License.

South Atlantic Logistics LLC (OFF), 891 Newark Avenue, Elizabeth, NJ 07208; Officer: Samuel Soremekun, Managing Member/Managing Director, (Qualifying Individual); Application Type: New OFF License.

White Horse Logistics, Inc. (NVO), 1419 NW 84th Avenue, Miami, FL 33126; Officers: Donald Oberfield, Vice President/Secretary, (Qualifying Individual); Peter Markson, President, Application Type: New NVO License.

Dated: November 23, 2011.

Karen V. Gregory,

Secretary.

[FR Doc. 2011–30803 Filed 11–29–11; 8:45 am]

BILLING CODE 6730–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Federal Financial Participation in State Assistance Expenditures; Federal Matching Shares for Medicaid, the Children's Health Insurance Program, and Aid to Needy Aged, Blind, or Disabled Persons for October 1, 2012 Through September 30, 2013

AGENCY: Office of the Secretary, DHHS.

ACTION: Notice.

SUMMARY: The Federal Medical Assistance Percentages (FMAP), Enhanced Federal Medical Assistance Percentages (eFMAP), and disaster-recovery FMAP adjustments for Fiscal Year 2013 have been calculated pursuant to the Social Security Act (the Act). These percentages will be effective from October 1, 2012 through September 30, 2013. This notice announces the calculated FMAP and eFMAP rates that the U.S. Department of Health and Human Services (HHS) will use in determining the amount of federal matching for state medical assistance (Medicaid) and Children's Health Insurance Program (CHIP) expenditures, Temporary Assistance for Needy Families (TANF) Contingency Funds, Child Support Enforcement collections, Child Care Mandatory and Matching Funds of the Child Care and Development Fund, Foster Care Title IV–E Maintenance payments, and Adoption Assistance payments. Table 1 gives figures for each of the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. This notice also announces the disaster-recovery FMAP adjustments for qualifying states for FY 2013 that the U.S. Department of Health and Human Services (HHS) will use in determining the amount of federal matching for state medical assistance (Medicaid) and title IV–E Foster Care, Adoption Assistance and Guardianship Assistance programs.

Programs under title XIX of the Act exist in each jurisdiction. Programs under titles I, X, and XIV operate only in Guam and the Virgin Islands, while a program under title XVI (Aid to the Aged, Blind, or Disabled) operates only in Puerto Rico. The percentages in this notice apply to state expenditures for most medical assistance and child health assistance, and assistance payments for certain social services. The Act provides separately for federal matching of administrative costs.

Sections 1905(b) and 1101(a)(8)(B) of the Social Security Act (the Act) require the Secretary of HHS to publish the FMAP rates each year. The Secretary calculates the percentages, using formulas in sections 1905(b) and 1101(a)(8), and calculations by the Department of Commerce of average income per person in each state and for the Nation as a whole. The percentages must fall within the upper and lower limits given in section 1905(b) of the Act. The percentages for the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands are specified in statute, and thus are not based on the statutory formula that determines the percentages for the 50 States.

Section 1905(b) of the Act specifies the formula for calculating FMAPs as follows:

''Federal medical assistance percentage'' for any State shall be 100 per centum less the State percentage; and the State percentage shall be that percentage which bears the same ratio to 45 per centum as the square of the per capita income of such State bears to the square of the per capita income of the continental United States (including Alaska) and Hawaii; except that (1) the Federal medical assistance percentage shall in no case be less than 50 per centum or more than 83 per centum, (2) the Federal medical assistance percentage for Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa shall be 55 percent* * *''.

Section 4725(b) of the Balanced Budget Act of 1997 amended section 1905(b) to provide that the FMAP for the District of Columbia for purposes of titles XIX and XXI shall be 70 percent. For the District of Columbia, we note

under Table 1 that other rates may apply in certain other programs. In addition, we note the rate that applies for Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands in certain other programs pursuant to section 1118 of the Act.

Section 2105(b) of the Act specifies the formula for calculating the eFMAP rates as follows:

> The ''enhanced FMAP,'' for a State for a fiscal year, is equal to the Federal medical assistance percentage (as defined in the first sentence of section 1905(b)) for the State increased by a number of percentage points equal to 30 percent of the number of percentage points by which (1) such Federal medical assistance percentage for the State, is less than (2) 100 percent; but in no case shall the enhanced FMAP for a state exceed 85 percent.

The eFMAP rates are used in the Children's Health Insurance Program under Title XXI, and in the Medicaid program for certain children for expenditures for medical assistance described in sections 1905(u)(2) and 1905(u)(3) of the Act. There is no specific requirement to publish the eFMAP rates. We include them in this notice for the convenience of the States.

Section 2006 of the Patient Protection and Affordable Care Act of 2010 (''Affordable Care Act'') amended section 1905 of the Social Security Act by adding section (aa) to provide for an increase in the FMAP rate for qualifying States for Medicaid and title IV–E Foster Care, Adoption Assistance and Guardianship Assistance programs. The purpose of the increase to the FMAP rate is to provide increased Federal financial participation for qualifying States that have experienced a major, statewide disaster. The methodology for calculating and publishing disaster-recovery adjustments to fiscal year FMAP rates was published on December 22, 2010 (75 FR 80501).

Section 2006 defines a ''disaster-recovery FMAP adjustment state'' as one of the 50 states or District of Columbia for which, at any time during the preceding 7 fiscal years, the President has declared a major disaster under section 401 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act under which every county or parish in the state is eligible for individual and public assistance or public assistance from the federal government, and for which the FMAP as determined for the fiscal year is less than the FMAP (for the first year of assistance) or the disaster-adjusted recovery FMAP (for each subsequent year of assistance) for the preceding fiscal year by at least three percentage points.

Qualifying States receive an adjustment to their annual FMAP rate based on a formula specified in statute. In the first year a State qualifies, this increase is applied to the FMAP as determined for the fiscal year. In the second or any succeeding fiscal year a State qualifies, the adjustment is applied to the prior year's disaster-adjusted recovery FMAP. This results in increased, rather than phased down, financial assistance to qualifying States each year, and allows States to continue to qualify for assistance after their underlying FMAP has stabilized. The resulting assistance will be higher than initially projected.

Based on the criteria for a qualifying state, only two States meet the requirement that the FMAP as determined for FY 2013 is less than the previous year FMAP by at least three percentage points. Of the two States, only one, Louisiana, has had a Presidential disaster declaration that applies to all counties and parishes within the state in the preceding 7 fiscal years. Hurricane Gustav was declared a state-wide disaster in Louisiana on September 2, 2008. Therefore, Louisiana is the only state that qualifies for a disaster-recovery adjustment to their FY2013 FMAP rate. The disaster-recovery adjusted FMAP rate for Louisiana for FY2013 is provided in Table 2.

DATES: *Effective Dates:* The percentages listed will be effective for each of the four quarter-year periods beginning October 1, 2012 and ending September 30, 2013.

FOR FURTHER INFORMATION CONTACT: Carrie Shelton or Tom Musco, Office of Health Policy, Office of the Assistant Secretary for Planning and Evaluation, Room 447D—Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201, (202) 690–6870.

(Catalog of Federal Domestic Assistance Program Nos. 93.558: TANF Contingency Funds; 93.563: Child Support Enforcement; 93.596: Child Care Mandatory and Matching Funds of the Child Care and Development Fund; 93.658: Foster Care Title IV–E; 93.659: Adoption Assistance; 93.769: Ticket-to-Work and Work Incentives Improvement Act (TWWIIA) Demonstrations to Maintain Independence and Employment; 93.778: Medical Assistance Program; 93.767: Children's Health Insurance Program)

Dated: November 23, 2011.

Kathleen Sebelius,

Secretary.

TABLE 1—FEDERAL MEDICAL ASSISTANCE PERCENTAGES AND ENHANCED FEDERAL MEDICAL ASSISTANCE PERCENTAGES, EFFECTIVE OCTOBER 1, 2012–SEPTEMBER 30, 2013 (FISCAL YEAR 2013)

State	Federal medical assistance percentages	Enhanced federal medical assistance percentages
Alabama	68.53	77.97
Alaska	50.00	65.00
American Samoa*	55.00	68.50
Arizona	65.68	75.98
Arkansas	70.17	79.12
California	50.00	65.00
Colorado	50.00	65.00
Connecticut	50.00	65.00
Delaware	55.67	68.97
District of Columbia**	70.00	79.00
Florida	58.08	70.66
Georgia	65.56	75.89
Guam*	55.00	68.50
Hawaii	51.86	66.30
Idaho	71.00	79.70
Illinois	50.00	65.00
Indiana	67.16	77.01
Iowa	59.59	71.71

TABLE 1—FEDERAL MEDICAL ASSISTANCE PERCENTAGES AND ENHANCED FEDERAL MEDICAL ASSISTANCE PERCENTAGES, EFFECTIVE OCTOBER 1, 2012–SEPTEMBER 30, 2013 (FISCAL YEAR 2013)—Continued

State	Federal medical assistance percentages	Enhanced federal medical assistance percentages
Kansas	56.51	69.56
Kentucky	70.55	79.39
Louisiana	61.24	72.87
Maine	62.57	73.80
Maryland	50.00	65.00
Massachusetts	50.00	65.00
Michigan	66.39	76.47
Minnesota	50.00	65.00
Mississippi	73.43	81.40
Missouri	61.37	72.96
Montana	66.00	76.20
Nebraska	55.76	69.03
Nevada	59.74	71.82
New Hampshire	50.00	65.00
New Jersey	50.00	65.00
New Mexico	69.07	78.35
New York	50.00	65.00
North Carolina	65.51	75.86
North Dakota	52.27	66.59
Northern Mariana Islands*	55.00	68.50
Ohio	63.58	74.51
Oklahoma	64.00	74.80
Oregon	62.44	73.71
Pennsylvania	54.28	68.00
Puerto Rico*	55.00	68.50
Rhode Island	51.26	65.88
South Carolina	70.43	79.30
South Dakota	56.19	69.33
Tennessee	66.13	76.29
Texas	59.30	71.51
Utah	69.61	78.73
Vermont	56.04	69.23
Virgin Islands*	55.00	68.50
Virginia	50.00	65.00
Washington	50.00	65.00
West Virginia	72.04	80.43
Wisconsin	59.74	71.82
Wyoming	50.00	65.00

* For purposes of section 1118 of the Social Security Act, the percentage used under titles I, X, XIV, and XVI will be 75 per centum.
** The values for the District of Columbia in the table were set for the state plan under titles XIX and XXI and for capitation payments and DSH allotments under those titles. For other purposes, the percentage for DC is 50.00, unless otherwise specified by law.

TABLE 2—FISCAL YEAR 2013 DISASTER-RECOVERY ADJUSTED FMAP RATES

A	B	C	D	E	F
State	FY13 FMAP	FY12 Disaster-recovery adjusted FMAP	Difference in FMAP	Disaster-recovery adjustment increase	FY13 Disaster-recovery adjusted FMAP
			Col C–B	25% × Col D	Col C + E
Louisiana	61.24	69.78	8.54	2.14	71.92

[FR Doc. 2011–30860 Filed 11–29–11; 8:45 am]
BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mandatory Guidelines for Federal Workplace Drug Testing Programs

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services.

ACTION: HHS Approval of Entities That Certify Medical Review Officers (MRO).

SUMMARY: The current version of the Department of Health and Human Services (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines), effective on October 1, 2010, addresses the role and qualifications of Medical

Review Officers (MROs) and HHS approval of entities that certify MROs.

Subpart M—Medical Review Officer (MRO), Section 13.1(b), ''Who may serve as an MRO?'' states as follows: ''Nationally recognized entities that certify MROs or subspecialty boards for physicians performing a review of Federal employee drug testing results that seek approval by the Secretary must submit their qualifications and a sample examination. Based on an annual objective review of the qualifications and content of the examination, the Secretary shall publish a list in the **Federal Register** of those entities and boards that have been approved.''

HHS has completed its review of entities that train and certify MROs, in accordance with requests submitted by such entities to HHS.

(1) The HHS Secretary approves the following MRO certifying entities that offer both MRO training and certification through examination:

American Association of Medical Review Officers (AAMRO), P.O. Box 12873, Research Triangle Park, NC 27709, *Phone:* (800) 489–1839, *Fax:* (919) 490–1010, *Email:* cferrell@aamro.com, *Web site: http://www.aamro.com/*.

Medical Review Officer Certification Council (MROCC), 836 Arlington Heights Road, #327, Elk Grove Village, IL 60007, *Phone:* (847) 631–0599, *Fax:* (847) 483–1282, *Email:* mrocc@mrocc.org, *Web site: http://www.mrocc.org/*.

(2) The HHS Secretary lists the following entities that offer MRO training as a prerequisite for MRO certification:

American College of Occupational and Environmental Medicine (ACOEM), 25 Northwest Point Boulevard, Suite 700, Elk Grove Village, IL 60007–1030, *Phone:* (847) 818–1800, *Fax:* (847) 818–9266, *Contact Form: http://www.acoem.org/contactacoem.aspx*, *Web site: http://www.acoem.org/*.

American Society of Addiction Medicine (ASAM), 4601 N. Park Avenue, Upper Arcade #101, Chevy Chase, MD 20815, *Phone:* (301) 656–3920, *Fax:* (301) 656–3815, *Email:* email@asam.org, *Web site: http://www.asam.org/*.

DATES: HHS approval is effective November 30, 2011.

FOR FURTHER INFORMATION CONTACT: Jennifer Fan, Pharm.D., J.D., Division of Workplace Programs (DWP), Center for Substance Abuse Prevention (CSAP), Substance Abuse and Mental Health Services Administration (SAMHSA), 1 Choke Cherry Road, Room 2–1031, Rockville, MD 20857; *Telephone:* (240) 276–1759; Email: *jennifer.fan@samhsa.hhs.gov*.

Dated: November 21, 2011.

Kathleen Sebelius,

Secretary.

[FR Doc. 2011–30846 Filed 11–29–11; 8:45 am]

BILLING CODE ;P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30-Day–12–0666]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an email to *omb@cdc.gov*. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

National Healthcare Safety Network (NHSN) (OMB No. 0920–0666 exp. 3/31/2012)—Revision—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The National Healthcare Safety Network (NHSN) is a system designed to accumulate, exchange, and integrate relevant information and resources among private and public stakeholders to support local and national efforts to protect patients and to promote healthcare safety. Specifically, the data is used to determine the magnitude of various healthcare-associated adverse events and trends in the rates of these events among patients and healthcare workers with similar risks. Healthcare institutions that participate in NHSN voluntarily report their data to CDC using a web browser based technology for data entry and data management. Data are collected by trained surveillance personnel using written standardized protocols. The data will be used to detect changes in the epidemiology of adverse events resulting from new and current medical therapies and changing risks.

This revision submission includes an amended Assurance of Confidentiality, which required an update of the Assurance of Confidentiality language on all forms included in the NHSN surveillance system. The scope of NHSN dialysis surveillance is being expanded to include all outpatient dialysis centers so that the existing Dialysis Annual Survey can be used to facilitate prevention objectives set forth in the HHS HAI tier 2 Action Plan and to assess national practices in all Medicare-certified dialysis centers if CMS re-establishes this survey method (as expected). The Patient Safety (PS) Component is being expanded to include long term care facilities to facilitate HAI surveillance in this setting, for which no standardized reporting methodology or mechanism currently exists. Four new forms are proposed for this purpose. A new form is proposed to be added to the Healthcare Personnel Safety (HPS) Component to facilitate summary reporting of influenza vaccination in healthcare workers, which is anticipated to be required by CMS in the near future. In addition to this new form, the scope of the HPS Annual Facility Survey is being expanded to include all acute care facilities that would enroll if CMS does implement this requirement. The NHSN Antimicrobial Use and Resistance module is transitioning from manual web entry to electronic data upload only, which results in a significant decrease to the reporting burden for this package. Finally, there are many updates, clarifications, and data collection revisions proposed in this submission.

CDC is requesting to delete four currently approved forms that are no longer needed by the NHSN and add five new forms

The previously-approved NHSN package included 47 individual data collection forms. If all proposed revisions are approved, the reporting burden will decrease by 1,258,119 hours, for a total estimated burden of 3,914,125 hours and 48 total data collection tools.

Participating institutions must have a computer capable of supporting an Internet service provider (ISP) and access to an ISP. There is no cost to respondents other than their time. The total estimated annual burden hours are 3,914,125.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Respondents	Form name	Number of respondents	Responses per respondent	Burden per response (hours)
Infection Preventionist	NHSN Registration Form	6,000	1	5/60
	Facility Contact Information	6,000	1	10/60
	Patient Safety Component—Annual Facility Survey	6,000	1	40/60
	Patient Safety Component—Outpatient Dialysis Center Practices Survey.	5,500	1	1
	Group Contact Information	6,000	1	5/60
	Patient Safety Monthly Reporting Plan	6,000	9	35/60
	Primary Bloodstream Infection (BSI)	6,000	36	32/60
	Dialysis Event	500	75	15/60
	Pneumonia (PNEU)	6,000	72	32/60
	Urinary Tract Infection (UTI)	6,000	27	32/60
Staff RN	Denominators for Neonatal Intensive Care Unit (NICU)	6,000	9	4
Denominators for Specialty Care Area (SCA).	6,000	9	5	
	Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA).	6,000	18	5
Staff RN	Denominator for Outpatient Dialysis	500	12	5/60
Infection Preventionist	Surgical Site Infection (SSI)	6,000	27	32/60
Staff RN	Denominator for Procedure	6,000	540	10/60
Laboratory Technician	Antimicrobial Use and Resistance (AUR)-Microbiology Data Electronic Upload Specification Tables.	6,000	12	5/60
Pharmacy Technician	Antimicrobial Use and Resistance (AUR)—Pharmacy Data Electronic Upload Specification Tables.	6,000	12	5/60
Infection Preventionist	Central Line Insertion Practices Adherence Monitoring	6,000	100	5/60
	MDRO or CDI Infection Form	6,000	72	32/60
	MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring.	6,000	24	10/60
	Laboratory-identified MDRO or CDI Event	6,000	240	25/60
	Vaccination Monthly Monitoring Form–Summary Method	6,000	5	14
	Vaccination Monthly Monitoring Form–Patient-Level Method.	2,000	5	2
	Patient Vaccination	2,000	250	10/60
	Patient Safety Component—Annual Facility Survey for LTCF.	250	1	25/60
	Laboratory-identified MDRO or CDI Event for LTCF	250	8	30/60
	MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF.	250	3	7/60
	Urinary Tract Infection (UTI) for LTCF	250	9	30/60
Occ Health RN	Healthcare Personnel Safety Component Annual Facility Survey.	6,000	1	8
	Healthcare Worker Survey	600	100	10/60
	Healthcare Personnel Safety Monthly Reporting Plan	600	9	10/60
	Healthcare Worker Demographic Data	600	200	20/60
	Exposure to Blood/Body Fluids	600	50	1
	Healthcare Worker Prophylaxis/Treatment	600	10	15/60
Laboratory Technician	Follow-Up Laboratory Testing	600	100	15/60
Occ Health RN	Healthcare Worker Vaccination History	600	300	10/60
Occ Health RN	Healthcare Worker Influenza Vaccination	600	500	10/60
	Healthcare Worker Prophylaxis/Treatment-Influenza	600	50	10/60
	Pre-season Survey on Influenza Vaccination Programs for Healthcare Personnel.	600	1	10/60
	Post-season Survey on Influenza Vaccination Programs for Healthcare Personnel.	600	1	10/60
	Healthcare Personnel Influenza Vaccination Monthly Summary.	6,000	6	2
Clinical Laboratory Technologist	Hemovigilance Module Annual Survey	500	1	2
	Hemovigilance Module Monthly Reporting Plan	500	12	2/60
	Hemovigilance Module Monthly Incident Summary	500	12	2
	Hemovigilance Module Monthly Reporting Denominators	500	12	30/60
	Hemovigilance Adverse Reaction	500	120	10/60
	Hemovigilance Incident	500	72	10/60

Dated: November 22, 2011

Daniel Holcomb,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011–30832 Filed 11–29–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30-Day–12–11IR]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an email to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Evaluation of Core Violence and Injury Prevention Program (Core VIPP)—New—National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Injuries and their consequences, including unintentional and violence-related injuries, are the leading cause of death for the first four decades of life, regardless of gender, race, or socioeconomic status. More than 179,000 individuals in the United States die each year as a result of unintentional injuries and violence, more than 29 million others suffer non-fatal injuries and over one-third of all emergency department (ED) visits each year are due to injuries. In 2000, injuries and violence ultimately cost the United States $406 billion, with over $80 billion in medical costs and the remainder lost in productivity.[1] Most events that result in injury and/or death from injury could be prevented if evidence-based public health strategies, practices, and policies were used throughout the nation.

CDC's National Center for Injury Prevention and Control (NCIPC) is committed to working with their partners to promote action that reduces injuries, violence, and disabilities by providing leadership in identifying priorities, promoting tools, and monitoring effectiveness of injury and violence prevention and to promote effective strategies for the prevention of injury and violence, and their consequences. One tool NCIPC will use to accomplish this is the Core Violence and Injury Prevention Program (VIPP). This program funds state health departments to build effective delivery systems for dissemination, implementation and evaluation of evidence based/best practice programs and policies.

Core VIPP also focuses on the integration of unintentional injury and violence prevention. Unintentional injury and violence prevention have many common risk and protective factors for children. In an endeavor to promote efforts to prevent child maltreatment, a NCIPC priority, CDC is collaborating with the Health Resources and Services Administration (HRSA) regarding the new Affordable Care Act (ACA) Maternal, Infant, and Early Childhood Home Visiting Program. The state health departments funded by the Core VIPP will be required to partner with the state agency responsible for administration of the State Home Visiting program.

CDC requests OMB approval to collect program evaluation data for Core VIPP over a three-year period. Specifically, CDC will use the Safe States Alliance State of the States (SOTS) survey as the template for annual evaluation surveys and an annual follow-up telephone interview. Both the SOTS and the telephone interviews will be conducted with state Violence and Injury Prevention programs directors and staff. This approach provides a means to collect standardized, systematic data from the Core VIPP grantees for program evaluation and improvement. Topics for data collection include: Program evaluation, state injury and violence prevention program (IVP) infrastructure, IVP strategies and partners, policy strategies, injury surveillance, quality of surveillance, and regional network leaders. Part of the requirement for receiving Core VIPP funding is for State Injury and Violence Programs (SIVPs) to develop and maintain their own evaluation capacity and data systems; thus, this data collection is not expected to entail significant burdens to respondents.

Estimates of burden for the survey are based on previous experience with evaluation data collections conducted by the evaluation staff. The State of the States (SOTS) web-based survey assessment will be completed by 28 Core Funded State Health Departments (SHDs) and 22 Non-Funded SHDs, taking 3 hours to complete. The SOTS Financial Module will also be completed by the 28 Core Funded and 22 Non-Funded SHD, taking 1 hour to complete. The telephone interviews will take 1.5 hours to conclude and will be completed by the 28 Core Funded States. We expect that each of the 28 Core Funded states will complete three web-based surveys and three telephone interviews during the first three years of Core funding. It is anticipated that up to 22 unfunded states will complete three web-based surveys during the first three years of Core funding.

There are no costs to respondents other than their time.

The total estimated annual burden hours are 242.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Core VIPP funded SVIP directors and staff	State of the States Survey (SOTS)	28	1	3
Core VIPP funded SVIP directors and staff	SOTS Financial Module	28	1	1
Core VIPP funded VIP directors and staff	Telephone interview	28	1	1.5
Non-funded SHD Injury Program management and staff.	SOTS	22	1	3
Non-funded SHD Injury Program management and staff.	SOTS Financial Module	22	1	1

Dated: November 22, 2011.

Daniel Holcomb,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011–30833 Filed 11–29–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30-Day–12–11IY]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an email to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Formative Research to Support the Development of Sickle Cell Disease Educational Messages and Materials for the Division of Blood Disorders—New—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC seeks to improve the quality of life of people living with sickle cell disease (SCD). To accomplish this goal, CDC aims to address the need for educational messages and materials for adolescents, young adults, adults, and older adults living with SCD. CDC is interested in understanding the informational needs of these audiences related to the adoption of healthy behaviors and the prevention of complications associated with sickle cell disease. To develop valuable messages and materials, CDC will conduct formative focus groups with people with SCD across the country. Participants will stem from four urban centers as well as more remote, rural areas. Based on the findings from the formative focus groups, CDC will develop and test draft messages.

A total of 10 focus groups will be conducted. Eight focus groups with people with SCD would be held in four cities: Atlanta, GA; Detroit, MI; Oakland, CA; and Philadelphia, PA. Two in-person focus groups—one with males and one with females—will be conducted in each city with each target audience: adolescents aged 15–17, young adults aged 18–25, adults aged 26–35, and older adults 36 and over. To reach more rural participants, two telephone focus groups will be conducted: one with female adolescents aged 15–17 and a second with male older adults aged 36 and older.

The focus groups will be conducted with eight to nine participants in each and will last 2 hours. As part of the focus group, participants will complete an informed consent or adolescent assent form before discussion begins. The parents of the expected 27 adolescent participants (three groups of 9 each) will fill out a permission form to provide their consent in advance of the groups. The use of trained moderators and a structured moderator's guide will ensure that consistent data are collected across the groups. In total, up to 90 people with SCD will participate in the focus group data collection. It is estimated that 120 potential participants will need to be screened to reach the target of 90 participants. The estimated time per response for screening and recruitment is 12 minutes.

CDC requests OMB approval to obtain clearance for one year. There is no cost to respondents other than their time. The estimated annualized burden hours for this data collection activity are 204.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Parents of adolescents (aged 15–17) living with SCD Young adults (aged 18–25) living with SCD. Adults (aged 26–35) living with SCD. Older adults (aged 36+) living with SCD.	Participant Screener and Recruitment Script.	120	1	12/60
Adolescents (aged 15–17) living with SCD Young adults (aged 18–25) living with SCD. Adults (aged 26–35) living with SCD. Older adults (aged 36+) living with SCD.	Focus Group Moderator's Guide.	90	1	2

Dated: November 21, 2011.

Daniel L. Holcomb,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011–30841 Filed 11–29–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–5505–N2]

Medicare Program; Announcement of a New Application Deadline for the Advance Payment Model

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces a new application deadline for participation in the Advance Payment Model for certain accountable care organizations participating in the Medicare Shared Savings Program scheduled to begin in 2012.

DATES: *Application Submission Deadlines for the Advance Payment Model:* Applications for the performance period beginning on April

1, 2012 will be accepted from January 3, 2012 through February 1, 2012.

The period during which applications will be accepted for the performance period beginning on July 1, 2012 will remain identical to the period for the Medicare Shared Savings Program. More information is available on the Advance Payment Model Web site at *http://www.innovations.cms.gov/initiatives/aco/advance-payment/index.html*.

FOR FURTHER INFORMATION CONTACT: Dan Farmer, (410) 786–5497.

SUPPLEMENTARY INFORMATION:

I. Background

The Centers for Medicare & Medicaid Services (CMS) is committed to achieving the three-part aim of better health for populations, better health care for individuals, and lower growth in expenditures through continuous improvement for Medicare, Medicaid, and Children's Health Insurance Program (CHIP) beneficiaries. One potential mechanism for achieving this goal is for CMS to partner with groups of health care providers of services and suppliers that have a mechanism for shared governance and have formed an Accountable Care Organization (ACO) through which they work together to coordinate care for a specified group of patients. We will pursue such partnerships through complementary efforts, including the Medicare Shared Savings Program and initiatives undertaken by the Center for Medicare and Medicaid Innovation (Innovation Center).

The Advance Payment Model is an Innovation Center initiative designed for participants in the Medicare Shared Savings Program in need of prepayment of expected shared savings to build their capacity to provide high quality, coordinated care and generate cost savings. The Advance Payment Model will test whether and how pre-paying a portion of future shared savings could increase participation in the Medicare Shared Savings Program, and whether advance payments will enhance the ability of ACOs to effectively coordinate care and generate Medicare savings, as well as the speed at which they attain that goal.

In the November 2, 2011 **Federal Register** (76 FR 68012), we published a notice announcing the Advance Payment Model. Additional information about the Advance Payment Model is available on the Advance Payment Model Web site at *http://www.innovations.cms.gov/initiatives/aco/advance-payment/index.html*.

II. Provisions of the Notice

This notice announces a new deadline for applications to the Advance Payment Model for the performance period beginning April 1, 2012. We will accept applications to the Advance Payment Model from January 3, 2012 through February 1, 2012. The period during which applications will be accepted for the performance period beginning on July 1, 2012 will remain identical to the period for the Medicare Shared Savings Program.

Organizations interested in applying to the Advance Payment Model must also complete an application for the Shared Savings Program. This modified deadline will provide organizations interested in the Advance Payment Model with more time to complete the additional application needed for the Advance Payment Model. Information about the application process and deadlines for the Shared Savings Program is available at http://*www.cms.gov/sharedsavingsprogram*.

Additional information about the application process for the Advance Payment Model is available on the Advance Payment Model Web site at *http://www.innovations.cms.gov/initiatives/aco/advance-payment/index.html*.

Authority: Section 1115A of the Social Security Act.

Dated: *November 23, 2011.*

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2011–30845 Filed 11–29–11; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2011–1084]

Guidance on Domestic Implementation of International Standards for Oceangoing Barges Carrying Noxious Liquid Substances

AGENCY: Coast Guard, DHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Coast Guard announces a public meeting to receive comments on new policy under consideration that would provide a domestic equivalency for international standards with respect to U.S. flagged oceangoing barges carrying noxious liquid substances (NLS).

DATES: A public meeting will be held on Thursday, December 1, 2011 from 2 p.m. to 4 p.m. to provide an opportunity for oral comments. Written comments and related material may be submitted to Coast Guard personnel specified at that meeting. Written comments may also be submitted in response to this notice. The comment period for this notice will close on December 30, 2011. All written comments and related material submitted before or after the meeting must either be submitted to our online docket via *http://www.regulations.gov* on or before December 30, 2011 or reach the Docket Management Facility by that date.

ADDRESSES: The public meeting will be held at the Ernest N. Morial Convention Center, Room 205, 900 Convention Center Boulevard, New Orleans, LA 70130, telephone (504) 582–3000.

You may submit written comments identified by docket number USCG–2011–1084 before or after the meeting using any one of the following methods:

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

(2) *Fax:* (202) 493–2251.

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

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

To avoid duplication, please use only one of these four methods. Our online docket for this notice is available on the Internet at *http://www.regulations.gov* under docket number USCG–2011–1084.

FOR FURTHER INFORMATION CONTACT: If you have questions concerning the meeting or the new policy under consideration, please call or email LT Sean Peterson, Commandant (CG–5223), Coast Guard; telephone (202) 372–1403, email *Sean.M.Peterson@uscg.mil*. If you have questions on viewing or submitting material to the docket, call Ms. Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Background and Purpose

The Coast Guard is considering new policy that would align Coast Guard guidance with the International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk (IBC Code) as it may relate to oceangoing barges carrying NLS.

The new policy under consideration by the Coast Guard would provide affected parties with an equivalent

means of compliance with the IBC Code. In crafting this guidance, the Coast Guard wishes to take into account public concerns and input. In that regard, this notice specifically requests information and public comments relating to the following topics:

1. Regulation 11.3.1 of the IBC Code requiring installation of fixed deck foam systems for all vessels carrying cargoes with a flashpoint less than 60 degrees (Celsius).

2. Secondary venting requirements according to Regulation 8.3 of the IBC Code.

3. Any additional comments or concerns regarding the implementation of the International Convention for the Prevention of Pollution from Ships (MARPOL) Annex II for oceangoing barges carrying NLS.

The Coast Guard believes that a public meeting would also benefit the impacted community by providing an additional forum to raise relevant issues. This will further enable the Coast Guard to craft policy that takes into account public concerns.

You may view the written comments and supporting documents (if any) in the online docket by going to *http://www.regulations.gov.* Once there, select the Advanced Docket Search option on the right side of the screen, insert USCG–2011–1084 in the Docket ID box, press Enter, and then click on the item in the Docket ID column. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.

We encourage you to participate by submitting comments either orally at the meeting or in writing. If you bring written comments to the meeting, you may submit them to Coast Guard personnel specified at the meeting to receive written comments. These comments will be submitted to our online public docket. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

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

Information on Services for Individuals With Disabilities

For information on facilities or services for individuals with disabilities or to request special assistance at the public meeting, contact Lt. Sean Peterson at the telephone number or email address indicated under the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Public Meeting

The Coast Guard will hold a public meeting regarding new policy under consideration that would provide a domestic equivalency for international standards with respect to U.S. flagged oceangoing barges carrying NLS on Thursday, December 1, 2011 from 2 p.m. to 4 p.m., at the Ernest N. Morial Convention Center, Room 205, 900 Convention Center Boulevard, New Orleans, LA 70130, telephone (504) 582–3000.

We plan to record this meeting using an audio-digital recorder and then make that audio recording available through a link in our online docket. We will also provide a written summary of the meeting and comments and will place that summary in the docket.

Dated: November 25, 2011.

F.J. Sturm,

Deputy, Director of Commercial Regulations and Standards, U.S. Coast Guard.

[FR Doc. 2011–30864 Filed 11–25–11; 4:15 pm]

BILLING CODE 9110–04–P

DEPARTMENT OF THE INTERIOR

Central Utah Project Completion Act; Finding of No Significant Impact Associated With the Environmental Assessment for Block Notice 1A Heber Sub-Area Agricultural Water to Municipal Industrial Water Conversion

AGENCY: Office of the Assistant Secretary for Water and Science, Interior.

ACTION: Notice of availability.

SUMMARY: On September 27, 2011, the Department of the Interior signed a Finding of No Significant Impact which documents the selection of the Proposed Action as presented in the Final Environmental Assessment for the Block Notice 1A Heber Sub-Area Agricultural Water to Municipal & Industrial Water Conversion.

ADDRESSES: A copy of the Final Environmental Assessment and Finding of No Significant Impact may be accessed on the Internet at *http://www.cuwcd.com* and *http://www.cupcao.gov.* CD and paper copies can be obtained by contacting Sarah Sutherland, 355 West University Parkway, Orem, Utah 84058, *sarah@cuwcd.com,* (801) 226–7146.

FOR FURTHER INFORMATION CONTACT: Mr. Lynn Hansen, Central Utah Project Completion Act Office, 302 East 1860 South, Provo, Utah 84606, (801) 379–1238, or email at *lhansen@usbr.gov.*

SUPPLEMENTARY INFORMATION: The Department of the Interior (Interior) has determined that implementing the Proposed Action described in the Environmental Assessment (EA) will not have a significant impact on the quality of the human environment and that an environmental impact statement is not required. The proposed action would:

1. Administratively convert up to 12,100 acre-feet of Central Utah Project Bonneville Unit agricultural water, delivered under Block Notice 1A and allotted to the Heber Sub-Area, from agricultural to municipal & industrial use.

2. Expand the Heber Sub-area.

3. Require modifying Block Notice 1A to reflect these administrative changes. Completing this EA would allow the administrative changes but would not automatically convert the water. The actual conversion would be completed by Central Utah Water Conservancy District and Interior consistent with Bureau of Reclamation law over time as requests are received from petitioners and contract holders.

4. Provide for installation and operation of a temporary water-delivery system in the event of an emergency that affects the water supply to the Jordanelle Special Service District (JSSD) Keetley Water Treatment Plant at Jordanelle Reservoir. During an emergency, this system would provide JSSD with a temporary method to receive its contracted portion of the Block Notice 1A water. Because the temporary water-delivery system would be installed on Federal land, Interior would need to issue a license agreement to JSSD as part of the process.

Dated: November 21, 2011.

Reed R. Murray,

Program Director, Central Utah Project Completion Act, Department of the Interior.

[FR Doc. 2011–30825 Filed 11–29–11; 8:45 am]

BILLING CODE 4310–MN–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R3–ES–2011–N246; FXES11130300000F3–123–FF03E00000]

Endangered and Threatened Species; Permits

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of issuance of permits.

SUMMARY: We, the U.S. Fish and Wildlife Service, have issued the following permits to conduct certain activities with endangered species under the authority of the Endangered Species Act, as amended (Act).

FOR FURTHER INFORMATION CONTACT: Ms. Lisa Mandell, at (612) 713–5343 (phone) or *lisa_mandell@fws.gov* (email).

SUPPLEMENTARY INFORMATION: We have issued the following permits in response to incidental take and recovery permit applications we received under the authority of section 10 of the Act (16 U.S.C. 1531 *et seq.*). Each permit listed below was issued only after we determined that it was applied for in good faith; that granting the permit would not be to the disadvantage of the listed species; and that the terms and conditions of the permit were consistent with purposes and policy set forth in the Act.

Applicant name	Permit no.	Date issued	Date expired
RECOVERY PERMITS			
ABR, INC.	224720	5/5/2010	12/31/2011
AHLSTEDT, STEVEN A	113009	4/8/2011	12/31/2012
APPLIED SCIENCE & TECHNOLOGY, INC.	48835A	11/3/2011	12/31/2013
BAT CONSERVATION AND MANAGEMENT, INC.	212440	4/8/2011	12/31/2012
BENEDICT, RUSSELL A	06820A	7/22/2010	12/31/2011
BERNARDIN—LOCHMUELLER & ASSOCIATES	06845A	6/7/2010	12/31/2011
BERNARDIN—LOCHMUELLER & ASSOCIATES	179711	6/19/2009	12/31/2009
BHE ENVIRONMENTAL, INC	38789A	5/16/2011	12/31/2012
BHE ENVIRONMENTAL, INC	809227	6/16/2010	12/31/2010
BIDART–BOUZAT, MARIA GABRIELA	43555A	7/25/2011	12/31/2011
BRADLEY, SARAH A	207149	4/20/2009	12/31/2010
BRADLEY, SARAH A	38769A	5/16/2011	12/31/2012
BRITZKE, ERIC R	023666	3/1/2011	12/31/2012
BRZYSKI, JESSICA R	212423	6/1/2009	12/31/2010
BURKE, THERESA SYDNEY	02360A	4/26/2010	12/31/2011
CARTER, TIMOTHY C	02560A	5/12/2010	12/31/2011
CDM MICHIGAN, INC	15061A	8/4/2010	12/31/2011
CENTER FOR BIODIVERSITY	006012	4/23/2010	12/31/2011
CENTRAL LAKE SUPERIOR LAND CONSERVANCY	212417	5/22/2009	12/31/2009
CHICAGO BOTANIC GARDENS	19173A	8/10/2011	12/31/2011
CIVIL AND ENVIRONMENTAL CONSULTANTS, INC.	07358A	4/20/2011	12/31/2011
CIVIL AND ENVIRONMENTAL CONSULTANTS, INC.	118259	7/2/2009	12/31/2009
CORPS OF ENGINEERS, ST PAUL DISTRICT	02378A	4/26/2010	12/31/2011
COX, DANIEL R	43605A	9/15/2011	12/31/2013
CUNNINGHAM, GEORGE R	38862A	6/30/2011	12/31/2012
CUTHBERT, FRANCESCA J.	212430	5/22/2009	12/31/2010
CUTHBERT, FRANCESCA J.	43541A	7/1/2011	12/31/2012
DAVEY RESOURCE GROUP	235639	4/23/2010	12/31/2011
ECOLOGICAL SPECIALISTS, INC.	206781	11/2/2011	12/31/2012
ECOLOGICAL SPECIALTIES LLC	09357A	6/22/2010	12/31/2011
ECOLOGY & ENVIRONMENT, INC.	212427	10/25/2011	12/31/2012
EMERY, SARAH MICHELLE	43607A	7/27/2011	12/31/2011
ENVIRONMENTAL SOLUTIONS AND INNOVATIONS, INC.	023664	6/19/2009	12/31/2009
ENVIRONMENTAL SOLUTIONS AND INNOVATIONS, INC.	02373A	9/9/2011	12/31/2011
ENVIROSCIENCE, INC.	130900	9/15/2011	12/31/2011
FOWLER RIDGE WIND FARM	15075A	3/31/2011	12/31/2011
GARVON, JASON MICHAEL	38860A	6/3/2011	12/31/2012
GEHRT, STANLEY D	08604A	6/24/2010	12/31/2011
HALSALL, AMY L	207178	3/29/2011	12/31/2012
HAMM, CHRISTOPHER ALAN	175852	7/9/2009	12/31/2009
HAMM, CHRISTOPHER ALAN	31215A	4/5/2011	12/31/2012
HELMS, DON R.	839777	3/28/2011	12/31/2012
HOGGARTH, MICHAEL A.	194099	5/31/2011	12/31/2011
ILLINOIS NATURAL HISTORY SURVEY	182436	3/29/2011	12/31/2012
ILLINOIS NATURAL HISTORY SURVEY	42196A	7/25/2011	12/31/2012
ILLINOIS STATE MUSEUM	10891A	6/4/2010	12/31/2011
ILLINOIS STATE MUSEUM	842313	6/8/2009	12/31/2009
IOWA DEPARTMENT OF NATURAL RESOURCES	120258	1/27/2010	12/31/2011
IOWA STATE UNIVERSITY	226335	2/22/2010	12/31/2011
J.F. NEW ASSOCIATES, INC.	02350A	4/26/2010	12/31/2011
J.F. NEW ASSOCIATES, INC.	38837A	5/20/2011	12/31/2012
KISER, ROBERT R	216605	11/5/2009	12/31/2011
KNIOWSKI, ANDREW B	06843A	6/17/2010	12/31/2011
KRIEGSHAUSER, SHAWNA R	43545A	7/26/2011	12/31/2011
KURTA, ALLEN	809630	4/10/2009	12/31/2013
LAND CONSERVANCY OF WEST MICHIGAN	06800A	6/11/2010	12/31/2010
LAND CONSERVANCY OF WEST MICHIGAN	38835A	5/16/2011	12/31/2012
LEWIS ENVIRONMENTAL CONSULTING	181256	4/5/2010	12/31/2011

Applicant name	Permit no.	Date issued	Date expired
LEWIS, JULIAN J	31208A	3/3/2011	12/31/2011
MACALESTER COLLEGE	02381A	6/23/2011	12/31/2011
MAINSTREAM COMMERCIAL DIVERS, INC.	02344A	4/26/2010	12/31/2011
MALACOLOGICAL CONSULTANTS	230947	12/24/2009	12/31/2010
MALCOSKY, MICHELLE	08603A	6/11/2010	12/31/2011
MARK TWAIN NATIONAL FOREST	31861A	4/21/2011	12/31/2012
MCCLANAHAN, ROD DANIEL	06797A	5/18/2010	12/31/2011
MCCLANE, M. BRENT	15057A	7/26/2010	12/31/2012
METROPOLITAN PARK DISTRICT OF THE TOLEDO AREA	174388	4/15/2011	12/31/2012
MICHIGAN DEPARTMENT OF NATURAL RESOURCES	207154	3/26/2009	12/31/2009
MICHIGAN DEPARTMENT OF NATURAL RESOURCES	219624	7/18/2011	12/31/2011
MIERZWA, KENNETH S	212393	6/29/2010	12/31/2010
MIERZWA, KENNETH S	38793A	5/18/2011	12/31/2012
MINNESOTA POLLUTION CONTROL AGENCY	31310A	4/20/2011	12/31/2012
MISSOURI DEPARTMENT OF CONSERVATION	120259	3/3/2010	12/31/2014
NATURAL RESOURCES RESEARCH INSTITUTE	207191	6/1/2009	12/31/2011
NORTHERN ILLINOIS UNIVERSITY	224719	11/27/2009	12/31/2011
OHIO DEPARTMENT OF NATURAL RESOURCES	207180	5/13/2011	12/31/2015
OHIO DIVISION OF WILDLIFE	151109	12/28/2010	12/31/2012
OWENS, NICHOLAS L	182430	6/2/2009	12/31/2009
PERDICAS, MARLO MARIE	206783	4/8/2011	12/31/2012
PITTSBURGH WILDLIFE & ENVIRONMENTAL, INC.	06801A	5/26/2010	12/31/2011
REDWING ECOLOGICAL SERVICES, INC.	07730A	7/20/2010	12/31/2012
REDWING ECOLOGICAL SERVICES, INC.	151107	5/23/2011	12/31/2011
ROBBINS, LYNN W.	02365A	11/8/2011	12/31/2012
ROE, KEVIN J.	48832A	10/18/2011	12/31/2013
SANDERS ENVIRONMENTAL INC	38842A	6/3/2011	12/31/2012
SHAWNEE NATIONAL FOREST	06778A	5/18/2010	12/31/2011
SKELLY AND LOY, INC.	38856A	10/21/2011	12/31/2012
SLACK, WILLIAM TODD	54326A	10/18/2011	12/31/2015
SMITHSONIAN INSTITUTION	06846A	4/30/2010	12/31/2011
SOLUK, DANIEL A	805269	12/17/2010	12/31/2014
SOUTHERN ILLINOIS UNIVERSITY	042946	4/26/2011	12/31/2012
ST. LOUIS ZOO	135297	4/25/2011	12/31/2012
STANTEC CONSULTING SERVICES	152002	4/27/2010	12/31/2010
STANTEC CONSULTING SERVICES	38821A	5/19/2011	12/31/2012
STANTEC CONSULTING SERVICES, INC.	15027A	7/23/2010	12/31/2011
STEFFEN, BRADLEY JAMES	207150	4/21/2009	12/31/2010
TAWSE, MERRILL BERNARD	207560	4/22/2009	12/31/2010
TAWSE, MERRILL BERNARD	38785A	5/16/2011	12/31/2012
THE FIELD MUSEUM OF NATURAL HISTORY	06795A	5/25/2010	12/31/2011
THE HOLDEN ARBORETUM	38858A	6/24/2011	12/31/2012
THE NATURE CONSERVANCY	127441	6/25/2010	12/31/2010
THE NATURE CONSERVANCY—MICHIGAN CHAPTER	207523	4/21/2011	12/31/2012
THE OHIO DEPARTMENT OF TRANSPORTATION	02651A	8/8/2011	12/31/2011
THE TOLEDO ZOO	106217	4/26/2010	12/31/2012
THIRD ROCK CONSULTANTS, LLC	049738	9/9/2011	12/31/2012
TIMPONE, JOHN CHARLES	120231	7/22/2011	12/31/2012
TOMASI, THOMAS E	195082	12/22/2010	12/31/2012
TRAGUS ENVIRONMENTAL CONSULTING, INC.	105320	4/6/2011	12/31/2012
U.S. ENVIRONMENTAL PROTECTION AGENCY	06844A	3/8/2011	12/31/2015
U.S. FISH AND WILDLIFE SERVICE	06841A	4/22/2011	11/30/2014
U.S. FISH AND WILDLIFE SERVICE	206778	4/18/2011	12/31/2012
U.S. FISH AND WILDLIFE SERVICE	697830	12/16/2010	12/31/2015
U.S. FOREST SERVICE	217351	8/18/2009	12/31/2011
U.S. GEOLOGICAL SURVEY	10887A	7/25/2011	12/31/2013
U.S. GEOLOGICAL SURVEY	38866A	5/25/2011	12/31/2012
U.S. GEOLOGICAL SURVEY	831774	3/16/2009	12/31/2010
UNIVERSITY OF WISCONSIN—STEVENS POINT	08602A	6/14/2010	12/31/2011
UPPER PENINSULA LAND CONSERVANCY	06822A	7/1/2011	12/31/2011
US GEOLOGICAL SURVEY	207526	9/29/2011	12/31/2011
USDA FOREST SERVICE	06809A	5/18/2010	12/31/2011
VANDE KOPPLE, ROBERT J	11035A	6/23/2010	12/31/2011
VOLK FIELD—CRTC—ANG	19777A	8/11/2010	3/31/2011
VUCETICH, JOHN A	212420	8/27/2009	12/31/2011
WALTERS, BRIANNE LORRAINE	106220	4/4/2011	12/31/2012
WATTERS, GEORGE THOMAS	088720	9/15/2011	12/31/2012
WESTERN ECOSYSTEMS TECHNOLOGY, INC.	234121	4/22/2011	12/31/2011
WHITAKER, JOHN O.	839763	7/1/2011	12/31/2012
WISCONSIN DEPARTMENT OF NATURAL RESOURCES	20323A	9/1/2011	8/6/2020
ZANATTA, DAVID T	212435	7/28/2009	6/30/2011
INCIDENTAL TAKE PERMITS			
EXELON GENERATION COMPANY, LLC	17852A	8/16/2010	8/15/2034

Applicant name	Permit no.	Date issued	Date expired
MICHIGAN DEPARTMENT OF NATURAL RESOURCES	213404	7/1/2010	12/31/2030
WISCONSIN DEPARTMENT OF NATURAL RESOURCES	010064	7/12/2010	12/31/2019

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 to Lisa Mandell (see **FOR FURTHER INFORMATION CONTACT**).

Authority: The authority for this notice is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: November 21, 2011.

Lynn M. Lewis,

Assistant Regional Director, Ecological Services, Midwest Region.

[FR Doc. 2011–30828 Filed 11–29–11; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R1–ES–2011–N235; 10120–1112–0000–F2]

Endangered and Threatened Wildlife and Plants; Incidental Take Permit Application; Habitat Conservation Plan and Associated Documents; Kaheawa Pastures Wind Energy Generation Facility, Maui County, HI

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the Fish and Wildlife Service, have received an application, under the Endangered Species Act of 1973, as amended (Act), from Kaheawa Wind Power I, LLC, for an amendment to incidental take permit (ITP) number TE118901–0 and the associated Kaheawa Pastures Wind Energy Generation Facility Habitat Conservation Plan (HCP). If approved, the ITP amendment would reduce the level of authorized incidental take of the endangered Hawaiian petrel (uau) and the threatened Newell's shearwater (ao) in the course of operating the Kaheawa Pastures Wind Energy Generation Facility (KWPI wind farm) for generating electricity on the island of Maui, Hawaii. We invite public comment on the proposed amendment of the ITP, HCP, and associated documents.

DATES: To ensure consideration, please send your written comments by December 30, 2011.

ADDRESSES: You may download a copy of the permit application, HCP, and associated documents on the Internet at *http://www.fws.gov/pacificislands/*. Alternatively, you may use one of the methods below to request hard copies or a CD–ROM of the documents. Please specify permit number TE118901–0 on all correspondence.

Submitting Comments: You may submit comments or requests for copies or more information by one of the following methods.

- *Email: Dawn_Greenlee@fws.gov.* Include ''Permit Number TE118901–0'' in the subject line of the message.
- *U.S. Mail:* Please address written comments to Loyal Mehrhoff, Project Leader, Pacific Islands Fish and Wildlife Office, U.S. Fish and Wildlife Service, 300 Ala Moana Boulevard, Room 3–122, Honolulu, HI 96850.
- *In-Person Drop-off, Viewing, or Pickup:* Call Dawn Greenlee, Fish and Wildlife Biologist, at (808) 792–9400 to make an appointment to view or pick up draft documents, or drop-off comments during regular business hours at the above address.
- *Fax:* Loyal Mehrhoff, Project Leader, (808) 792–9580, Attn.: Permit number TE118901–0.

FOR FURTHER INFORMATION CONTACT: Dawn Greenlee, Fish and Wildlife Biologist, U.S. Fish and Wildlife Service, (808) 792–9400 (phone); *Dawn_Greenlee@fws.gov* (email, include ''Permit Number TE118901–0'' in the subject line of the message). If you use a telecommunications device for the deaf (TDD), please call the Federal Information Relay Service (FIRS) at (800) 877–8339.

SUPPLEMENTARY INFORMATION:

Introduction

Kaheawa Wind Power I, LLC (KWPI), a subsidiary of First Wind Energy LLC, has requested an amendment to their existing incidental take permit (ITP) number TE118901–0, and the associated Kaheawa Pastures Wind Energy Generation Facility Habitat Conservation Plan (HCP), under section 10(a)(1)(B) of the Act. If we approve the amendment, the ITP would reduce the level of authorized incidental take of the endangered Hawaiian petrel (uau, *Pterodroma sandwichensis*) and the threatened Newell's shearwater (ao, *Puffinus auricularis newelli*) in the course of operating the Kaheawa Pastures Wind Energy Generation Facility (KWPI wind farm) for generating electricity on the island of Maui, Hawaii. Project-related permit-authorized take of the Hawaiian goose (nene, *Branta sandvicensis*) and the Hawaiian hoary bat (opeapea, Lasiurus cinereus semotus) would remain unchanged.

The take would be incidental to KWPI's continued operation of the 20-turbine, 30-megawatt KWPI wind farm that generates electricity on Maui. The Service listed the Hawaiian petrel as endangered on March 11, 1967 (32 FR 4001); the Hawaiian goose as endangered on March 11, 1967 (32 FR 4001); the Hawaiian hoary bat as endangered on October 13, 1970 (35 FR 16047); and the Newell's shearwater as threatened on September 25, 1975 (40 FR 44150).

The notice for the existing ITP was published in the **Federal Register** on October 4, 2005 (70 FR 57888), and the ITP was issued on January 30, 2006.

Background

Section 9 of the Act (16 U.S.C. 1531 et seq.) and our implementing Federal regulations in the *Code of Federal Regulations* (CFR) at 50 CFR 17 prohibit the ''take'' of fish or wildlife species listed as endangered or threatened. Take of listed fish or wildlife is defined under the Act as ''to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct'' (16 U.S.C. 1532). However, under limited circumstances, we issue permits to authorize incidental take—i.e., take that is incidental to, and not the purpose of, the carrying out of an otherwise lawful activity.

Regulations governing incidental take permits for threatened and endangered species are at 50 CFR 17.32 and 17.22, respectively. In addition to meeting other criteria, an ITP must not jeopardize the continued existence of federally listed threatened or endangered species.

Applicant's Proposal

KWPI currently holds permit number TE118901–0, and now seeks an amendment to this existing permit to reduce the permitted level of take for the Hawaiian petrel and the Newell's shearwater. The existing permit

authorizes the applicant to take 40 Hawaiian petrels, 40 Newell's shearwaters, 60 Hawaiian geese, and 20 Hawaiian hoary bats incidental to operation of the KWPI wind farm. The amendment would reduce the permitted level of take to 30 Hawaiian petrels and 8 Newell's shearwaters, with no change to the permitted level of take for the Hawaiian goose and the Hawaiian hoary bat. The KWPI wind farm project is located on the island of Maui, Hawaii.

The requested amendment to permitted take levels is based on the results of monitoring the take of listed species during the first six seasons of operation of the KWPI wind farm project. Monitoring has detected two Hawaiian petrel carcasses, but no Newell's shearwater carcasses were detected at the wind farm site. Under the approved HCP, KWPI is required to mitigate for the take of the covered species by implementing predator control at nesting areas of the Hawaiian petrel, Newell's shearwater, and the Hawaiian goose on Maui, and by contributing to Hawaiian hoary bat research. No changes to the mitigation program under the KWPI HCP are being proposed. The HCP's mitigation for take of Hawaiian petrels and Newell's shearwaters is conducted based on observed levels of take. The KWPI project's mitigation plans are being implemented pursuant to the KWPI HCP. Pursuant to the adaptive management aspects of the KWPII HCP, the mitigation program for Hawaiian petrel and Newell's shearwater has been refined. Summaries of the KWPI project's seabird mitigation plans are outlined in the October 2011 Draft Seabird Mitigation Plan for KWPI and KWPII. The document outlines the applicant's plans to attract both seabird species to protected areas in west Maui, and to develop, within five years, additional mitigation measures that would be implemented, if necessary, to offset project take. These additional mitigation measures include in-situ management of Newell's shearwater in west Maui, east Maui, Molokai, and Lanai, in-situ management of Hawaiian petrel colonies on the Haleakala Crater in east Maui, and additional social attraction projects for Newell's shearwater in east Maui, Molokai, and Lanai.

The application for a permit amendment includes KWPI's 2006 Kaheawa Pastures Wind Energy Generation Facility HCP, Implementing Agreement, Guarantee Agreement, a proposed amendment to the HCP, a proposed amendment to the Implementing Agreement, and the October 2011 Draft Seabird Mitigation Plan for KWPI and KWPII.

Our Preliminary Determination

The Service has made a preliminary determination that the Biological Opinion, Set of Findings, Environmental Assessment, and Finding of No Significant Impact, all of which were previously approved in support of issuance of the original incidental take permit, do not require revision, because there is no new information relating to the impacts of this action that warrant such a change, and there are no additional impacts expected beyond those originally assessed.

Next Steps

The public process for the proposed Federal permit action will be completed after the public comment period, at which time we will evaluate the permit amendment application and comments submitted thereon to determine whether the application meets the requirements of section 10(a) of the Act, applicable regulations, and NEPA requirements. If we determine that those requirements are met, we will amend the ITP to reflect the revised HCP, Implementing Agreement, Guarantee Agreement, and the October 2011 Draft Seabird Mitigation Plan for KWPI and KWPII.

Public Comments

We invite public comment on the proposed amendments of the ITP, HCP, Implementing Agreement, and the October 2011 Draft Seabird Mitigation Plan for KWPI and KWPII. If you wish to comment on the proposed amendment of the ITP, HCP, and associated documents, you may submit comments by any one of the methods discussed above under **ADDRESSES**.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comments, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: We provide this notice under section 10 of the Act (16 U.S.C. 1531 *et seq.*) and NEPA regulations (40 CFR 1506.6).

Dated: November 8, 2011.

Richard R. Hannan,

Deputy Regional Director, Pacific Region, Portland, Oregon.

[FR Doc. 2011–30824 Filed 11–29–11; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF INTERIOR

Bureau of Land Management

[LLCO956000.L14200000 BJ0000]

Notice of Filing of Plats

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Filing of Plats; Colorado

SUMMARY: The Bureau of Land Management (BLM) Colorado State Office is publishing this notice to inform the public of the intent to file the land survey plats listed below, and to afford all affected parties a proper period of time to protest this action, prior to the plat filing.

DATES: Unless there are protests of this action, the filing of the plats described in this notice will happen on December 30, 2011.

ADDRESSES: BLM Colorado State Office, Cadastral Survey, 2850 Youngfield Street, Lakewood, Colorado 80215–7093.

FOR FURTHER INFORMATION CONTACT: Randy Bloom, Chief Cadastral Surveyor for Colorado, (303) 239–3856.

SUPPLEMENTARY INFORMATION: The supplemental plat of the SW1/4 of Tract 38 in Township 41 North, Range 7 West, New Mexico Principal Meridian, Colorado, was accepted on July 1, 2011.

The plat and field notes of the dependent resurvey and survey in Township 7 South, Range 69 West, Sixth Principal Meridian, Colorado, were accepted on July 7, 2011.

The plat and field notes of the dependent resurvey and a metes-and-bounds survey in Township 9 North, Range 78 West, Sixth Principal Meridian, Colorado, were accepted on July 15, 2011.

The plat and field notes of the dependent resurvey and a metes-and-bounds survey in Township 9 North, Range 79 West, Sixth Principal Meridian, Colorado, were accepted on July 15, 2011.

The supplemental plat, in 4 sheets, of Section 19, in Township 1 North, Range 71 West, Sixth Principal Meridian, Colorado, was accepted on August 3, 2011.

The plat and field notes of the dependent resurvey and survey in

Township 11 North, Range 88 West, Sixth Principal Meridian, Colorado, were accepted on August 4, 2011.

The plat and field notes of the dependent resurvey and survey in Fractional Township 12 North, Range 88 West, Sixth Principal Meridian, Colorado, were accepted on August 4, 2011.

The plat and field notes of the corrective dependent resurvey, dependent resurvey and survey in Township 14 South, Range 68 West, Sixth Principal Meridian, Colorado, were accepted on August 10, 2011.

The plat and field notes of the dependent resurvey and survey in Township 35 North, Range 8 East, New Mexico Principal Meridian, Colorado, were accepted on August 10, 2011.

The plat and field notes of the dependent resurvey in Township 33 North, Range 17 West, New Mexico Principal Meridian, Colorado, were accepted on August 19, 2011.

The plat and field notes of the dependent resurvey and survey in Township 1 South, Range 76 West, Sixth Principal Meridian, Colorado, were accepted on September 13, 2011.

The plat and field notes of the dependent resurvey and survey in Township 1 South, Range 77 West, Sixth Principal Meridian, Colorado, were accepted on September 13, 2011.

The plat incorporating the field notes of the dependent resurvey and survey in Township 42 North, Range 10 East, New Mexico Principal Meridian, Colorado, was accepted on September 22, 2011.

The plat and field notes of the dependent resurvey and survey in Fractional Township 2 South, Range 1 East, Ute Meridian, Colorado, were accepted on October 13, 2011.

The plat and field notes of the dependent resurvey and survey in Township 26 South, Range 71 West, Sixth Principal Meridian, Colorado, were accepted on October 28, 2011.

The plat and field notes of the dependent resurvey in Township 11 North, Range 89 West, Sixth Principal Meridian, Colorado, were accepted on October 28, 2011.

Randy Bloom,

Chief Cadastral Surveyor for Colorado.

[FR Doc. 2011–30826 Filed 11–29–11; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

Final Environmental Impact Statement for the Windy Gap Firming Project, Colorado

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of availability.

SUMMARY: The Final Environmental Impact Statement (EIS) for the Windy Gap Firming Project is available for public review. The Bureau of Reclamation (Reclamation) has evaluated comments and has identified Alternative 2 as the Preferred Alternative. The Preferred Alternative includes construction of Chimney Hollow Reservoir, pre-positioning of Colorado-Big Thompson (C–BT) water in the new reservoir, and a new pipeline to convey water to the reservoir from existing C–BT facilities.

DATES: Reclamation will not make a decision on the Proposed Action until at least 30 days after release of the Final EIS.

ADDRESSES: The Final EIS and related documents are available for review at *http://www.usbr.gov/gp/ecao*.

To obtain a compact disk of the Final EIS, contact Lucy Maldonado at the Bureau of Reclamation, 11056 West County Rd. 18E, Loveland, CO 80537–9711; (970) 962–4369, facsimile (970) 663–3212, *lmaldonado@usbr.gov*; or Kara Lamb at (970) 962–4326; *klamb@usbr.gov*.

Refer to the **SUPPLEMENTARY INFORMATION** section for locations of libraries where paper and electronic copies of the Final EIS are available for reading.

FOR FURTHER INFORMATION CONTACT: Lucy Maldonado at (970) 962–4369, *lmaldonado@usbr.gov*; or Kara Lamb at (970) 962–4326, *klamb@usbr.gov*.

SUPPLEMENTARY INFORMATION:

Background: The Windy Gap Firming Project was proposed by the Municipal Subdistrict, Northern Colorado Water Conservancy District, acting by and through the Windy Gap Firming Project Water Activity Enterprise (Subdistrict). The Preferred Alternative (Proposed Action) described in the Final EIS includes:

- Construction of Chimney Hollow Reservoir (90,000 acre-feet) by the Subdistrict;
- Pre-positioning of Colorado-Big Thompson (C–BT) water in the new reservoir;
- A new pipeline to convey water to the new reservoir from existing C–BT facilities.

The Subdistrict completed the Windy Gap Project by 1985 following a final environmental statement and a Record of Decision prepared by Reclamation in 1981. The Windy Gap Project is neither federally owned nor operated, although Windy Gap Project water is conveyed through Reclamation's C–BT Project facilities.

Reclamation allows the storage and transport of Windy Gap Project water in the C–BT Project through an excess capacity contract with the Subdistrict. The Windy Gap Project was originally planned to divert an estimated long-term annual average of 56,000 acre feet (AF) of water from the Colorado River. During actual operation, the Windy Gap Project has been unable to provide the expected yield due to its junior water right and periodic lack of excess capacity in the C–BT Project.

The Subdistrict concluded that the firm yield (the amount it can guarantee annually) of the Windy Gap Project is actually zero because it is unable to deliver Windy Gap water to Colorado's Front Range community participants in all years. The purpose of the Windy Gap Firming Project is to increase the annual firm yield to about 30,000 AF. This would be based upon a long-term average annual diversion of about 46,000 AF from the Colorado River basin. From 1985 to 2005, Windy Gap diverted an average annual 11,080 AF of water per year. However, demands among the participants have been increasing so that diversions for 1999 through 2008 have averaged 21,957 AF per year.

The Subdistrict developed this proposal to improve their ability to deliver water from Windy Gap. The proposal is to construct Chimney Hollow Reservoir on the eastern slope near Carter Lake (C–BT Project), along with a connecting pipeline from C–BT Project facilities to deliver Windy Gap water to Chimney Hollow Reservoir. Reclamation's Preferred Alternative in the Final EIS is implementation of the Proposed Action. This new reservoir would be used to store and pre-position Windy Gap Project water for delivery to participants along the Front Range. Under the pre-positioning proposal included in the Preferred Alternative, Chimney Hollow Reservoir would also store C–BT Project water when it is pre-positioned in Chimney Hollow Reservoir to make space in Granby Reservoir for Windy Gap water. The Preferred Alternative would continue to use C–BT Project facilities to deliver Windy Gap Project water to the Front Range.

Reclamation is the lead agency in compliance under the National

Environmental Policy Act, while the U.S. Army Corps of Engineers (Corps), the Western Area Power Administration (Western), and the Board of County Commissioners, Grand County, Colorado (Grand County) helped prepare the EIS as cooperating agencies. Each agency has separate decision-making processes. Reclamation has the lead role because of its permitting authority in allowing the Subdistrict to use federal infrastructure. The Corps is involved due to the requirement for a Clean Water Act Section 404 permit. Western is involved due to an electric power line that would be affected by the project, while Grand County is involved because of its stated position on permitting authority under Colorado's 1041 regulations for matters of State interest.

If selected in the Record of Decision, implementing the Preferred Alternative will require the following federal actions:

(1) Reclamation would need to issue the Subdistrict a permit for the proposed connection to C–BT Project facilities and amend the existing Windy Gap Project excess capacity water contract, or provide a new contract.

(2) The Corps would need to issue the Subdistrict a Clean Water Act Section 404 permit for fill to be placed in waters of the United States for dam construction and address any project impacts to waters of the United States and jurisdictional wetlands.

(3) Western would need to relocate a segment of power line that would otherwise be inundated by Chimney Hollow Reservoir. Relocation of the power line including road access would require Western to obtain a right-of-way across private and county lands.

Five alternatives presented in the Draft EIS were brought forward into the Final EIS. The five alternatives evaluated in the EIS include:

- *Alternative 1 (No Action)*—Continuation of existing operations and agreements between Reclamation and the Subdistrict for conveyance of Windy Gap water through C–BT facilities.
- *Alternative 2 (Preferred Alternative)*—Chimney Hollow Reservoir (90,000 AF) with pre-positioning.
- *Alternative 3*—Chimney Hollow Reservoir (70,000 AF) and Jasper East Reservoir (20,000 AF).
- *Alternative 4*—Chimney Hollow Reservoir (70,000 AF) and Rockwell/Mueller Creek Reservoir (20,000 AF).
- *Alternative 5*—Dry Creek Reservoir (60,000 AF) and Rockwell/Mueller Creek Reservoir (30,000 AF).

All action alternatives include development of 90,000 AF of new storage either in a single reservoir on the east slope or a combination of east and west slope reservoirs. All of the action alternatives require a connection to C–BT facilities. Alternative 2 is the Subdistrict's Proposed Action and Reclamation's Preferred Alternative.

Reclamation expects to complete the National Environmental Policy Act process with a Record of Decision no sooner than 30 days after the Final EIS is made available to the public. The Record of Decision will document Reclamation's selection of an alternative for the Windy Gap Firming Project and discuss the factors, including C–BT water rights, considered in making that decision. If the selected alternative includes issuing a water contract, Reclamation intends to determine whether the proposed contract complies with Senate Document 80 and other applicable authorities before execution of the proposed contract.

Public Comments: Copies of the Draft EIS were distributed to Members of Congress; Native American Tribal governments; Federal, State, and local officials; and organizations and individuals interested in or affected by the proposed project. A Notice of Availability announcing the release of the Draft EIS was published in the **Federal Register** on August 29, 2008 (73 FR 50999). The public comment period was open from August 29, 2008, through December 29, 2008. Two public hearings were held: One on October 7, 2008, in Loveland, Colorado, and one on October 9, 2008, in Granby, Colorado. Reclamation considered all comments received during the comment period, and the Final EIS contains revisions and new information based in part on these comments. The comments and Reclamation's responses to these comments are included in the Final EIS.

Locations in Colorado Where Hard Copies and Electronic Copies of the Final EIS May Be Reviewed

- Berthoud, Berthoud Public Library, 236 Welch Avenue
- Broomfield, Mamie Eisenhower Public Library, 3 Community Park Road
- Ft. Collins, Ft. Collins Public Library, 201 Peterson Street
- Ft. Collins, Morgan Library, Colorado State University, 501 University Avenue
- Ft. Lupton, Ft. Lupton Public Library, 425 South Denver Avenue
- Granby, Granby Branch Library, 13 East Jasper Avenue
- Grand Lake, Juniper Library, 316 Garfield Street
- Greeley, Centennial Park Branch, Weld Library District, 2227 23rd Avenue
- Greeley, Farr Branch, Weld Library District, 1939 61st Avenue
- Greeley, Lincoln Park Branch, Weld Library District, 919 7th Street
- Hot Sulphur Springs, Hot Sulphur Springs Branch Library, 105 Moffat
- Kremmling, Kremmling Branch Library, 300 South 8th Street
- Littleton, Corps of Engineers, 9307 South Wadsworth Blvd.
- Longmont, Longmont Public Library, 409 4th Avenue
- Louisville, Louisville Public Library, 950 Spruce Street
- Loveland, Bureau of Reclamation, 11056 W. County Rd. 18E
- Loveland, Loveland Public Library, 300 North Adams Avenue
- Lyons, Lyons Depot Library, 5th and Broadway

Dated: November 23, 2011.

John F. Soucy,

Deputy Regional Director, Great Plains Region.

[FR Doc. 2011–30827 Filed 11–29–11; 8:45 am]

BILLING CODE 4310–MN–P

DEPARTMENT OF JUSTICE

Notice of Meeting; Office on Violence Against Women

AGENCY: Office on Violence Against Women, United States Department of Justice.

ACTION: Notice of meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of the forthcoming public meeting of the Section 904 Violence Against Women in Indian Country Task Force (hereinafter ''the Task Force'').

DATES: The meeting will take place on December 14, 2011 from 8:30 a.m. to 5:30 p.m.

ADDRESSES: The meeting will take place at Hyatt Regency Tamaya, 1300 Tujunga Trail, and Santa Ana Pueblo, New Mexico, 87004. The public is asked to preregister by December 1, 2011 for the meeting (see below for information on pre-registration).

FOR FURTHER INFORMATION CONTACT: Lorraine Edmo, Deputy Tribal Director, Office on Violence Against Women, United States Department of Justice, 145 N Street NE., Suite 10W.121, Washington, DC 20530; by telephone at: (202) 514–8804; *email: Lorraine.edmo@usdoj.gov;* or *fax:* (202) 307–3911. You may also view information about the Task Force on the Office on Violence Against Women Web site at: *http://www.ovw.usdoj.gov/siw.htm.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is required under section 10(a)(2) of the Federal Advisory Committee Act. Title IX of the Violence Against Women Act of 2005 (VAWA 2005) requires the Attorney General to establish a Task Force to assist the National Institute of Justice (NIJ) to develop and implement a program of research on violence against American Indian and Alaska Native women, including domestic violence, dating violence, sexual assault, stalking, and murder. The program will evaluate the effectiveness of the Federal, state, and tribal response to violence against Indian women, and will propose recommendations to improve the government response. The Attorney General, acting through the Director of the Office on Violence Against Women, established the Task Force on March 31, 2008 and re-chartered on April 6, 2010.

This meeting will be the first meeting of the re-chartered Task Force and will include an introduction of the new Task Force members, presentation of the recommendations from the previous members of the Task Force, a presentation of NIJ's program of research, a panel on other related Violence Against Indian Women studies and partnerships, and facilitated Task Force discussion of the program of research. In addition, the Task Force is also welcoming public oral comment at this meeting and has reserved an estimated 30 minutes for this. Members of the public wishing to address the Task Force must contact Lorraine Edmo, Deputy Tribal Director, Office on Violence Against Women, United States Department of Justice, 145 N Street NE., Suite 10W.121, Washington, DC 20530; by telephone at: (202) 514–8804; *email: Lorraine.edmo@usdoj.gov;* or *fax:* (202) 307–3911. The meeting will take place on December 14, 2011 from 8:30 a.m. to 5:30 p.m. and will include breaks and a working lunch. Time will be reserved for public comment from 4:30 p.m. to 5 p.m. See the section below for information on reserving time for public comment.

Access: This meeting will be open to the public but registration on a space available basis is required. Persons who wish to attend must register at least six (6) day in advance of the meeting by contacting Lorraine Edmo, Deputy Tribal Director, Office on Violence Against Women, United States Department of Justice, by *email: Lorraine.edmo@usdoj.gov;* or *fax:* (202) 307–3911. All attendees will be required to sign in at the meeting registration desk.

The meeting site is accessible to individuals with disabilities. Individuals who require special accommodation in order to attend the meeting should notify Lorraine Edmo, Deputy Tribal Director, Office on Violence Against Women, United States Department of Justice, by *email: Lorraine.edmo@usdoj.gov;* or *fax:* (202) 307–3911 no later than December 1, 2011. After this date, we will attempt to satisfy accommodation requests but cannot guarantee the availability of any requests.

Written Comments: Interested parties are invited to submit written comments by December 1, 2011 to Lorraine Edmo, Deputy Tribal Director, Office on Violence Against Women, United States Department of Justice, 145 N Street NE., Suite 10W.121, Washington, DC 20530 by mail; or by *email: Lorraine.edmo@usdoj.gov;* or by *fax:* (202) 307–3911.

Public Comment: Persons interested in participating during the public comment period of the meeting are requested to reserve time on the agenda by contacting Lorraine Edmo, Deputy Tribal Director, Office on Violence Against Women, United States Department of Justice, by *email: Lorraine.edmo@usdoj.gov;* or *fax:* (202) 307–3911 by December 21, 2011. Requests must include the participant's name, organization represented, if appropriate, and a brief description of the subject of the comments. Each participant will be permitted approximately 3 to 5 minutes to present comments, depending on the number of individuals reserving time on the agenda. Participants are also encouraged to submit written copies of their comments at the meeting. Comments that are submitted to Lorraine Edmo, Deputy Tribal Director, Office on Violence Against Women, United States Department of Justice, 145 N Street NE., Suite 10W.121, Washington, DC 20530 by mail; by *email: Lorraine.edmo@usdoj.gov;* or *fax:* (202) 307–3911 before December 1, 2011 will be circulated to Task Force members prior to the meeting.

Given the expected number of individuals interested in presenting comments at the meeting, reservations should be made as soon as possible. Persons unable to obtain reservations to speak during the meeting are encouraged to submit written comments, which will be accepted at the meeting location or may be mailed to the Section 904 Violence Against Women in Indian Country Task Force, to the attention of Lorraine Edmo, Deputy Tribal Director, Office on Violence Against Women, United States Department of Justice, 145 N Street NE., Suite 10W.121, Washington, DC 20530.

Dated: November 21, 2011.

Susan B. Carbon,

Director, Office on Violence Against Women.

[FR Doc. 2011–30541 Filed 11–29–11; 8:45 am]

BILLING CODE 4410–FX–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Random Assignment Study To Evaluate the YouthBuild Program; Final Notice

AGENCY: Employment and Training Administration (ETA), Labor.

ACTION: Notice.

SUMMARY: The Department of Labor (Department) will conduct an evaluation to provide rigorous, nationally-representative estimates of the net impacts of the YouthBuild program. The Department has determined that it is in the public interest to use a random assignment impact methodology for the study. In the sites randomly selected to participate in this evaluation, all applicants for YouthBuild during a 12–18 month enrollment period will be required to participate in the study. On August 17, 2011 (76 FR 51056–51058), the Department solicited comments concerning the Department's plan to carry out the study. No comments were received. The Department will proceed with the study as explained in the previous notice.

FOR FURTHER INFORMATION CONTACT: Eileen Pederson, U.S. Department of Labor, Employment and Training Administration, Office of Policy Development and Research, 200 Constitution Avenue NW., Frances Perkins Bldg., Room N–5641, Washington, DC 20210. *Telephone:* (202) 693–3647 (this is not a toll-free number) *or email: pederson.eileen@dol.gov.* Individuals with hearing or speech impairments may access the telephone number above via TTY by calling the toll-free Federal Information Relay Service at 1–(877) 889–5627 (TTY/TDD).

Signed: At Washington, DC, this 16th day of November, 2011.

Jane Oates,

Assistant Secretary for Employment and Training.

[FR Doc. 2011–30834 Filed 11–29–11; 8:45 am]

BILLING CODE 4510–FN–P

MILLENNIUM CHALLENGE CORPORATION

[MCC FR 11–13]

Notice of the December 15, 2011, Millennium Challenge Corporation Board of Directors Meeting; Sunshine Act Meeting

AGENCY: Millennium Challenge Corporation.

TIME AND DATE: 3 p.m. to 5 p.m., Thursday, December 15, 2011.

PLACE: Department of State, 2201 C Street NW., Washington, DC 20520.

FOR FURTHER INFORMATION CONTACT: Information on the meeting may be obtained from Melvin F. Williams, Jr., Vice President, General Counsel and Corporate Secretary via email at *Corporatesecretary@mcc.gov* or by telephone at (202) 521–3600.

STATUS: Meeting will be closed to the public.

MATTERS TO BE CONSIDERED: The Board of Directors (the ''Board'') of the Millennium Challenge Corporation (''MCC'') will hold a meeting to discuss the Cape Verde Compact and the 2012 Selection Process. The agenda items are expected to involve the consideration of classified information and the meeting will be closed to the public.

Dated: November 28, 2011.

Melvin F. Williams, Jr.,

VP/General Counsel and Corporate Secretary, Millennium Challenge Corporation.

[FR Doc. 2011–30917 Filed 11–28–11; 4:15 pm]

BILLING CODE 9211–03–P

NATIONAL SCIENCE FOUNDATION

National Science Board; Sunshine Act Meetings; Notice

The National Science Board's *ad hoc* Committee on Honorary Awards, pursuant to NSF regulations (45 CFR part 614), the National Science Foundation Act, as amended (42 U.S.C. 1862n–5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of meetings for the transaction of National Science Board business and other matters specified, as follows:

DATE AND TIME: Monday, December 5, 2011 at 3 p.m., EST.

SUBJECT MATTER: Continued discussion of candidates for the 2012 Vannevar Bush Award and 2012 National Science Board Public Service Award.

STATUS: Closed.

This meeting will be held by teleconference originating at the National Science Board Office, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230.

Please refer to the National Science Board Web site (*http://www.nsf.gov/nsb*) for information or schedule updates, or contact: Ann Ferrante, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. *Telephone:* (703) 292–7000.

Ann Bushmiller,

NSB Senior Legal Counsel.

[FR Doc. 2011–30908 Filed 11–28–11; 4:15 pm]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

National Science Board; Sunshine Act Meetings; Notice

The National Science Board's Subcommittee on Facilities, Committee on Strategy and Budget, pursuant to NSF regulations (45 CFR part 614), the National Science Foundation Act, as amended (42 U.S.C. 1862n–5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of meetings for the transaction of National Science Board business as follows:

DATE AND TIME: Monday, December 5, 2011 at 2 p.m.to 3 p.m., EST.

SUBJECT MATTER: Discuss and approve COMPETES Mid-scale Instrumentation Report.

STATUS: Open.

LOCATION: This meeting will be held by teleconference at the National Science Board Office, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. A public listening room will be available for this teleconference meeting. All visitors must contact the Board Office (call (703) 292–7000 or send an email message to *nationalsciencebrd@nsf.gov*) at least 24 hours prior to the teleconference for the public room number and to arrange for a visitor's badge. All visitors must report to the NSF visitor desk located in the lobby at the 9th and N. Stuart Streets entrance on the day of the teleconference to receive a visitor's badge.

UPDATES AND POINT OF CONTACT: Please refer to the National Science Board Web site *http://www.nsf.gov/nsb* for additional information and schedule updates (time, place, subject matter or status of meeting). The point of contact for this meeting is: Blane Dahl, National Science Board Office, 4201 Wilson Blvd., Arlington, VA 22230. *Telephone:* (703) 292–7000.

Ann Bushmiller,

NSB Senior Legal Counsel.

[FR Doc. 2011–30915 Filed 11–28–11; 4:15 pm]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on the Medical Uses of Isotopes: Meeting Notice

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Notice of meeting.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) will convene a teleconference meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) on December 15, 2011, to discuss the ACMUI's recommendations on proposed revisions to the Abnormal Occurrence medical event criteria. A copy of the agenda for the meeting will be available at *http://www.nrc.gov/reading-rm/doc-collections/acmui/agenda* or by contacting Ms. Ashley Cockerham using the information below.

DATES: The teleconference meeting will be held on Thursday, December 15, 2011, 2 p.m. to 3 p.m. Eastern Standard Time (EST).

Public Participation: Any member of the public who wishes to participate in the teleconference discussions should contact Ms. Cockerham using the contact information below.

Contact Information: Ashley M. Cockerham, email: *ashley.cockerham@nrc.gov*, telephone: (240) 888–7129.

Conduct of the Meeting

Leon S. Malmud, M.D., will chair the meeting. Dr. Malmud will conduct the meeting in a manner that will facilitate the orderly conduct of business. The following procedures apply to public participation in the meeting:

1. Persons who wish to provide a written statement should submit an electronic copy to Ms. Cockerham at the contact information listed above. All submittals must be received by December 8, 2011, and must pertain to the topic on the agenda for the meeting.

2. Questions and comments from members of the public will be permitted during the meetings, at the discretion of the Chairman.

3. The transcripts will be available on the ACMUI's web site (*http://www.nrc.gov/reading-rm/doc-collections/acmui/tr/)* approximately 30

calendar days following the meeting, on January 16, 2012. A meeting summary will be available approximately 30 business days following the meeting, on January 31, 2012.

The meetings will be held in accordance with the Atomic Energy Act of 1954, as amended (primarily Section 161a); the Federal Advisory Committee Act (5 U.S.C. App); and the Commission's regulations in Title 10, *U.S. Code of Federal Regulations,* Part 7.

Dated: November 25, 2011.

Andrew L. Bates,

Advisory Committee Management Officer.

[FR Doc. 2011–30863 Filed 11–29–11; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket No. MT2011–3; Order No. 998]

Standard Mail Market Test

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recently-filed Postal Service application for an exemption from the annual revenue limitation that applies to market tests of experimental market dominant products. It seeks the exemption for Every Door Direct Mail Retail, a Standard Flats experiment now underway. This document describes the Postal Service's reasons for seeking the exemption, addresses procedural aspects of the filing, and invites public comment.

DATES: *Comment deadline:* December 5, 2011; *reply comment deadline:* December 12, 2011.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, (202) 789–6820 or *stephen.sharfman@prc.gov.*

SUPPLEMENTARY INFORMATION: On November 18, 2011, the Postal Service filed a request, pursuant to 39 U.S.C. 3641, for an exemption from the $10,000,000 revenue limitation in any year during the test of an experimental market dominant product.[1] Pursuant to 39 U.S.C. 3641, the Commission previously approved the market test.[2]

EDDM–R is a Standard Mail Flats experimental product. It must meet the preparation requirements of the Simplified Address option for Standard Mail Saturation Mail, be flat-shaped, and weigh less than 3.3 ounces. Neither a permit nor mailing fee is required but it must be entered and paid for at a local Destination Delivery Unit (DDU) and not exceed 5,000 pieces per delivery unit. Request at 1.

The Postal Service explains that EDDM–R service commenced on March 31, 2011, and since then revenue has grown rapidly to about $8.5 million. If growth continues, revenue for FY 2012 will reach the $10 million limitation within 2 or 3 months. *Id.* at 2.

Pursuant to 39 U.S. C. 3641(e), revenues from a test product may not exceed $10 million in any year unless, upon written application, the Commission exempts the test from that limit, up to $50 million in any year subject to an adjustment for inflation under 39 U.S.C. 3641(g). The Commission shall approve the application for exemption if it determines under 39 U.S.C. 3641(e)(2) that the product is likely to benefit the public and meet an expected demand; likely to contribute to the financial stability of the Postal Service; and not likely to result in unfair or otherwise inappropriate competition.

The Postal Service asserts EDDM–R is likely to benefit the public and meet an expected demand. In support, it points to widespread interest in the product, revenues of $3.4 million this fiscal year, and 87 percent of revenues are from new customers. EDDM–R permits small and medium-sized businesses to communicate at low cost in their marketing areas by mailing without permits or fees and simplifying mail entry. *Id.* at 3. The Postal Service states EDDM–R revenue has been about $8.5 million and contribution to date has been approximately $4.9 million which contributes to financial stability. *Id.* at 4. The Postal Service also states EDDM–R is unlikely to result in unfair or inappropriate competition. All customers, including Mail Service Providers (MSPs) are eligible to participate in the program. *Id.* EDDM–R does not eliminate or increase the cost to small or medium-sized businesses that use or may use MSP services. Non-mail options for advertising have remained competitive. Rather than a substitute for other media, EDDM–R enhances businesses' ability to use mail as a part of an integrated marketing plan. *Id.* at 5.

The Commission will receive comments on the Postal Service's Request. Interested persons may submit comments on whether the Postal Service's Request is consistent with the policies of 39 U.S.C. 3641(e)(2) and (g). Comments are due not later than December 5, 2011. Reply comments are due not later than December 12, 2011. The filing can be accessed via the Commission's Web Site (*http://www.prc.gov*).

The Commission has previously appointed Larry Fenster to serve as Public Representative in this docket.

It is ordered:

1. The Commission will receive comments on the Request in this Docket No. MT2011–3 for consideration of the matters raised by the Request.

2. Pursuant to 39 U.S.C. 505, Larry Fenster remains appointed to serve as officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

3. Comments by interested persons are due no later than December 5, 2011.

4. Reply comments are due no later than December 12, 2011.

5. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission,

Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2011–30829 Filed 11–29–11; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Board of Governors; Sunshine Act Meeting

DATE AND TIME: Tuesday, December 13, 2011, at 9 a.m.

PLACE: Washington, DC, at U.S. Postal Service Headquarters, 475 L'Enfant Plaza SW.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

Tuesday, December 13, at 9 a.m. (Closed)

1. Strategic Issues.
2. Financial Matters.
3. Pricing.
4. Personnel Matters and Compensation Issues.
5. Governors' Executive Session—Discussion of prior agenda items and Board Governance.

[1] Request of the United States Postal Service for Exemption from Revenue Limitation on Market Test of Experimental Product—Every Door Direct Mail Retail, November 18, 2011 (Request). The product was originally named Marketing Mail Made Easy, but was renamed Every Door Direct Mail (EDDM)—Retail. Request at 1.

[2] Order Approving Market Test of Experimental Product—Marketing Mail Made Easy (Order No. 687), March 1, 2011.

CONTACT PERSON FOR MORE INFORMATION: Julie S. Moore, Secretary of the Board, U.S. Postal Service, 475 L'Enfant Plaza SW., Washington, DC 20260–1000. Telephone (202) 268–4800.

Julie S. Moore,

Secretary.

[FR Doc. 2011–30962 Filed 11–28–11; 4:15 pm]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65809; File No. SR–BATS–2011–047]

Self-Regulatory Organizations; BATS Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Modify Exchange Rule 14.1, entitled ''The Qualification, Listing, and Delisting of Companies—Definitions''

November 23, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 22, 2011, BATS Exchange, Inc. (the ''Exchange'' or ''BATS'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing with the Commission a proposal to amend Rule 14.1, entitled ''The Qualification, Listing, and Delisting of Companies—Definitions.''

The text of the proposed rule change is available at the Exchange's Web site at *http://www.batstrading.com*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

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 Rule 14.1 to include all securities listed on the Exchange pursuant to Rule 14.11 as Tier I securities. Exchange Rule 14.11 sets forth the criteria for listing certain exchange traded products, including exchange traded funds, portfolio depository receipts, index fund shares and various other types of securities (collectively, ''ETPs''). Under the Exchange's current rules, ETPs are not designated as either Tier I or Tier II securities. The Exchange proposes to modify the definitions of ''Tier I'' in Rule 14.1(a)(29), and ''Tier I security'' in Rule 14.1(a)(30), to make clear that ETPs are considered Tier I securities for purposes of the Exchange's rules. The Exchange notes that the Nasdaq Rule 5700 series, upon which Rule 14.11 was based, does make clear that other securities listed pursuant to the Nasdaq Rule 5700 series are considered to be listed on the Nasdaq Global Market.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[3] in general, and furthers the objectives of Section 6(b)(5),[4] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system. Specifically, the Exchange believes that treatment of ETPs as Tier I securities will help to alleviate confusion regarding the applicable Exchange listing tier into which such products fall.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change imposes any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not significantly affect the protection of investors or the public interest, does not impose any significant burden on competition, and, by its terms, does not become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[5] and Rule 19b–4(f)(6) thereunder.[6]

The Exchange has requested that the Commission waive the 30-day operative delay. The Exchange believes that the proposed rule change is consistent with the protection of investors and the public interest because it would permit the Exchange to operate its listing market as soon as possible and avoid confusion with respect to the treatment of ETPs as either Tier I or Tier II securities. The Commission believes that waiver of the operative delay is consistent with the protection of investors and the public interest because such waiver would allow the Exchange to clarify its rules with respect to the definitions of ''Tier I'' and ''Tier I security'' before the Exchange begins to operate its listing market.[7] Therefore, the Commission designates the proposal operative upon filing.[8]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78f(b).

[4] 15 U.S.C. 78f(b)(5).

[5] 15 U.S.C. 78s(b)(3)(A).

[6] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[7] *See* Securities Exchange Act Release No. 34–65225 (August 30, 2011), 76 FR 55148 (September 6, 2011) (SR–BATS–2011–018) (approving a proposed rule change to adopt rules for the qualification, listing, and delisting of companies on the Exchange).

[8] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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–BATS–2011–047 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–BATS–2011–047. 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 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–BATS–2011–047 and should be submitted on or before December 21, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–30742 Filed 11–29–11; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65810; File No. SR–NYSE–2011–57]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending NYSE Rule 80C to Exclude All Rights and Warrants From the Single Stock Circuit Breaker Under the Rule

November 23, 2011.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that November 17, 2011, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend NYSE Rule 80C to exclude all rights and warrants from the single stock circuit breaker under the rule. The text of the proposed rule change is available at the Exchange, the Commission's Public Reference Room, *http://www.nyse.com,* and *http://www.sec.gov.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend NYSE Rule 80C to exclude all rights and warrants from the single stock circuit breaker under the rule. The Commission approved NYSE Rule 80C on a pilot basis on June 10, 2010 to provide for trading pauses in individual securities due to extraordinary market volatility (''Trading Pause'') in all securities included within the S&P 500® Index (''S&P 500'') (''Pause Pilot'').[4] The Exchange noted in its filing to adopt NYSE Rule 80C that during the Pause Pilot period it would continue to assess whether additional securities need to be added and whether the parameters of NYSE Rule 80C would need to be modified to accommodate trading characteristics of different securities. The Exchange subsequently received approval to add to the Pause Pilot the securities included in the Russell 1000® Index (''Russell 1000'') and a specified list of Exchange Traded Products (''ETPs'').[5]

[9] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Commission approved the Pause Pilot for all equities exchanges and FINRA. *See* Securities Exchange Act Release No. 62252 (June 10, 2010), 75 FR 34186 (June 16, 2010) (File Nos. SR–BATS–2010–014; SR–EDGA–2010–01; SR–EDGX–2010–01; SR–BX–2010–037; SR–ISE–2010–48; SR–NYSE–2010–39; SR–NYSEAmex–2010–46; SR–NYSEArca–2010–41; SR–NASDAQ–2010–061; SR–CHX–2010–10; SR–NSX–2010–05; and SR–CBOE–2010–047) and Securities Exchange Act Release No. 62251 (June 10, 2010), 75 FR 34183 (June 16, 2010) (SR–FINRA–2010–025).

[5] The Commission approved the addition to the Pause Pilot of the securities included in the Russell 1000 and ETPs, where applicable, for all equities exchanges and FINRA. *See* Securities Exchange Act Release No. 62884 (September 10, 2010), 75 FR 56618 (September 16, 2010) (File Nos. SR–BATS–2010–018; SR–BX–2010–044; SR–CBOE–2010–065; SR–CHX–2010–14; SR–EDGA–2010–05; SR–EDGX–2010–05; SR–ISE–2010–66; SR–NASDAQ–2010–079; SR–NYSE–2010–49; SR–NYSEAmex–2010–63; SR–NYSEArca–2010–61; and SR–NSX–2010–08 and Securities Exchange Act Release No. 62883 (September 10, 2010), 75 FR 56608 (September 16, 2010) (SR–FINRA–2010–033). The Exchange submitted a proposed rule change shortly after the addition of the Russell 1000 securities and ETPs to extend the operation of the Pause Pilot, which was set to expire on December 10, 2010, until April 11, 2011. *See* Securities Exchange Act Release No. 63500 (December 9, 2010), 75 FR 78309 (December 15, 2010) (NYSE–2010–81). The Exchange submitted a proposed rule change to further extend the Pause Pilot until the earlier of January 31, 2012 or the date on which a limit up/limit down mechanism to address extraordinary market volatility, if adopted, applies. *See* Securities Exchange Act Release No. 65090 (August 10, 2011), 76 FR 50790 (August 16, 2011) (NYSE–2011–40).

On June 23, 2011, the Commission approved proposed rule changes of the Exchanges to amend certain of their respective rules to expand the Pause Pilot to include all remaining NMS stocks (''Phase III Securities''), which included rights and warrants.[6] Unlike the original Pause Pilot securities, amended NYSE Rule 80C applies wider percentage price moves to the Phase III Securities before a trading pause is triggered.[7] The changes to NYSE Rule 80C became effective on August 8, 2011.

The nature of the trading pauses triggered since adoption of the Pause Pilot has been analyzed and over 25% of such pauses have occurred in rights and warrants. Further, exchanges have experienced a significant increase in trading pauses involving rights and warrants since the implementation of the Phase III Securities, with such pauses representing as much as 52% [sic] all trading pauses occurring through the end of August 2011 on one exchange. Rights and warrants trade on equity exchanges, but are closely related to call options. Rights and warrants entitle owners to purchase shares of stock at predetermined prices subject to various timing and other conditions. Like options, the price of rights and warrants are affected by the price of the underlying stock as well as other factors, particularly the volatility of the stock. As a consequence, the prices of rights and warrants may move more dramatically than the prices of the underlying stocks even when the rights and warrants (and the underlying stock) are trading in an orderly manner. This difference in trading behavior may result in a scenario whereby the rights and warrants trigger the circuit breaker under NYSE Rule 80C and are subject to a trading pause, even while the underlying stock continues to trade. This can be particularly true of rights and warrants that have low prices. Accordingly, the Exchange is proposing to exclude rights and warrants from the trading pause under NYSE Rule 80C.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[8] in general, and furthers the objectives of Section 6(b)(5),[9] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system. The proposed rule change also is designed to support the principles of Section 11A(a)(1)[10] of the Act in that it seeks to ensure fair competition among brokers and dealers and among exchange markets. The Exchange believes that the proposed rule meets these requirements because it excludes certain securities from the rule's coverage that are prone to triggering pauses because of their unique characteristics. These securities are unique in that they may move more dramatically than the prices of the underlying stocks to which they are related even when both securities are trading in an orderly manner. As such, the securities that are subject to this proposal may trigger the circuit breaker under NYSE Rule 80C and be subject to a trading pause, even while the underlying security continues to trade. Although there is little benefit in pausing trading in these securities, such pauses sequester regulatory resources that are better applied to the review of trading pauses in other securities that have a greater impact on the national market system.

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 Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[11] and Rule 19b–4(f)(6) thereunder.[12] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[13] and Rule 19b–4(f)(6)(iii) thereunder.[14]

A proposed rule change filed under Rule 19b–4(f)(6)[15] normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii)[16] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Including rights and warrants in the pilot program which may trigger a circuit breaker and be subject to a trading pause, even while the underlying security continues to trade, provides little benefit and has the potential to create confusion among investors. Excluding rights and warrants from the pilot program should minimize investor confusion that could result from temporary trading pauses in these securities. For this reason, the Commission designates the proposed rule change as operative upon the date of this Notice.[17]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

[6] *See* Securities Exchange Act Release No. 64735 (June 23, 2011), 76 FR 38243 (June 29, 2011) (SR–NYSE–2011–21, *et al.*).

[7] Under amended NYSE Rule 80C, a pause is triggered by a 30% or more price move in a Phase III Security priced at $1 or higher, and by a 50% or more price move to such a security priced less than $1. The price of a security is based on the closing price on the previous trading day, or, if no closing price exists, the last sale reported to the Consolidated Tape on the previous trading day.

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78k–1(a)(1).

[11] 15 U.S.C. 78s(b)(3)(A)(iii).

[12] 17 CFR 240.19b–4(f)(6).

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[15] 17 CFR 240.19b–4(f)(6).

[16] 17 CFR 240.19b–4(f)(6)(iii).

[17] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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–NYSE–2011–57 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–NYSE–2011–57. 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 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 No. SR–NYSE–2011–57 and should be submitted on or before December 21, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–30805 Filed 11–29–11; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65811; File No. SR–NYSEAmex–2011–88]

Self-Regulatory Organizations; NYSE Amex LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending NYSE Amex Equities Rule 80C to Exclude All Rights and Warrants From the Single Stock Circuit Breaker Under the Rule

November 23, 2011.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on November 17, 2011, NYSE Amex LLC (the ''Exchange'' or ''NYSE Amex'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend NYSE Amex Equities Rule 80C to exclude all rights and warrants from the single stock circuit breaker under the rule. The text of the proposed rule change is available at the Exchange, the Commission's Public Reference Room, *http://www.nyse.com,* and *http://www.sec.gov.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend NYSE Amex Equities Rule 80C to exclude all rights and warrants from the single stock circuit breaker under the rule. The Commission approved NYSE Amex Equities Rule 80C on a pilot basis on June 10, 2010 to provide for trading pauses in individual securities due to extraordinary market volatility (''Trading Pause'') in all securities included within the S&P 500® Index (''S&P 500'') (''Pause Pilot'').[4] The Exchange noted in its filing to adopt NYSE Amex Equities Rule 80C that during the Pause Pilot period it would continue to assess whether additional securities need to be added and whether the parameters of NYSE Amex Equities Rule 80C would need to be modified to accommodate trading characteristics of different securities. The Exchange subsequently received approval to add to the Pause Pilot the securities included in the Russell 1000® Index (''Russell 1000'') and a specified list of Exchange Traded Products (''ETPs'').[5]

[18] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Commission approved the Pause Pilot for all equities exchanges and FINRA. *See* Securities Exchange Act Release No. 62252 (June 10, 2010), 75 FR 34186 (June 16, 2010) (File Nos. SR–BATS–2010–014; SR–EDGA–2010–01; SR–EDGX–2010–01; SR–BX–2010–037; SR–ISE–2010–48; SR–NYSE–2010–39; SR–NYSEAmex–2010–46; SR–NYSEArca–2010–41; SR–NASDAQ–2010–061; SR–CHX–2010–10; SR–NSX–2010–05; and SR–CBOE–2010–047) and Securities Exchange Act Release No. 62251 (June 10, 2010), 75 FR 34183 (June 16, 2010) (SR–FINRA–2010–025).

[5] The Commission approved the addition to the Pause Pilot of the securities included in the Russell 1000 and ETPs, where applicable, for all equities exchanges and FINRA. *See* Securities Exchange Act Release No. 62884 (September 10, 2010), 75 FR 56618 (September 16, 2010) (File Nos. SR–BATS–2010–018; SR–BX–2010–044; SR–CBOE–2010–065; SR–CHX–2010–14; SR–EDGA–2010–05; SR–EDGX–2010–05; SR–ISE–2010–66; SR–NASDAQ–2010–079; SR–NYSE–2010–49; SR–NYSEAmex–2010–63; SR–NYSEArca–2010–61; and SR–NSX–2010–08 and Securities Exchange Act Release No. 62883 (September 10, 2010), 75 FR 56608 (September 16, 2010) (SR–FINRA–2010–033). The Exchange submitted a proposed rule change shortly after the addition of the Russell 1000 securities and ETPs to extend the operation of the Pause Pilot, which was set to expire on December 10, 2010, until April 11, 2011. *See* Securities Exchange Act Release No. 63501 (December 9, 2010), 75 FR 78307 (December 15, 2010) (NYSEAmex–2010–117). The Exchange submitted a proposed rule change to further extend the Pause Pilot until the earlier of January 31, 2012 or the date on which a limit up/limit down mechanism to address extraordinary market volatility, if adopted, applies. *See* Securities Exchange Act Release No. 65089 (August 10, 2011),

On June 23, 2011, the Commission approved proposed rule changes of the Exchanges to amend certain of their respective rules to expand the Pause Pilot to include all remaining NMS stocks (''Phase III Securities''), which included rights and warrants.[6] Unlike the original Pause Pilot securities, amended NYSE Amex Equities Rule 80C applies wider percentage price moves to the Phase III Securities before a trading pause is triggered.[7] The changes to NYSE Amex Equities Rule 80C became effective on August 8, 2011.

The nature of the trading pauses triggered since adoption of the Pause Pilot has been analyzed and over 25% of such pauses have occurred in rights and warrants. Further, exchanges have experienced a significant increase in trading pauses involving rights and warrants since the implementation of the Phase III Securities, with such pauses representing as much as 52% [sic] all trading pauses occurring through the end of August 2011 on one exchange. Rights and warrants trade on equity exchanges, but are closely related to call options. Rights and warrants entitle owners to purchase shares of stock at predetermined prices subject to various timing and other conditions. Like options, the price of rights and warrants are affected by the price of the underlying stock as well as other factors, particularly the volatility of the stock. As a consequence, the prices of rights and warrants may move more dramatically than the prices of the underlying stocks even when the rights and warrants (and the underlying stock) are trading in an orderly manner. This difference in trading behavior may result in a scenario whereby the rights and warrants trigger the circuit breaker under NYSE Amex Equities Rule 80C and are subject to a trading pause, even while the underlying stock continues to trade. This can be particularly true of rights and warrants that have low prices. Accordingly, the Exchange is proposing to exclude rights and warrants from the trading pause under NYSE Amex Equities Rule 80C.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[8] in general, and furthers the objectives of Section 6(b)(5),[9] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system. The proposed rule change also is designed to support the principles of Section 11A(a)(1)[10] of the Act in that it seeks to ensure fair competition among brokers and dealers and among exchange markets. The Exchange believes that the proposed rule meets these requirements because it excludes certain securities from the rule's coverage that are prone to triggering pauses because of their unique characteristics. These securities are unique in that they may move more dramatically than the prices of the underlying stocks to which they are related even when both securities are trading in an orderly manner. As such, the securities that are subject to this proposal may trigger the circuit breaker under NYSE Amex Equities Rule 80C and be subject to a trading pause, even while the underlying security continues to trade. Although there is little benefit in pausing trading in these securities, such pauses sequester regulatory resources that are better applied to the review of trading pauses in other securities that have a greater impact on the national market system.

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 Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[11] and Rule 19b–4(f)(6) thereunder.[12] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[13] and Rule 19b–4(f)(6)(iii) thereunder.[14]

A proposed rule change filed under Rule 19b–4(f)(6)[15] normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii)[16] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Including rights and warrants in the pilot program which may trigger a circuit breaker and be subject to a trading pause, even while the underlying security continues to trade, provides little benefit and has the potential to create confusion among investors. Excluding rights and warrants from the pilot program should minimize investor confusion that could result from temporary trading pauses in these securities. For this reason, the Commission designates the proposed rule change as operative upon the date of this Notice.[17]

76 FR 50791 (August 16, 2011) (NYSEAmex–2011–57).

[6] *See* Securities Exchange Act Release No. 64735 (June 23, 2011), 76 FR 38243 (June 29, 2011) (NYSEAmex–2011–32, *et al.*).

[7] Under amended NYSE Amex Equities Rule 80C, a pause is triggered by a 30% or more price move in a Phase III Security priced at $1 or higher, and by a 50% or more price move to such a security priced less than $1. The price of a security is based on the closing price on the previous trading day, or, if no closing price exists, the last sale reported to the Consolidated Tape on the previous trading day.

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78k–1(a)(1).

[11] 15 U.S.C. 78s(b)(3)(A)(iii).

[12] 17 CFR 240.19b–4(f)(6).

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[15] 17 CFR 240.19b–4(f)(6).

[16] 17 CFR 240.19b–4(f)(6)(iii).

[17] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on

Continued

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–NYSEAmex–2011–88 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–NYSEAmex–2011–88. 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 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 No. SR–NYSEAmex–2011–88 and should be submitted on or before December 21, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–30806 Filed 11–29–11; 8:45 am]

BILLING CODE 8011–01–P

efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65814; File No. SR–NASDAQ–2011–154]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Exclude All Rights and Warrants from the Pilot Rule for Trading Pauses Due to Extraordinary Market Volatility

November 23, 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 NASDAQ Stock Market LLC (''NASDAQ''), filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by NASDAQ. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

NASDAQ proposes to exclude all rights and warrants from the pilot trading pause process under Rule 4120(a)(11).

The text of the proposed rule change is available from NASDAQ's Web site at *http://nasdaq.cchwallstreet.com/Filings/,* at NASDAQ's principal office, and at the Commission's Public Reference Room, and *http://www.sec.gov.*

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NASDAQ included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. NASDAQ has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

NASDAQ proposes to amend Rule 4120(a)(11) to exclude all rights and warrants from the trading pause process under the rule. The Commission approved Rule 4120(a)(11) on a pilot basis on June 10, 2010, together with the analogous rules of other equity exchanges (collectively with NASDAQ, the ''Exchanges'') and FINRA, to provide for trading pauses in individual securities due to extraordinary market volatility in all securities included within the S&P 500 Index (''S&P 500'') (the ''Pause Pilot'').[3] NASDAQ noted in its filing to adopt Rule 4120(a)(11) that during the Pause Pilot period it would continue to assess whether additional securities need to be added and whether the parameters of Rule 4120(a)(11) would need to be modified to accommodate trading characteristics of different securities. The Exchanges and FINRA subsequently received approval to add to the Pause Pilot the securities included in the Russell 1000 Index (''Russell 1000'') and a specified list of Exchange Traded Products (''ETPs'').[4]

[3] The Commission approved the Pause Pilot for all equities exchanges and FINRA. *See* Securities Exchange Act Release No. 62252 (June 10, 2010), 75 FR 34186 (June 16, 2010) (File Nos. SR–BATS–2010–014; SR–EDGA–2010–01; SR–EDGX–2010–01; SR–BX–2010–037; SR–ISE–2010–48; SR–NYSE–2010–39; SR–NYSEAmex-2010–46; SR–NYSEArca-2010–41; SR–NASDAQ–2010–061; SR–CHX–2010–10; SR–NSX–2010–05; and SR–CBOE–2010–047), and Securities Exchange Act Release No. 62251 (June 10, 2010), 75 FR 34183 (June 16, 2010) (SR–FINRA–2010–025).

[4] The Commission approved the addition to the Pause Pilot of the securities included in the Russell 1000 and ETPs, where applicable, for all equities exchanges and FINRA. *See* Securities Exchange Act Release No. 62884 (September 10, 2010), 75 FR 56618 (September 16, 2010) (File Nos. SR–BATS–2010–018; SR–BX–2010–044; SR–CBOE–2010–065; SR–CHX–2010–14; SR–EDGA–2010–05; SR–EDGX–2010–05; SR–ISE–2010–66; SR–NASDAQ–2010–079; SR–NYSE–2010–49; SR–NYSEAmex–2010–63;

On June 23, 2011, the Commission approved proposed rule changes of the Exchanges and FINRA to amend their respective rules to expand the Pause Pilot to include all remaining NMS stocks (''Phase III Securities''), which includes rights and warrants.[5] Unlike the original Pause Pilot securities, amended Rule 4120(a)(11) applies wider percentage price moves to the Phase III Securities before a trading pause is triggered.[6] The changes to Rule 4120(a)(11) became effective on August 8, 2011.

The Exchanges and FINRA analyzed the nature of the trading pauses triggered since adoption of the Pause Pilot and found that over 25% of such pauses have occurred in rights and warrants. Further, the Exchanges and FINRA have experienced a significant increase in trading pauses involving rights and warrants since the implementation of the Phase III Securities, with such pauses representing approximately 52% [sic] all trading pauses occurring through the end of August 2011. Rights and warrants trade on equity exchanges, but are closely related to call options. Rights and warrants entitle owners to purchase shares of stock at predetermined prices subject to various timing and other conditions. Like options, the price of rights and warrants are affected by the price of the underlying stock as well as other factors, particularly the volatility of the stock. As a consequence, the prices of rights and warrants may move more dramatically than the prices of the underlying stocks even when the rights and warrants (and the underlying stock) are trading in an orderly manner. This difference in trading behavior may result in the rights and warrants triggering the circuit breaker under Rule 4120(a)(11) and being subject to a trading pause, even while the underlying stock continues to trade. This can be particularly true of rights and warrants that have low prices. As such, the Exchanges and FINRA have determined to exclude rights and warrants from the Pause Pilot, and accordingly, NASDAQ is proposing to amend Rule 4120(a)(11) to exclude rights and warrants from the rule's application.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[7] in general, and furthers the objectives of Section 6(b)(5),[8] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system. The proposed rule change also is designed to support the principles of Section 11A(a)(1)[9] of the Act in that it seeks to ensure fair competition among brokers and dealers and among exchange markets. NASDAQ believes that the proposed rule meets these requirements because it excludes certain securities from the rule's coverage that are prone to triggering pauses because of their unique characteristics. These securities are unique in that they may move more dramatically than the prices of the underlying stocks to which they are related even when both securities are trading in an orderly manner. As such, the securities that are subject to this proposal may trigger the circuit breaker under Rule 4120(a)(11) and be subject to a trading pause, even while the underlying security continues to trade. Although there is little benefit in pausing trading in these securities, such pauses sequester regulatory resources that are better applied to the review of trading pauses in other securities that have a greater impact on the national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

NASDAQ does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[10] and Rule 19b–4(f)(6) thereunder.[11] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[12] and Rule 19b–4(f)(6)(iii) thereunder.[13]

A proposed rule change filed under Rule 19b–4(f)(6)[14] normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii)[15] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Including rights and warrants in the pilot program which may trigger a circuit breaker and be subject to a trading pause, even while the

SR–NYSEArca–2010–61; and SR–NSX–2010–08, and Securities Exchange Act Release No. 62883 (September 10, 2010), 75 FR 56608 (September 16, 2010) (SR–FINRA–2010–033). NASDAQ submitted a proposed rule change shortly after the addition of the Russell 1000 securities and ETPs to extend the operation of the Pause Pilot, which was set to expire on December 10, 2010, until April 11, 2011. *See* Securities Exchange Act Release No. 63505 (December 9, 2010), 75 FR 78302 (December 15, 2010) (SR–NASDAQ–2010–162). On March 31, 2011, NASDAQ submitted a proposed rule change to further extend the Pause Pilot until the earlier of August 11, 2011 or the date on which a limit up/limit down mechanism to address extraordinary market volatility, if adopted, applies. *See* Securities Exchange Act Release No. 64174 (April 4, 2011), 76 FR 19819 (April 8, 2011) (SR–NASDAQ–2011–042). On August 8, 2011, NASDAQ submitted a proposed rule change to further extend the Pause Pilot until January 31, 2012. *See* Securities Exchange Act Release No. 65094 (August 10, 2011), 76 FR 50779 (August 16, 2011) (SR–NASDAQ–2011–115).

[5] *See* Securities Exchange Act Release No. 64735 (June 23, 2011), 76 FR 38243 (June 29, 2011) (SR–NASDAQ–2011–067, *et al.*).

[6] Under amended Rule 4120(a)(11), a pause is triggered by a 30% or more price move in a Phase III Security priced at $1 or higher, and by a 50% or more price move to such a security priced less than $1. The price of a security is based on the closing price on the previous trading day, or, if no closing price exists, the last sale reported to the Consolidated Tape on the previous trading day.

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78k–1(a)(1).

[10] 15 U.S.C. 78s(b)(3)(A)(iii).

[11] 17 CFR 240.19b–4(f)(6).

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[14] 17 CFR 240.19b–4(f)(6).

[15] 17 CFR 240.19b–4(f)(6)(iii).

underlying security continues to trade, provides little benefit and has the potential to create confusion among investors. Excluding rights and warrants from the pilot program should minimize investor confusion that could result from temporary trading pauses in these securities. For this reason, the Commission designates the proposed rule change as operative upon the date of this Notice.[16]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File No. SR–NASDAQ–2011–154 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–NASDAQ–2011–154. 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 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 No. SR–NASDAQ–2011–154 and should be submitted on or before December 21, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–30809 Filed 11–29–11; 8:45 am]

BILLING CODE 8011–01–P

[16] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65816; File No. SR–BATS–2011–048]

Self-Regulatory Organizations; BATS Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Modify Exchange Rule 11.18 Relating to Trading Pauses Due to Extraordinary Market Volatility

November 23, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 22, 2011, BATS Exchange, Inc. (the ''Exchange'' or ''BATS'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing with the Commission a proposal to amend Rule 11.18, entitled ''Trading Halts Due to Extraordinary Market Volatility.''

The text of the proposed rule change is available at the Exchange's Web site at *http://www.batstrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 11.18 to exclude all rights and warrants from the single stock circuit breaker under the rule. The Commission approved Rule 11.18(d) and Interpretation and Policy .05 to Rule 11.18 (the ''Trading Pause Rule'') on a pilot basis on June 10, 2010 to provide for trading pauses in individual securities due to extraordinary market volatility (''Trading Pause'') in all securities included within the S&P 500® Index (''S&P 500'') (''Pause Pilot'').[3] The Exchange noted in its filing to adopt the Trading Pause Rule that during the Pause Pilot period it would continue to assess whether additional securities need to be added and whether the parameters of Rule 11.18 would need to be modified to accommodate trading characteristics of different securities. The Exchange subsequently received approval to add to the Pause Pilot the securities included in the Russell 1000® Index (''Russell 1000'') and a specified list of Exchange Traded Products (''ETPs'').[4]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Commission approved the Pause Pilot for all equities exchanges and FINRA. *See* Securities Exchange Act Release No. 62252 (June 10, 2010), 75 FR 34186 (June 16, 2010) (File Nos. SR–BATS–2010–014; SR–EDGA–2010–01; SR–EDGX–2010–01; SR–BX–2010–037; SR–ISE–2010–48; SR–NYSE–2010–39; SR–NYSEAmex–2010–46; SR–NYSEArca–2010–41; SR–NASDAQ–2010–061; SR–CHX–2010–10; SR–NSX–2010–05; and SR–CBOE–2010–047) and Securities Exchange Act Release No. 62251 (June 10, 2010), 75 FR 34183 (June 16, 2010) (SR–FINRA–2010–025).

[4] The Commission approved the addition to the Pause Pilot of the securities included in the Russell

On June 23, 2011, the Commission approved proposed rule changes of the Exchanges to amend certain of their respective rules to expand the Pause Pilot to include all remaining NMS stocks (''Phase III Securities''), which included rights and warrants.[5] Unlike the original Pause Pilot securities, the amended Trading Pause Rule applies wider percentage price moves to the Phase III Securities before a trading pause is triggered.[6] The changes to the Trading Pause Rule became effective on August 8, 2011.

Over 25% of the trading pauses have occurred in rights and warrants since adoption of the Pause Pilot. Further, there has been a significant increase in trading pauses involving rights and warrants since the implementation of the Phase III Securities, with such pauses representing approximately 52% [sic] all trading pauses occurring through the end of August 2011. Rights and warrants trade on equity exchanges, but are closely related to call options. Rights and warrants entitle owners to purchase shares of stock at predetermined prices subject to various timing and other conditions. Like options, the prices of rights and warrants are affected by the price of the underlying stock as well as other factors, particularly the volatility of the stock. As a consequence, the prices of rights and warrants may move more dramatically than the prices of the underlying stocks even when the rights and warrants (and the underlying stock) are trading in an orderly manner. This difference in trading behavior may result in a scenario whereby the rights and warrants trigger the circuit breaker under the Trading Pause Rule and are subject to a trading pause, even while the underlying stock continues to trade. This can be particularly true of rights and warrants that have low prices. Accordingly, the Exchange is proposing to exclude rights and warrants from the trading pause under the Trading Pause Rule.

2. *Statutory Basis*

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[7] in general, and furthers the objectives of Section 6(b)(5),[8] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system. The proposed rule change also is designed to support the principles of Section 11A(a)(1)[9] of the Act in that it seeks to ensure fair competition among brokers and dealers and among exchange markets. The Exchange believes that the proposed rule meets these requirements because it excludes certain securities from the rule's coverage that are prone to triggering pauses because of their unique characteristics. These securities are unique in that they may move more dramatically than the prices of the underlying stocks to which they are related even when both securities are trading in an orderly manner. As such, the securities that are subject to this proposal may trigger the circuit breaker under the Trading Pause Rule and be subject to a trading pause, even while the underlying security continues to trade. Although there is little benefit in pausing trading in these securities, such pauses sequester regulatory resources that are better applied to the review of trading pauses in other securities that have a greater impact on the national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change imposes any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[10] and Rule 19b–4(f)(6) thereunder.[11] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[12] and Rule 19b–4(f)(6)(iii) thereunder.[13]

A proposed rule change filed under Rule 19b–4(f)(6)[14] normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii)[15] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Including rights and warrants in the pilot program which may trigger a circuit breaker and be subject to a trading pause, even while the underlying security continues to trade, provides little benefit and has the potential to create confusion among investors. Excluding rights and warrants from the pilot program should minimize investor confusion that could result from temporary trading pauses in these

1000 and ETPs, where applicable, for all equities exchanges and FINRA. *See* Securities Exchange Act Release No. 62884 (September 10, 2010), 75 FR 56618 (September 16, 2010) (File Nos. SR–BATS–2010–018; SR–BX–2010–044; SR–CBOE–2010–065; SR–CHX–2010–14; SR–EDGA–2010–05; SR–EDGX–2010–05; SR–ISE–2010–66; SR–NASDAQ–2010–079; SR–NYSE–2010–49; SR–NYSEAmex–2010–63; SR–NYSEArca–2010–61; and SR–NSX–2010–08 and Securities Exchange Act Release No. 62883 (September 10, 2010), 75 FR 56608 (September 16, 2010) (SR–FINRA–2010–033). The Exchange submitted a proposed rule change shortly after the addition of the Russell 1000 securities and ETPs to extend the operation of the Pause Pilot, which was set to expire on December 10, 2010, until April 11, 2011. Securities Exchange Act Release No. 63497 (December 9, 2010), 75 FR 78315 (December 15, 2010) (SR–BATS–2010–037). On March 31, 2011, the Exchange submitted a proposed rule change to further extend the Pause Pilot until the earlier of August 11, 2011 or the date on which a limit up/limit down mechanism to address extraordinary market volatility, if adopted, applies. Securities Exchange Act Release No. 64207 (April 6, 2011), 76 FR 20424 (April 12, 2011) (SR–BATS–2011–011).

[5] *See* Securities Exchange Act Release No. 64735 (June 23, 2011), 76 FR 38243 (June 29, 2011) (SR–BATS–2011–016, *et al.*).

[6] Under amended rules, a pause is triggered by a 30% or more price move in a Phase III Security priced at $1 or higher, and by a 50% or more price move to such a security priced less than $1. The price of a security is based on the closing price on the previous trading day, or, if no closing price exists, the last sale reported to the Consolidated Tape on the previous trading day.

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78k–1(a)(1).

[10] 15 U.S.C. 78s(b)(3)(A)(iii).

[11] 17 CFR 240.19b–4(f)(6).

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[14] 17 CFR 240.19b–4(f)(6).

[15] 17 CFR 240.19b–4(f)(6)(iii).

securities. For this reason, the Commission designates the proposed rule change as operative upon the date of this Notice.[16]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–BATS–2011–048 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–BATS–2011–048. 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 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 No. SR–BATS–2011–048 and should be submitted on or before December 21, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–30811 Filed 11–29–11; 8:45 am]

BILLING CODE 8011–01–P

[16] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65818; File No. SR–CHX–2011–32]

Self-Regulatory Organizations; Chicago Stock Exchange, Incorporated; Notice of Filing Proposed Rule Change To Exclude Rights and Warrants From the Individual Securities Circuit Breaker Rule

November 23, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 [2] thereunder, notice is hereby given that on November 21, 2011, the Chicago Stock Exchange, Inc. (''CHX'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the CHX. CHX has filed this proposal pursuant to Exchange Act Rule 19b–4(f)(6) [3] which is effective upon filing with the Commission.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

CHX proposes to amend Article 20, Rule 2(e) to exclude all rights and warrants from the individual securities circuit breaker rule. The text of this proposed rule change is available on the Exchange's Web site at (*http://www.chx.com*), in the Commission's Public Reference Room, and at *http://www.sec.gov*.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6).

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the CHX included statements concerning the purpose of and basis for the proposed rule changes and discussed any comments it received regarding the proposal. The text of these statements may be examined at the places specified in Item IV below. The CHX has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Article 20, Rule 2(e) to exclude all rights and warrants from the individual securities circuit breaker under the rule. The Commission approved Article 20, Rule 2(e) on a pilot basis on June 10, 2010 to provide for trading pauses in individual securities due to extraordinary market volatility (''Trading Pause'') in all securities included within the S&P 500® Index (''S&P 500'') (''Pause Pilot'').[4] The Exchange noted in its filing to adopt Article 20, Rule 2(e) that during the Pause Pilot period it would continue to assess whether additional securities need to be added and whether the parameters of Article 20, Rule 2(e) would need to be modified to accommodate trading characteristics of different securities. The Exchange subsequently received approval to add to the Pause Pilot the securities included in the Russell 1000® Index (''Russell 1000'') and a specified list of Exchange Traded Products (''ETPs'').[5]

[4] The Commission approved the Pause Pilot for all equities exchanges and FINRA. *See* Securities Exchange Act Release No. 62252 (June 10, 2010), 75 FR 34186 (June 16, 2010) (File Nos. SR–BATS–2010–014; SR–EDGA–2010–01; SR–EDGX–2010–01; SR–BX–2010–037; SR–ISE–2010–48; SR–NYSE–2010–39; SR–NYSEAmex-2010–46; SR–NYSEArca-2010–41; SR–NASDAQ–2010–061; SR–CHX–2010–10; SR–NSX–2010–05; and SR–CBOE–2010–047) and Securities Exchange Act Release No. 62251 (June 10, 2010), 75 FR 34183 (June 16, 2010) (SR–FINRA–2010–025).

[5] The Commission approved the addition to the Pause Pilot of the securities included in the Russell 1000 and ETPs, where applicable, for all equities exchanges and FINRA. *See* Securities Exchange Act Release No. 62884 (September 10, 2010), 75 FR 56618 (September 16, 2010) (File Nos. SR–BATS–2010–018; SR–BX–2010–044; SR–CBOE–2010–065; SR–CHX–2010–14; SR–EDGA–2010–05; SR–EDGX–2010–05; SR–ISE–2010–66; SR–NASDAQ–2010–079; SR–NYSE–2010–49; SR–NYSEAmex-2010–63; SR–NYSEArca-2010–61; and SR–NSX–2010–08 and Securities Exchange Act Release No. 62883

On June 23, 2011, the Commission approved proposed rule changes of the Exchanges to amend certain of their respective rules to expand the Pause Pilot to include all remaining NMS stocks (''Phase III Securities''), which included rights and warrants.[6] Unlike the original Pause Pilot securities, amended Article 20, Rule 2(e) applies wider percentage price moves to the Phase III Securities before a trading pause is triggered.[7] The changes to Article 20, Rule 2(e) became effective on August 8, 2011.

CHX analyzed the nature of the trading pauses triggered since adoption of the Pause Pilot and noted that over 25% of such pauses have occurred in rights and warrants. Further, CHX has experienced a significant increase in trading pauses involving rights and warrants since the implementation of the Phase III Securities, with such pauses representing approximately 52% [sic] all trading pauses occurring through the end of August 2011. Rights and warrants trade on equity exchanges, but are closely related to call options. Rights and warrants entitle owners to purchase shares of stock at predetermined prices subject to various timing and other conditions. Like options, the price of rights and warrants are affected by the price of the underlying stock as well as other factors, particularly the volatility of the stock. As a consequence, the prices of rights and warrants may move more dramatically than the prices of the underlying stocks even when the rights and warrants (and the underlying stock) are trading in an orderly manner. This difference in trading behavior may result in a scenario whereby the rights and warrants trigger the circuit breaker under Article 20, Rule 2(e) and are subject to a trading pause, even while the underlying stock continues to trade. This can be particularly true of rights and warrants that have low prices. Accordingly, CHX is proposing to exclude rights and warrants from the trading pause under Article 20, Rule 2(e).

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[8] in general, and furthers the objectives of Section 6(b)(5),[9] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system. The proposed rule change also is designed to support the principles of Section 11A(a)(1)[10] of the Act in that it seeks to ensure fair competition among brokers and dealers and among exchange markets.

The Exchange believes that the proposed rule meets these requirements because it excludes certain securities from the rule's coverage that are prone to triggering pauses because of their unique characteristics. These securities are unique in that they may move more dramatically than the prices of the underlying stocks to which they are related even when both securities are trading in an orderly manner. As such, the securities that are subject to this proposal may trigger the circuit breaker under Article 20, Rule 2(e) and be subject to a trading pause, even while the underlying security continues to trade. Although there is little benefit in pausing trading in these securities, such pauses sequester regulatory resources that are better applied to the review of trading pauses in other securities that have a greater impact on the national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[11] and Rule 19b–4(f)(6) thereunder.[12] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[13] and Rule 19b–4(f)(6)(iii) thereunder.[14]

A proposed rule change filed under Rule 19b-4(f)(6)[15] normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii)[16] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Including rights and warrants in the pilot program which may trigger a circuit breaker and be subject to a trading pause, even while the underlying security continues to trade, provides little benefit and has the potential to create confusion among investors. Excluding rights and warrants from the pilot program should minimize investor confusion that could result from temporary trading pauses in these securities. For this reason, the

(September 10, 2010), 75 FR 56608 (September 16, 2010) (SR–FINRA–2010–033). The Exchange submitted a proposed rule change shortly after the addition of the Russell 1000 securities and ETPs to extend the operation of the Pause Pilot, which was set to expire on December 10, 2010, until April 11, 2011. *See* Securities Exchange Act Release No. 63505 (December 9, 2010), 75 FR 78302 (December 15, 2010) (SR–CHX–2010–24). On March 31, 2011, the Exchange submitted a proposed rule change to further extend the Pause Pilot until the earlier of August 11, 2011 or the date on which a limit up/limit down mechanism to address extraordinary market volatility, if adopted, applies. *See* Securities Exchange Act Release No. 64174 (April 4, 2011), 76 FR 19819 (April 8, 2011) (SR–CHX–2011–05).

[6] *See* Securities Exchange Act Release No. 64735 (June 23, 2011), 76 FR 38243 (June 29, 2011) (SR–CHX–2011–09, *et al.*).

[7] Under amended Article 20, Rule 2(e), a pause is triggered by a 30% or more price move in a Phase III Security priced at $1 or higher, and by a 50% or more price move to such a security priced less than $1. The price of a security is based on the closing price on the previous trading day, or, if no closing price exists, the last sale reported to the Consolidated Tape on the previous trading day.

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78k–1(a)(1).

[11] 15 U.S.C. 78s(b)(3)(A)(iii).

[12] 17 CFR 240.19b–4(f)(6).

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[15] 17 CFR 240.19b–4(f)(6).

[16] 17 CFR 240.19b–4(f)(6)(iii).

Commission designates the proposed rule change as operative upon the date of this Notice.[17]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments:

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File No. SR–CHX–2011–32 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–CHX–2011–32. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–CHX–2011–32 and should be submitted on or before December 21, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–30813 Filed 11–29–11; 8:45 am]

BILLING CODE 8011–01–P

[17] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65827; File No. SR–EDGX–2011–35]

Self-Regulatory Organizations; EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule To Amend EDGX Rule 11.9

November 23, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 17, 2011, the EDGX Exchange, Inc. (the ''Exchange'' or the ''EDGX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Item II below, which item have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to introduce an additional routing option to Rule 11.9 and amend existing routing options. The text of the proposed rule change is available on the Exchange's Web site at *www.directedge.com*, on the Commission's Web site at *www.sec.gov*, at the Exchange's principal office, and at the Public Reference Room of the Commission.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange's current list of routing options are codified in Rule 11.9(b)(3). In this filing, the Exchange proposes to amend the language of two routing options contained in Rule 11.9(b)(3) to modify the behavior of unexecuted shares and distinguish the execution path if an order is sent as a Day Order [3] versus an Immediate-or-Cancel (''IOC'') [4] order.

Specifically, Rule 11.9(b)(3)(h) provides that the RDOT routing option checks the System for available shares and then is sent sequentially to destinations on the System routing table. If shares remain unexecuted after routing, they are sent to the NYSE. The Exchange proposes to modify this strategy to provide that any unexecuted shares can be re-routed by the NYSE and any remainder after routing will be posted to the NYSE book, unless otherwise instructed by the User. The phrase ''unless otherwise instructed by the User'' is proposed to be added to the rule to account for the fact that if a User sends an IOC order, it will not post to the NYSE book.

Rule 11.9(b)(3)(i) provides that the RDOX routing option checks the System for available shares and then is sent to the NYSE. The Exchange proposes to amend this strategy to provide that the unexecuted shares can be re-routed by the NYSE and any remainder after routing will be posted to the NYSE book, unless otherwise instructed by the User. The phrase ''unless otherwise instructed by the User'' is proposed to be added to the rule [sic] account for the fact that if a User sends an IOC order, it will not post to the NYSE book.

[3] As defined in Rule 11.5(b)(2).

[4] As defined in Rule 11.5(b)(1).

The Exchange also proposes to amend Rule 11.9(b)(3)(n), which currently has an incorrect cross reference to the ROUT routing option as being in paragraph (h) in its description. The Exchange proposes to correct the citation to cross reference paragraph (c) for the ROUT routing option.

The Exchange believes the proposed modification of the routing options described above will provide additional specificity to the Exchange's rulebook regarding routing strategies and will further enhance transparency with respect to Exchange routing offerings.

2. Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b)(5) of the Act,[5] which requires the rules of an exchange to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. The proposed changes to the two routing options described above will provide additional specificity to the Exchange's rulebook regarding routing strategies and will further enhance transparency with respect to Exchange routing offerings.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not 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 has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[6] and Rule 19b–4(f)(6)(iii) thereunder.[7]

A proposed rule change filed under 19b–4(f)(6) normally may not become operative prior to 30 days after the date of filing.[8] However, Rule 19b–4(f)(6)(iii)[9] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay. The Exchange notes that waiver of this requirement will allow the Exchange to offer Exchange Users the modified routing strategies, on or about December 5, 2011. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because such waiver would allow the modified routing strategies to become available on or about December 5, 2011, and would immediately provide additional specificity to the Exchange's rules regarding routing strategies and further enhance transparency with respect to Exchange routing offerings. For this reason, the Commission designates the proposed rule change to be operative upon filing with the Commission.[10]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–EDGX–2011–35 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–EDGX–2011–35. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 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–EDGX–2011–35 and should be submitted on or before December 21, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–30831 Filed 11–29–11; 8:45 am]

BILLING CODE 8011–01–P

[5] 15 U.S.C. 78f(b)(5).

[6] 15 U.S.C. 78s(b)(3)(A).

[7] 17 CFR 240.19b–4(f)(6)(iii).

[8] 17 CFR 240.19b–4(f)(6)(iii). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[9] Id.

[10] For the purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65826; File No. SR–EDGA–2011–37]

Self-Regulatory Organizations; EDGA Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule To Amend EDGA Rule 11.9

November 23, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 17, 2011, the EDGA Exchange, Inc. (the ''Exchange'' or the ''EDGA'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Item II below, which item have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to introduce an additional routing option to Rule 11.9 and amend existing routing options. The text of the proposed rule change is available on the Exchange's Web site at *www.directedge.com,* on the Commission's Web site at *www.sec.gov,* at the Exchange's principal office, and at the Public Reference Room of 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 Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange's current list of routing options are codified in Rule 11.9(b)(3). In this filing, the Exchange proposes to amend the language of two routing options contained in Rule 11.9(b)(3) to modify the behavior of unexecuted shares and distinguish the execution path if an order is sent as a Day Order [3] versus an Immediate-or-Cancel (''IOC'') [4] order.

Specifically, Rule 11.9(b)(3)(h) provides that the RDOT routing option checks the System for available shares and then is sent sequentially to destinations on the System routing table. If shares remain unexecuted after routing, they are sent to the NYSE. The Exchange proposes to modify this strategy to provide that any unexecuted shares can be re-routed by the NYSE and any remainder after routing will be posted to the NYSE book, unless otherwise instructed by the User. The phrase ''unless otherwise instructed by the User'' is proposed to be added to the rule to account for the fact that if a User sends an IOC order, it will not post to the NYSE book.

Rule 11.9(b)(3)(i) provides that the RDOX routing option checks the System for available shares and then is sent to the NYSE. The Exchange proposes to amend this strategy to provide that the unexecuted shares can be re-routed by the NYSE and any remainder after routing will be posted to the NYSE book, unless otherwise instructed by the User. The phrase ''unless otherwise instructed by the User'' is proposed to be added to the rule to account for the fact that if a User sends an IOC order, it will not post to the NYSE book.

The Exchange also proposes to amend Rule 11.9(b)(3)(n), which currently has an incorrect cross reference to the ROUT routing option as being in paragraph (h) in its description. The Exchange proposes to correct the citation to cross reference paragraph (c) for the ROUT routing option.

The Exchange believes the proposed modification of the routing options described above will provide additional specificity to the Exchange's rulebook regarding routing strategies and will further enhance transparency with respect to Exchange routing offerings.

2. Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b)(5) of the Act,[5] which requires the rules of an exchange to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. The proposed changes to the two routing options described above will provide additional specificity to the Exchange's rulebook regarding routing strategies and will further enhance transparency with respect to Exchange routing offerings.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not 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 has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [6] and Rule 19b–4(f)(6)(iii) thereunder.[7]

A proposed rule change filed under 19b–4(f)(6) normally may not become operative prior to 30 days after the date of filing.[8] However, Rule 19b–4(f)(6)(iii) [9] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay. The Exchange notes that waiver of this requirement will allow the Exchange to offer Exchange Users the modified routing strategies, on or about December 5, 2011. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] As defined in Rule 11.5(b)(2).

[4] As defined in Rule 11.5(b)(1).

[5] 15 U.S.C. 78f(b)(5).

[6] 15 U.S.C. 78s(b)(3)(A).

[7] 17 CFR 240.19b–4(f)(6)(iii).

[8] 17 CFR 240.19b–4(f)(6)(iii). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[9] *Id.*

interest because such waiver would allow the modified routing strategies to become available on or about December 5, 2011, and would immediately provide additional specificity to the Exchange's rules regarding routing strategies and further enhance transparency with respect to Exchange routing offerings. For this reason, the Commission designates the proposed rule change to be operative upon filing with the Commission.[10]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–EDGA–2011–37 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–EDGA–2011–37. 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 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–EDGA–2011–37 and should be submitted on or before December 21, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–30830 Filed 11–29–11; 8:45 am]

BILLING CODE 8011–01–P

[10] For the purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65823; File No. SR–EDGX–2011–36]

Self-Regulatory Organizations; EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend EDGX Rule 11.14 to Exclude from the Pilot Rule All Rights and Warrants

November 23, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 22, 2011, the EDGX Exchange, Inc. (the ''Exchange'' or the ''EDGX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule 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 EDGX Rule 11.14 to exclude from the pilot rule all rights and warrants. The text of the proposed rule change is attached as Exhibit 5[3] and is available on the Exchange's Web site at *http://www.directedge.com,* at the Exchange's principal office, at the Public Reference Room of the Commission, and at *http://www.sec.gov.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend EDGX Rule 11.14(d) to exclude all rights and warrants from the single stock circuit breaker under the rule. The Commission approved EDGX Rule 11.14 on a pilot basis on June 10, 2010 to provide for trading pauses in individual securities due to extraordinary market volatility (''Trading Pause'') in all securities included within the S&P 500® Index (''S&P 500'') (''Pause Pilot'').[4] The Exchange noted in its filing to adopt EDGX Rule 11.14 that during the Pause Pilot period it would continue to assess whether additional securities need to be added and whether the parameters of EDGX Rule 11.14 would need to be modified to accommodate trading characteristics of different securities. The Exchange subsequently received approval to add to the Pause Pilot the securities included in the Russell 1000® Index (''Russell 1000'') and a specified

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Commission notes that Exhibit 5 is attached to the rule filing, but not to this Notice.

[4] The Commission approved the Pause Pilot for all equities exchanges and FINRA. *See* Securities Exchange Act Release No. 62252 (June 10, 2010), 75 FR 34186 (June 16, 2010) (File Nos. SR–BATS–2010–014; SR–EDGA–2010–01; SR–EDGX–2010–01; SR–BX–2010–037; SR–ISE–2010–48; SR–NYSE–2010–39; SR–NYSEAmex–2010–46; SR–NYSEArca–2010–41; SR–NASDAQ–2010–061; SR–CHX–2010–10; SR–NSX–2010–05; and SR–CBOE–2010–047) and Securities Exchange Act Release No. 62251 (June 10, 2010), 75 FR 34183 (June 16, 2010) (SR–FINRA–2010–025).

list of Exchange Traded Products (''ETPs'').[5]

On June 23, 2011, the Commission approved proposed rule changes of the Exchanges to amend certain of their respective rules to expand the Pause Pilot to include all remaining NMS stocks (''Phase III Securities''), which included rights and warrants.[6] Unlike the original Pause Pilot securities, the rules of primary listing markets apply wider percentage price moves to the Phase III Securities before a trading pause is triggered.[7] These changes to the rules of primary listing markets became effective on August 8, 2011.

Various exchanges and national securities associations, including the Exchange, have analyzed the nature of the trading pauses triggered since adoption of the Pause Pilot and noted that over 25% of such pauses have occurred in rights and warrants. Further, several primary listing markets have experienced a significant increase in trading pauses involving rights and warrants since the implementation of the Phase III Securities, with such pauses representing approximately 52% [sic] all trading pauses occurring through the end of August 2011. Rights and warrants trade on equity exchanges, but are closely related to call options. Rights and warrants entitle owners to purchase shares of stock at predetermined prices subject to various timing and other conditions. Like options, the price of rights and warrants are affected by the price of the underlying stock as well as other factors, particularly the volatility of the stock. As a consequence, the prices of rights and warrants may move more dramatically than the prices of the underlying stocks even when the rights and warrants (and the underlying stock) are trading in an orderly manner. This difference in trading behavior may result in a scenario whereby the rights and warrants trigger the circuit breaker under the rules of various primary listing markets and are subject to a trading pause, even while the underlying stock continues to trade. This can be particularly true of rights and warrants that have low prices. Accordingly, EDGX is proposing to exclude rights and warrants from the trading pauses issued by primary listing markets, as referenced in EDGX Rule 11.14(d).

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[8] in general, and furthers the objectives of Section 6(b)(5),[9] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system. The proposed rule change also is designed to support the principles of Section 11A(a)(1)[10] of the Act in that it seeks to ensure fair competition among brokers and dealers and among exchange markets. The Exchange believes that the proposed rule meets these requirements because it excludes certain securities from the rule's coverage that are prone to triggering pauses because of their unique characteristics. These securities are unique in that they may move more dramatically than the prices of the underlying stocks to which they are related even when both securities are trading in an orderly manner. As such, the securities that are subject to this proposal may trigger the circuit breaker under the rules of various primary listing markets and be subject to a trading pause, even while the underlying security continues to trade. Although there is little benefit in pausing trading in these securities, such pauses sequester regulatory resources that are better applied to the review of trading pauses in other securities that have a greater impact on the national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not 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 has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[11] and Rule 19b–4(f)(6) thereunder.[12] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[13] and Rule 19b–4(f)(6)(iii) thereunder.[14]

A proposed rule change filed under Rule 19b–4(f)(6)[15] normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii)[16] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that

[5] The Commission approved the addition to the Pause Pilot of the securities included in the Russell 1000 and ETPs, where applicable, for all equities exchanges and FINRA. *See* Securities Exchange Act Release No. 62884 (September 10, 2010), 75 FR 56618 (September 16, 2010) (File Nos. SR–BATS–2010–018; SR–BX–2010–044; SR–CBOE–2010–065; SR–CHX–2010–14; SR–EDGA–2010–05; SR–EDGX–2010–05; SR–ISE–2010–66; SR–NASDAQ–2010–079; SR–NYSE–2010–49; SR–NYSEAmex–2010–63; SR–NYSEArca–2010–61; and SR–NSX–2010–08 and Securities Exchange Act Release No. 62883 (September 10, 2010), 75 FR 56608 (September 16, 2010) (SR–FINRA–2010–033). The Exchange submitted a proposed rule change shortly after the addition of the Russell 1000 securities and ETPs to extend the operation of the Pause Pilot, which was set to expire on December 10, 2010, until April 11, 2011. *See* Securities Exchange Act Release No. 63514 (December 9, 2010), 75 FR 78783 (December 16, 2010) (SR–EDGX–2010–23). On April 5, 2011, the Exchange submitted a proposed rule change to further extend the Pause Pilot until the earlier of August 11, 2011 or the date on which a limit up/limit down mechanism to address extraordinary market volatility, if adopted, applies. *See* Securities Exchange Act Release No. 64204 (April 6, 2011), 76 FR 20394 (April 12, 2011) (SR–EDGX–2011–11).

[6] *See* Securities Exchange Act Release No. 64735 (June 23, 2011), 76 FR 38243 (June 29, 2011) (SR–EDGX–2011–14 and Amendment No. 1 thereto, *et al.*).

[7] Under the rules of primary listing markets, (i.e. Nasdaq Rule 4120(a)(11)), a pause is triggered by a 30% or more price move in a Phase III Security priced at $1 or higher, and by a 50% or more price move to such a security priced less than $1. The price of a security is based on the closing price on the previous trading day, or, if no closing price exists, the last sale reported to the Consolidated Tape on the previous trading day.

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78k–1(a)(1).

[11] 15 U.S.C. 78s(b)(3)(A)(iii).

[12] 17 CFR 240.19b–4(f)(6).

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[15] 17 CFR 240.19b–4(f)(6).

[16] 17 CFR 240.19b–4(f)(6)(iii).

the proposal may become operative immediately upon filing.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Including rights and warrants in the pilot program which may trigger a circuit breaker and be subject to a trading pause, even while the underlying security continues to trade, provides little benefit and has the potential to create confusion among investors. Excluding rights and warrants from the pilot program should minimize investor confusion that could result from temporary trading pauses in these securities. For this reason, the Commission designates the proposed rule change as operative upon the date of this Notice.[17]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–EDGX–2011–36 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–EDGX–2011–36. 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 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 No. SR–EDGX–2011–36 and should be submitted on or before December 21, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–30818 Filed 11–29–11; 8:45 am]

BILLING CODE 8011–01–P

[17] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65820; File No. SR–ISE–2011–79]

Self-Regulatory Organizations; International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend ISE Rule 2102(f) to Exclude From the Pilot Rule All Rights and Warrants

November 23, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 22, 2011, the International Securities Exchange, LLC (the ''Exchange'' or the ''ISE'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 2102(f) to exclude from the pilot rule all rights and warrants.

The text of the proposed rule change is available on the Exchange's Internet Web site at *http://www.ise.com*, at the principal office of the Exchange, and at the Commission's Public Reference Room, and at the Commission's Web site at *http://www.sec.gov*.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

ISE proposes to amend Rule 2102(f) to exclude all rights and warrants from the trading pause process under the rule. The Securities and Exchange Commission (''Commission'') approved Rule 2102(f) on a pilot basis on June 10, 2010, together with the analogous rules of other equity exchanges (collectively with NASDAQ, the ''Exchanges'') and FINRA, to provide for trading pauses in individual securities due to extraordinary market volatility in all securities included within the S&P 500 Index (''S&P 500'') (the ''Pause Pilot'').[3] NASDAQ noted in its filing to adopt Rule 2102(f) that during the Pause Pilot period it would continue to assess whether additional securities need to be

[3] The Commission approved the Pause Pilot for all equities exchanges and FINRA. *See* Securities Exchange Act Release No. 62252 (June 10, 2010), 75 FR 34186 (June 16, 2010) (File Nos. SR–BATS–2010–014; SR–EDGA–2010–01; SR–EDGX–2010–01; SR–BX–2010–037; SR–ISE–2010–48; SR–NYSE–2010–39; SR–NYSEAmex–2010–46; SR–NYSEArca–2010–41; SR–NASDAQ–2010–061; SR–CHX–2010–10; SR–NSX–2010–05; and SR–CBOE–2010–047), and Securities Exchange Act Release No. 62251 (June 10, 2010), 75 FR 34183 (June 16, 2010) (SR–FINRA–2010–025).

added and whether the parameters of Rule 2102(f) would need to be modified to accommodate trading characteristics of different securities. The Exchanges and FINRA subsequently received approval to add to the Pause Pilot the securities included in the Russell 1000 Index (''Russell 1000'') and a specified list of Exchange Traded Products (''ETPs'').[4]

On June 23, 2011, the Commission approved proposed rule changes of the Exchanges and FINRA to amend their respective rules to expand the Pause Pilot to include all remaining NMS stocks (''Phase III Securities''), which includes rights and warrants.[5] Unlike the original Pause Pilot securities, amended Rule 2102(f) applies wider percentage price moves to the Phase III Securities before a trading pause is triggered.[6] The changes to Rule 2102(f) became effective on August 8, 2011.

The Exchanges and FINRA analyzed the nature of the trading pauses triggered since adoption of the Pause Pilot and found that over 25% of such pauses have occurred in rights and warrants. Further, the Exchanges and FINRA have experienced a significant increase in trading pauses involving rights and warrants since the implementation of the Phase III Securities, with such pauses representing approximately 52% of all trading pauses occurring through the end of August 2011. Rights and warrants trade on equity exchanges, but are closely related to call options. Rights and warrants entitle owners to purchase shares of stock at predetermined prices subject to various timing and other conditions. Like options, the price of rights and warrants are affected by the price of the underlying stock as well as other factors, particularly the volatility of the stock. As a consequence, the prices of rights and warrants may move more dramatically than the prices of the underlying stocks even when the rights and warrants (and the underlying stock) are trading in an orderly manner. This difference in trading behavior may result in the rights and warrants triggering the circuit breaker under Rule 2102(f) and being subject to a trading pause, even while the underlying stock continues to trade. This can be particularly true of rights and warrants that have low prices. As such, the Exchanges and FINRA have determined to exclude rights and warrants from the Pause Pilot, and accordingly, ISE is proposing to amend Rule 2102(f) to exclude rights and warrants from the rule's application.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[7] in general, and furthers the objectives of Section 6(b)(5),[8] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system. The proposed rule change also is designed to support the principles of Section 11A(a)(1)[9] of the Act in that it seeks to ensure fair competition among brokers and dealers and among exchange markets. ISE believes that the proposed rule meets these requirements because it excludes certain securities from the rule's coverage that are prone to triggering pauses because of their unique characteristics. These securities are unique in that they may move more dramatically than the prices of the underlying stocks to which they are related even when both securities are trading in an orderly manner. As such, the securities that are subject to this proposal may trigger the circuit breaker under Rule 2102(f) and be subject to a trading pause, even while the underlying security continues to trade. Although there is little benefit in pausing trading in these securities, such pauses sequester regulatory resources that are better applied to the review of trading pauses in other securities that have a greater impact on the national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not 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 has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[10] and Rule 19b–4(f)(6) thereunder.[11] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[12] and Rule 19b–4(f)(6)(iii) thereunder.[13]

A proposed rule change filed under Rule 19b–4(f)(6)[14] normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii)[15] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that

[4] The Commission approved the addition to the Pause Pilot of the securities included in the Russell 1000 and ETPs, where applicable, for all equities exchanges and FINRA. *See* Securities Exchange Act Release No. 62884 (September 10, 2010), 75 FR 56618 (September 16, 2010) (File Nos. SR–BATS–2010–018; SR–BX–2010–044; SR–CBOE–2010–065; SR–CHX–2010–14; SR–EDGA–2010–05; SR–EDGX–2010–05; SR–ISE–2010–66; SR–NASDAQ–2010–079; SR–NYSE–2010–49; SR–NYSEAmex–2010–63; SR–NYSEArca–2010–61; and SR–NSX–2010–08, and Securities Exchange Act Release No. 62883 (September 10, 2010), 75 FR 56608 (September 16, 2010) (SR–FINRA–2010–033). ISE submitted a proposed rule change shortly after the addition of the Russell 1000 securities and ETPs to extend the operation of the Pause Pilot, which was set to expire on December 10, 2010, until April 11, 2011. *See* Securities Exchange Act Release No. 63506 (December 9, 2010), 75 FR 78301 (December 15, 2010) (SR–ISE–2010–117). On March 31, 2011, ISE submitted a proposed rule change to further extend the Pause Pilot until the earlier of August 11, 2011 or the date on which a limit up/limit down mechanism to address extraordinary market volatility, if adopted, applies. *See* Securities Exchange Act Release No. 64193 (April 5, 2011), 76 FR 20062 (April 11, 2011) (SR–ISE–2011–17). On August 8, 2011, ISE submitted a proposed rule change to further extend the Pause Pilot until January 31, 2012. *See* Securities Exchange Act Release No. 65072 (August 9, 2011), 76 FR 50513 (August 15, 2011) (SR–ISE–2011–52).

[5] *See* Securities Exchange Act Release No. 64735 (June 23, 2011), 76 FR 38243 (June 29, 2011) (SR–ISE–2011–028, *et al.*).

[6] *Id.*

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78k–1(a)(1).

[10] 15 U.S.C. 78s(b)(3)(A)(iii).

[11] 17 CFR 240.19b–4(f)(6).

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[14] 17 CFR 240.19b–4(f)(6).

[15] 17 CFR 240.19b–4(f)(6)(iii).

the proposal may become operative immediately upon filing.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Including rights and warrants in the pilot program which may trigger a circuit breaker and be subject to a trading pause, even while the underlying security continues to trade, provides little benefit and has the potential to create confusion among investors. Excluding rights and warrants from the pilot program should minimize investor confusion that could result from temporary trading pauses in these securities. For this reason, the Commission designates the proposed rule change as operative upon the date of this Notice.[16]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*);

or

- Send an email to *rule-comments@sec.gov.* Please include File No. SR–ISE–2011–79 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–ISE–2011–79. 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 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 No. SR–ISE–2011–79 and should be submitted on or before December 21, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–30815 Filed 11–29–11; 8:45 am]

BILLING CODE 8011–01–P

[16] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65825; File No. SR–C2–2011–036]

Self-Regulatory Organizations; C2 Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Related to Trading Halts

November 23, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b-4 thereunder,[2] notice is hereby given that on November 23, 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.

[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).

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is proposing to make a conforming amendment to C2 Rule 6.32, *Trading Halts,* as it relates to individual stock trading pauses in underlying stocks. 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's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The individual stock trading pause pilot rule was developed in consultation with U.S. listing markets to provide for uniform market-wide trading pause standards for certain underlying individual stocks that experience rapid price movement. In conjunction with the pilot, C2 (and other options exchanges) adopted rules that provide that trading in the overlying options on an eligible stock would halt when the primary listing market for the underlying stock issues a trading pause.

The underlying individual stock trading pause pilot was recently expanded to include all NMS stocks.[5]

[5] The pilot list of stocks originally included all stocks in the S&P 500 Index, but it has been expanded over time to include all NMS stocks. *See, e.g.,* Securities Exchange Act Release Nos. 62884 (September 10, 2010), 75 FR 56618 (September 16, 2010)(SR–CBOE–2010–065)(order approving

Continued

However, it is currently being revised to exclude all rights and warrants.[6] In light of the revision to the underlying individual stock trading pause pilot, C2 is proposing a conforming amendment to its Rule 6.32. Specifically, the Exchange is proposing to replace a reference to ''an underlying NMS stock'' with a conforming reference to ''underlying eligible NMS stock'' and to define the term ''eligible NMS stocks'' to mean NMS stocks, other than rights and warrants.

2. Statutory Basis

The statutory basis for the proposed rule change is Section 6(b)(5) of the Act,[7] which requires the rules of an exchange to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. The proposed rule change also is designed to support the principles of Section 11A(a)(1)[8] of the Act in that it seeks to assure fair competition among brokers and dealers and among exchange markets. The Exchange believes that the proposed rule change meets these requirements because it conforms the rule text to reflect the recent modification to underlying individual stock trading pause pilot to exclude all rights and warrants, which pilot promotes uniformity across markets concerning decisions to pause trading in a stock when there are significant price movements.

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.

expansion of the individual stock trading pause pilot to include all stocks in the Russell 1000 index and a pilot list of Exchange Traded Products) and 64735 (June 23, 2011), 76 FR 38243 (June 29, 2011)(SR–CBOE–2011–049)(order approving further expansion of the individual stock trading pause pilot to include all NMS stocks effective August 8, 2011).

[6] *See, e.g.,* SR–CBOE–2011–111.

[7] 15 U.S.C. 78f(b)(5).

[8] 15 U.S.C. 78k–1(a)(1).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[9] and Rule 19b–4(f)(6) thereunder.[10] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[11] and Rule 19b-4(f)(6)(iii) thereunder.[12]

A proposed rule change filed under Rule 19b–4(f)(6)[13] normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii)[14] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Including rights and warrants in the pilot program which may trigger a circuit breaker and be subject to a trading pause, even while the underlying security continues to trade, provides little benefit and has the potential to create confusion among investors. Excluding rights and warrants from the pilot program should minimize investor confusion that could result from temporary trading pauses in these securities. For this reason, the Commission designates the proposed rule change as operative upon the date of this Notice.[15]

[9] 15 U.S.C. 78s(b)(3)(A)(iii).

[10] 17 CFR 240.19b–4(f)(6).

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[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 also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File No. SR–C2–2011–036 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–C2–2011–036. 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 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 No. SR–C2–2011–036 and should be submitted on or before December 21, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–30820 Filed 11–29–11; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65812; File No. SR–NYSEArca–2011–87]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending NYSE Arca Equities Rule 7.11 to Exclude All Rights and Warrants From the Single Stock Circuit Breaker Under the Rule

November 23, 2011.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on November 17, 2011, NYSE Arca, Inc. (the ''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend NYSE Arca Equities Rule 7.11 to exclude all rights and warrants from the single stock circuit breaker under the rule. The text of the proposed rule change is available at the Exchange, the Commission's Public Reference Room, *http://www.nyse.com,* and *http://www.sec.gov.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend NYSE Arca Equities Rule 7.11 to exclude all rights and warrants from the single stock circuit breaker under the rule. The Commission approved NYSE Arca Equities Rule 7.11 on a pilot basis on June 10, 2010 to provide for trading pauses in individual securities due to extraordinary market volatility (''Trading Pause'') in all securities included within the S&P 500® Index (''S&P 500'') (''Pause Pilot'').[4] The Exchange noted in its filing to adopt NYSE Arca Equities Rule 7.11 that during the Pause Pilot period it would continue to assess whether additional securities need to be added and whether the parameters of NYSE Arca Equities Rule 7.11 would need to be modified to accommodate trading characteristics of different securities. The Exchange subsequently received approval to add to the Pause Pilot the securities included in the Russell 1000® Index (''Russell 1000'') and a specified list of Exchange Traded Products (''ETPs'').[5]

On June 23, 2011, the Commission approved proposed rule changes of the Exchanges to amend certain of their respective rules to expand the Pause Pilot to include all remaining NMS stocks (''Phase III Securities''), which included rights and warrants.[6] Unlike the original Pause Pilot securities, amended NYSE Arca Equities Rule 7.11 applies wider percentage price moves to the Phase III Securities before a trading pause is triggered.[7] The changes to NYSE Arca Equities Rule 7.11 became effective on August 8, 2011.

The nature of the trading pauses triggered since adoption of the Pause Pilot has been analyzed and over 25% of such pauses have occurred in rights and warrants. Further, exchanges have experienced a significant increase in trading pauses involving rights and warrants since the implementation of the Phase III Securities, with such pauses representing as much as 52% [sic] all trading pauses occurring through the end of August 2011 on one exchange. Rights and warrants trade on equity exchanges, but are closely related to call options. Rights and warrants entitle owners to purchase shares of stock at predetermined prices subject to various timing and other conditions. Like options, the price of rights and warrants are affected by the price of the underlying stock as well as other factors, particularly the volatility of the stock. As a consequence, the prices of rights and warrants may move more dramatically than the prices of the underlying stocks even when the rights and warrants (and the underlying stock) are trading in an orderly manner. This difference in trading behavior may result in a scenario whereby the rights and warrants trigger the circuit breaker under NYSE Arca Equities Rule 7.11 and are subject to a trading pause, even while the underlying stock continues to trade. This can be particularly true of rights and warrants that have low prices. Accordingly, the Exchange is proposing to exclude rights and

[16] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Commission approved the Pause Pilot for all equities exchanges and FINRA. *See* Securities Exchange Act Release No. 62252 (June 10, 2010), 75 FR 34186 (June 16, 2010) (File Nos. SR–BATS–2010–014; SR–EDGA–2010–01; SR–EDGX–2010–01; SR–BX–2010–037; SR–ISE–2010–48; SR–NYSE–2010–39; SR–NYSEAmex–2010–46; SR–NYSEArca–2010–41; SR–NASDAQ–2010–061; SR–CHX–2010–10; SR–NSX–2010–05; and SR–CBOE–2010–047) and Securities Exchange Act Release No. 62251 (June 10, 2010), 75 FR 34183 (June 16, 2010) (SR–FINRA–2010–025).

[5] The Commission approved the addition to the Pause Pilot of the securities included in the Russell 1000 and ETPs, where applicable, for all equities exchanges and FINRA. *See* Securities Exchange Act Release No. 62884 (September 10, 2010), 75 FR 56618 (September 16, 2010) (File Nos. SR–BATS–2010–018; SR–BX–2010–044; SR–CBOE–2010–065; SR–CHX–2010–14; SR–EDGA–2010–05; SR–EDGX–2010–05; SR–ISE–2010–66; SR–NASDAQ–2010–079; SR–NYSE–2010–49; SR–NYSEAmex–2010–63; SR–NYSEArca–2010–61; and SR–NSX–2010–08 and Securities Exchange Act Release No. 62883 (September 10, 2010), 75 FR 56608 (September 16, 2010) (SR–FINRA–2010–033). The Exchange submitted a proposed rule change shortly after the addition of the Russell 1000 securities and ETPs to extend the operation of the Pause Pilot, which was set to expire on December 10, 2010, until April 11, 2011. *See* Securities Exchange Act Release No. 63496 (December 9, 2010), 75 FR 78285 (December 15, 2010) (NYSEArca–2010–114). The Exchange submitted a proposed rule change to further extend the Pause Pilot until the earlier of January 31, 2012 or the date on which a limit up/limit down mechanism to address extraordinary market volatility, if adopted, applies. *See* Securities Exchange Act Release No. 65088 (August 10, 2011), 76 FR 50793 (August 16, 2011) (NYSEArca–2011–55).

[6] *See* Securities Exchange Act Release No. 64735 (June 23, 2011), 76 FR 38243 (June 29, 2011) (NYSEArca–2011–26, *et al.*).

[7] Under amended NYSE Arca Equities Rule 7.11, a pause is triggered by a 30% or more price move in a Phase III Security priced at $1 or higher, and by a 50% or more price move to such a security priced less than $1. The price of a security is based on the closing price on the previous trading day, or, if no closing price exists, the last sale reported to the Consolidated Tape on the previous trading day.

warrants from the trading pause under NYSE Arca Equities Rule 7.11.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[8] in general, and furthers the objectives of Section 6(b)(5),[9] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system. The proposed rule change also is designed to support the principles of Section 11A(a)(1)[10] of the Act in that it seeks to ensure fair competition among brokers and dealers and among exchange markets. The Exchange believes that the proposed rule meets these requirements because it excludes certain securities from the rule's coverage that are prone to triggering pauses because of their unique characteristics. These securities are unique in that they may move more dramatically than the prices of the underlying stocks to which they are related even when both securities are trading in an orderly manner. As such, the securities that are subject to this proposal may trigger the circuit breaker under NYSE Arca Equities Rule 7.11 and be subject to a trading pause, even while the underlying security continues to trade. Although there is little benefit in pausing trading in these securities, such pauses sequester regulatory resources that are better applied to the review of trading pauses in other securities that have a greater impact on the national market system.

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.

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78k–1(a)(1).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[11] and Rule 19b–4(f)(6) thereunder.[12] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[13] and Rule 19b–4(f)(6)(iii) thereunder.[14]

A proposed rule change filed under Rule 19b–4(f)(6)[15] normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii)[16] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Including rights and warrants in the pilot program which may trigger a circuit breaker and be subject to a trading pause, even while the underlying security continues to trade, provides little benefit and has the potential to create confusion among investors. Excluding rights and warrants from the pilot program should minimize investor confusion that could result from temporary trading pauses in these securities. For this reason, the Commission designates the proposed rule change as operative upon the date of this Notice.[17]

[11] 15 U.S.C. 78s(b)(3)(A)(iii).

[12] 17 CFR 240.19b–4(f)(6).

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[15] 17 CFR 240.19b–4(f)(6).

[16] 17 CFR 240.19b–4(f)(6)(iii).

[17] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–NYSEArca–2011–87 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–NYSEArca–2011–87. 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 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 No. SR–NYSEArca–2011–87 and should be submitted on or before December 21, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–30807 Filed 11–29–11; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65822; File No. SR–EDGA–2011–38]

Self-Regulatory Organizations; EDGA Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Amend EDGA Rule 11.14 to Exclude From the Pilot Rule All Rights and Warrants

November 23, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 22, 2011, the EDGA Exchange, Inc. (the ''Exchange'' or the ''EDGA'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend EDGA Rule 11.14 to exclude from the pilot rule all rights and warrants. The text of the proposed rule change is attached as Exhibit 5[3] and is available on the Exchange's Web site at *http://www.directedge.com*, at the Exchange's principal office, at the Public Reference Room of the Commission, and at *http://www.sec.gov*.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend EDGA Rule 11.14(d) to exclude all rights and warrants from the single stock circuit breaker under the rule. The Commission approved EDGA Rule 11.14 on a pilot basis on June 10, 2010 to provide for trading pauses in individual securities due to extraordinary market volatility (''Trading Pause'') in all securities included within the S&P 500® Index (''S&P 500'') (''Pause Pilot'').[4] The Exchange noted in its filing to adopt EDGA Rule 11.14 that during the Pause Pilot period it would continue to assess whether additional securities need to be added and whether the parameters of EDGA Rule 11.14 would need to be modified to accommodate trading characteristics of different securities. The Exchange subsequently received approval to add to the Pause Pilot the securities included in the Russell 1000 reg; Index (''Russell 1000'') and a specified list of Exchange Traded Products (''ETPs'').[5]

On June 23, 2011, the Commission approved proposed rule changes of the Exchanges to amend certain of their respective rules to expand the Pause Pilot to include all remaining NMS stocks (''Phase III Securities''), which included rights and warrants.[6] Unlike the original Pause Pilot securities, the rules of primary listing markets apply wider percentage price moves to the Phase III Securities before a trading pause is triggered.[7] These changes to the rules of primary listing markets became effective on August 8, 2011.

Various exchanges and national securities associations, including the Exchange, have analyzed the nature of the trading pauses triggered since adoption of the Pause Pilot and noted that over 25% of such pauses have occurred in rights and warrants. Further, several primary listing markets have experienced a significant increase in trading pauses involving rights and warrants since the implementation of the Phase III Securities, with such pauses representing approximately 52% [sic] all trading pauses occurring through the end of August 2011. Rights and warrants trade on equity exchanges, but are closely related to call options. Rights and warrants entitle owners to purchase shares of stock at predetermined prices subject to various timing and other conditions. Like options, the price of rights and warrants are affected by the price of the underlying stock as well as other factors, particularly the volatility of the stock. As a consequence, the prices of rights and warrants may move more dramatically than the prices of the underlying stocks even when the rights and warrants (and the underlying stock) are trading in an orderly manner. This difference in trading behavior may result in a scenario whereby the rights and warrants trigger the circuit breaker under the rules of various primary listing markets and are subject to a trading pause, even while the

[18] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Commission notes that Exhibit 5 is attached to the rule filing, but not to this Notice.

[4] The Commission approved the Pause Pilot for all equities exchanges and FINRA. *See* Securities Exchange Act Release No. 62252 (June 10, 2010), 75 FR 34186 (June 16, 2010) (File Nos. SR–BATS–2010–014; SR–EDGA–2010–01; SR–EDGX–2010–01; SR–BX–2010–037; SR–ISE–2010–48; SR–NYSE–2010–39; SR–NYSEAmex-2010–46; SR–NYSEArca-2010–41; SR–NASDAQ–2010–061; SR–CHX–2010–10; SR–NSX–2010–05; and SR–CBOE–2010–047) and Securities Exchange Act Release No. 62251 (June 10, 2010), 75 FR 34183 (June 16, 2010) (SR–FINRA–2010–025).

[5] The Commission approved the addition to the Pause Pilot of the securities included in the Russell 1000 and ETPs, where applicable, for all equities exchanges and FINRA. *See* Securities Exchange Act Release No. 62884 (September 10, 2010), 75 FR 56618 (September 16, 2010) (File Nos. SR–BATS–2010–018; SR–BX–2010–044; SR–CBOE–2010–065; SR–CHX–2010–14; SR–EDGA–2010–05; SR–EDGX–2010–05; SR–ISE–2010–66; SR–NASDAQ–2010–079; SR–NYSE–2010–49; SR–NYSEAmex–2010–63; SR–NYSEArca–2010–61; and SR–NSX–2010–08 and Securities Exchange Act Release No. 62883 (September 10, 2010), 75 FR 56608 (September 16, 2010) (SR–FINRA–2010–033). The Exchange submitted a proposed rule change shortly after the addition of the Russell 1000 securities and ETPs to extend the operation of the Pause Pilot, which was set to expire on December 10, 2010, until April 11, 2011. *See* Securities Exchange Act Release No. 63514 (December 9, 2010), 75 FR 78783 (December 16, 2010) (SR–EDGA–2010–23). On April 5, 2011, the Exchange submitted a proposed rule change to further extend the Pause Pilot until the earlier of August 11, 2011 or the date on which a limit up/limit down mechanism to address extraordinary market volatility, if adopted, applies. *See* Securities Exchange Act Release No. 64204 (April 6, 2011), 76 FR 20394 (April 12, 2011) (SR–EDGA–2011–11).

[6] *See* Securities Exchange Act Release No. 64735 (June 23, 2011), 76 FR 38243 (June 29, 2011) (SR–EDGA–2011–15 and Amendment No. 1 thereto, *et al*).

[7] Under the rules of primary listing markets, (i.e. Nasdaq Rule 4120(a)(11)), a pause is triggered by a 30% or more price move in a Phase III Security priced at $1 or higher, and by a 50% or more price move to such a security priced less than $1. The price of a security is based on the closing price on the previous trading day, or, if no closing price exists, the last sale reported to the Consolidated Tape on the previous trading day.

underlying stock continues to trade. This can be particularly true of rights and warrants that have low prices. Accordingly, EDGA is proposing to exclude rights and warrants from the trading pauses issued by primary listing markets, as referenced in EDGA Rule 11.14(d).

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[8] in general, and furthers the objectives of Section 6(b)(5),[9] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system. The proposed rule change also is designed to support the principles of Section 11A(a)(1)[10] of the Act in that it seeks to ensure fair competition among brokers and dealers and among exchange markets. The Exchange believes that the proposed rule meets these requirements because it excludes certain securities from the rule's coverage that are prone to triggering pauses because of their unique characteristics. These securities are unique in that they may move more dramatically than the prices of the underlying stocks to which they are related even when both securities are trading in an orderly manner. As such, the securities that are subject to this proposal may trigger the circuit breaker under the rules of various primary listing markets and be subject to a trading pause, even while the underlying security continues to trade. Although there is little benefit in pausing trading in these securities, such pauses sequester regulatory resources that are better applied to the review of trading pauses in other securities that have a greater impact on the national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not 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 has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[11] and Rule 19b-4(f)(6) thereunder.[12] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[13] and Rule 19b-4(f)(6)(iii) thereunder.[14]

A proposed rule change filed under Rule 19b–4(f)(6)[15] normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii)[16] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Including rights and warrants in the pilot program which may trigger a circuit breaker and be subject to a trading pause, even while the underlying security continues to trade, provides little benefit and has the potential to create confusion among investors. Excluding rights and warrants from the pilot program should minimize investor confusion that could result from temporary trading pauses in these securities. For this reason, the Commission designates the proposed rule change as operative upon the date of this Notice.[17]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–EDGA–2011–38 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–EDGA–2011–38. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet 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

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78k–1(a)(1).

[11] 15 U.S.C. 78s(b)(3)(A)(iii).

[12] 17 CFR 240.19b–4(f)(6).

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[15] 17 CFR 240.19b–4(f)(6).

[16] 17 CFR 240.19b–4(f)(6)(iii).

[17] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–EDGA–2011–38 and should be submitted on or before December 21, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–30817 Filed 11–29–11; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65821; File No. SR–NSX–2011–13]

Self-Regulatory Organizations; National Stock Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Exclude All Rights and Warrants From the Definition of ''Circuit Breaker Securities'' and Providing the Appropriate Provisions for an Early Scheduled Close

November 23, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 18, 2011, National Stock Exchange, Inc. filed with the Securities and Exchange Commission (''Commission'') the proposed rule change, as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comment on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

National Stock Exchange, Inc. (''NSX®'' or the ''Exchange''), proposes to amend NSX Rule 11.20 to coordinate its rule with those of other markets, by excluding all rights and warrants from the definition of ''Circuit Breaker Securities'' and providing the appropriate provisions for an early scheduled close.

The text of the proposed rule change is available on the Exchange's Web site at *http://www.nsx.com*, at the principal office of the Exchange, at the Commission's Public Reference Room, and at the Commission's Web site at *http://www.sec.gov.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend NSX Rule 11.20B Commentary .05 to exclude all rights and warrants from the single stock circuit breaker under the rule and add additional direction for when pauses are triggered on early closing days. The Commission approved NSX Rule 11.20B on a pilot basis on June 10, 2010 to provide for trading pauses in individual securities due to extraordinary market volatility (''Trading Pause'') in all securities included within the S&P 500® Index (''S&P 500'') (''Pause Pilot'').[3] The Exchange noted in its filing to adopt NSX Rule 11.20B that during the Pause Pilot period it would continue to assess whether additional securities need to be added and whether the parameters of NSX Rule 11.20B would need to be modified to accommodate trading characteristics of different securities. The Exchange subsequently received approval to add to the Pause Pilot the securities included in the Russell 1000® Index (''Russell 1000'') and a specified list of Exchange Traded Products (''ETPs'').[4]

On June 23, 2011, the Commission approved proposed rule changes of the Exchanges to amend certain of their respective rules to expand the Pause Pilot to include all remaining NMS stocks (''Phase III Securities''), which included rights and warrants.[5] Unlike the original Pause Pilot securities, amended NSX Rule 11.20B applies wider percentage price moves to the Phase III Securities before a trading pause is triggered.[6] The changes to NSX Rule 11.20B became effective on August 8, 2011.

Since then, the markets have analyzed the nature of the trading pauses triggered since adoption of the Pause Pilot and noted that over 25% of such pauses have occurred in rights and warrants. Further, the markets have experienced a significant increase in trading pauses involving rights and warrants since the implementation of the Phase III Securities, with such pauses representing approximately 52% [sic] all trading pauses occurring through the end of August 2011. Rights and warrants trade on equity exchanges, but are closely related to call options. Rights and warrants entitle owners to purchase shares of stock at predetermined prices subject to various timing and other conditions. Like options, the price of rights and warrants

[18] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Commission approved the Pause Pilot for all equities exchanges and FINRA. *See* Securities Exchange Act Release No. 62252 (June 10, 2010), 75 FR 34186 (June 16, 2010) (File Nos. SR–BATS–2010–014; SR–EDGA–2010–01; SR–EDGX–2010–01; SR–BX–2010–037; SR–ISE–2010–48; SR–NYSE–2010–39; SR–NYSEAmex–2010–46; SR–NYSEArca–2010–41; SR–NASDAQ–2010–061; SR–CHX–2010–10; SR–NSX–2010–05; and SR–CBOE–2010–047) and Securities Exchange Act Release No. 62251 (June 10, 2010), 75 FR 34183 (June 16, 2010) (SR–FINRA–2010–025).

[4] The Commission approved the addition to the Pause Pilot of the securities included in the Russell 1000 and ETPs, where applicable, for all equities exchanges and FINRA. *See* Securities Exchange Act Release No. 62884 (September 10, 2010), 75 FR 56618 (September 16, 2010) (File Nos. SR–BATS–2010–018; SR–BX–2010–044; SR–CBOE–2010–065; SR–CHX–2010–14; SR–EDGA–2010–05; SR–EDGX–2010–05; SR–ISE–2010–66; SR–NASDAQ–2010–079; SR–NYSE–2010–49; SR–NYSEAmex–2010–63; SR–NYSEArca–2010–61; and SR–NSX–2010–08 and Securities Exchange Act Release No. 62883 (September 10, 2010), 75 FR 56608 (September 16, 2010) (SR–FINRA–2010–033). The Exchange submitted a proposed rule change shortly after the addition of the Russell 1000 securities and ETPs to extend the operation of the Pause Pilot, which was set to expire on December 10, 2010, until April 11, 2011. *See* Securities Exchange Act Release No. 63512 (December 9, 2010), 75 FR 78786 (December 16, 2010) (SR–NSX–2010–17). On March 31, 2011, the Exchange submitted a proposed rule change to further extend the Pause Pilot until the earlier of August 11, 2011 or the date on which a limit up/limit down mechanism to address extraordinary market volatility, if adopted, applies. *See* Securities Exchange Act Release No. 64213 (April 6, 2011), 76 FR 20409 (April 12, 2011) (SR–NSX–2011–04).

[5] *See* Securities Exchange Act Release No. 64735 (June 23, 2011), 76 FR 38243 (June 29, 2011) (SR–NSX–2011–06, *et al.*).

[6] Under amended NSX Rule 11.20B, a pause is triggered by a 30% or more price move in a Phase III Security priced at $1 or higher, and by a 50% or more price move to such a security priced less than $1. The price of a security is based on the closing price on the previous trading day, or, if no closing price exists, the last sale reported to the Consolidated Tape on the previous trading day.

are affected by the price of the underlying stock as well as other factors, particularly the volatility of the stock. As a consequence, the prices of rights and warrants may move more dramatically than the prices of the underlying stocks even when the rights and warrants (and the underlying stock) are trading in an orderly manner. This difference in trading behavior may result in a scenario whereby the rights and warrants trigger the circuit breaker under NSX Rule 11.20B and are subject to a trading pause, even while the underlying stock continues to trade. This can be particularly true of rights and warrants that have low prices. Accordingly, the Exchange is proposing to exclude rights and warrants from the trading pause under NSX Rule 11.20B.

Finally, as a conforming edit, the Exchange has added language to address when individual trading pauses would occur on a day of an early close. This change ensures the Exchange remains in agreement with the other markets with respect to when the pauses will be triggered on early closing days.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[7] in general, and furthers the objectives of Section 6(b)(5),[8] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system. The proposed rule change also is designed to support the principles of Section 11A(a)(1)[9] of the Act in that it seeks to ensure fair competition among brokers and dealers and among exchange markets. The Exchange believes that the proposed rule meets these requirements because it excludes certain securities from the rule's coverage that are prone to triggering pauses because of their unique characteristics. These securities are unique in that they may move more dramatically than the prices of the underlying stocks to which they are related even when both securities are trading in an orderly manner. As such, the securities that are subject to this proposal may trigger the circuit breaker under NSX Rule 11.20B and be subject to a trading pause, even while the underlying security continues to trade. Although there is little benefit in pausing trading in these securities, such pauses sequester regulatory resources that are better applied to the review of trading pauses in other securities that have a greater impact on the national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[10] and Rule 19b–4(f)(6) thereunder.[11] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[12] and Rule 19b–4(f)(6)(iii) thereunder.[13]

A proposed rule change filed under Rule 19b–4(f)(6)[14] normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii)[15] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Including rights and warrants in the pilot program which may trigger a circuit breaker and be subject to a trading pause, even while the underlying security continues to trade, provides little benefit and has the potential to create confusion among investors. Excluding rights and warrants from the pilot program should minimize investor confusion that could result from temporary trading pauses in these securities. For this reason, the Commission designates the proposed rule change as operative upon the date of this Notice.[16]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–NSX–2011–13 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–NSX–2011–13. 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/*

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78k–1(a)(1).

[10] 15 U.S.C. 78s(b)(3)(A)(iii).

[11] 17 CFR 240.19b–4(f)(6).

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[14] 17 CFR 240.19b–4(f)(6).

[15] 17 CFR 240.19b–4(f)(6)(iii).

[16] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–NSX–2011–13 and should be submitted on or before December 21, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–30816 Filed 11–29–11; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65819; File No. SR–FINRA–2011–068]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend FINRA Rule 6121.01 (Trading Pauses) To Exclude Rights and Warrants From the Trading Pause Pilot

November 23, 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 21, 2011, Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by FINRA. FINRA has designated the proposed rule change as constituting a ''non-controversial'' rule change under paragraph (f)(6) of Rule 19b–4 under the Act,[3] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to amend Supplementary Material .01 (Trading Pauses) to FINRA Rule 6121 (Trading Halts Due to Extraordinary Market Volatility) to exclude all rights and warrants from the trading pause pilot.

The text of the proposed rule change is available on FINRA's Web site at *http://www.finra.org,* at the principal office of FINRA and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

FINRA proposes to amend FINRA Rule 6121.01 (Trading Pauses) to exclude all rights and warrants from the trading pause pilot. The Commission approved FINRA Rule 6121.01 on a pilot basis on June 10, 2010 to provide for trading pauses in individual securities due to extraordinary market volatility (''Trading Pause Pilot'').[4] The pilot was developed and implemented as a market-wide initiative by FINRA and other self-regulatory organizations (''SROs'') in consultation with Commission staff. Initially, the pilot covered only the securities included in the S&P 500® Index (''S&P 500'') (''Phase I securities''). FINRA and the other SROs subsequently expanded the Trading Pause Pilot to add the securities included in the Russell 1000® Index and a specified list of exchange traded products (''Phase II securities'').[5] FINRA and the other SROs have stated in previous filings that they would continue to review whether and when to add securities to the pilot and whether the parameters of the pilot should be adjusted for different securities.[6]

On June 23, 2011, the Commission approved proposed amendments by FINRA and the other SROs to expand the Trading Pause Pilot to include all remaining NMS stocks (''Phase III securities''), which included rights and warrants.[7] With respect to the Phase III securities, the SRO rules[8] apply wider percentage price moves for triggering a trading pause than apply to the Phase I or Phase II securities.[9]

The trading pauses triggered since the adoption of the Trading Pause Pilot have been analyzed and over 25% of trading pauses have occurred in rights and warrants. Further, the SROs have experienced a significant increase in trading pauses involving rights and warrants since the inclusion of the Phase III securities, with such pauses representing as much as 52% of all trading pauses occurring through the end of August 2011 on one exchange. Rights and warrants trade on equity exchanges, but are closely related to call options.[10] Like options, the price of rights and warrants are affected by the price of the underlying stock as well as other factors, particularly the volatility of the stock. Consequently, the price of rights and warrants may move more dramatically than the price of the underlying stock, even when the rights and warrants (and the underlying stock)

[17] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6).

[4] *See* Securities Exchange Act Release No. 62251 (June 10, 2010), 75 FR 34183 (June 16, 2010) (Order Approving File No. SR–FINRA–2010–025).

[5] *See* Securities Exchange Act Release No. 62883 (September 10, 2010), 75 FR 56608 (September 16, 2010) (Order Approving File No. SR–FINRA–2010–033).

[6] *See e.g.,* Securities Exchange Act Release No. 62416 (June 30, 2010), 75 FR 39069 (July 7, 2010) (Notice of Filing of File No. SR–FINRA–2010–033).

[7] *See* Securities Exchange Act Release No. 64735 (June 23, 2011), 76 FR 38243 (June 29, 2011) (Order Approving File No. SR–FINRA–2011–023). This amendment became effective on August 8, 2011.

[8] FINRA's trading pause rule does not include specific trigger percentages, but rather provides that FINRA will halt trading otherwise than on an exchange in a security if a primary listing market has issued an individual stock trading pause under its rules.

[9] For example, under amended NASDAQ Rule 4120(a)(11), a pause is triggered by a 30% or more price move in a Phase III Security priced at $1.00 or higher, and by a 50% or more price move to such a security priced less than $1.00. The price of a security is based on the closing price on the previous trading day or, if no closing price exists, the last sale reported to the consolidated tape on the previous trading day.

[10] Rights and warrants entitle owners to purchase shares of stock at predetermined prices subject to timing and various other conditions.

are trading in an orderly manner. This difference in trading behavior may result in a scenario whereby the rights and warrants trigger, and are subject to, a trading pause, even while the underlying stock continues to trade. This can be particularly true of lower-priced rights and warrants. Accordingly, FINRA, in consultation with the other SROs, is proposing to exclude rights and warrants from the trading pause pilot of Rule 6121.01.

FINRA has filed the proposed rule change for immediate effectiveness and has requested that the Commission waive the requirement that the proposed rule change not become operative for 30 days after the date of filing to avoid further triggers of trading pauses in rights and warrants, thereby avoiding the potential confusion caused by such pauses.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[11] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade and, in general, to protect investors and the public interest. FINRA believes that the proposed rule change meets these requirements because it is consistent with the trading pause rules of the primary listing markets and refines the trading pause pilot to exclude certain securities that are prone to triggering pauses because of their unique characteristics. Given the fact that the price of rights and warrants may move more dramatically than the prices of the underlying stocks to which they are related, even when both are trading in an orderly manner, FINRA questions the benefit of applying the trading pause pilot to such securities. FINRA also believes that the proposed rule change promotes uniformity across markets concerning decisions to pause trading in a security when there are significant price movements.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

[11] 15 U.S.C. 78*o*–3(b)(6).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

FINRA has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [12] and Rule 19b–4(f)(6) thereunder.[13] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [14] and Rule 19b–4(f)(6)(iii) thereunder.[15]

A proposed rule change filed under Rule 19b–4(f)(6) [16] normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii) [17] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. FINRA has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Including rights and warrants in the pilot program which may trigger a circuit breaker and be subject to a trading pause, even while the underlying security continues to trade, provides little benefit and has the potential to create confusion among investors. Excluding rights and warrants from the pilot program should minimize investor confusion that could result from temporary trading pauses in these securities. For this reason, the Commission designates the proposed rule change as operative upon the date of this Notice.[18]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File No. SR–FINRA–2011–068 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–FINRA–2011–068. 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

[12] 15 U.S.C. 78s(b)(3)(A)(iii).

[13] 17 CFR 240.19b–4(f)(6).

[14] 15 U.S.C. 78s(b)(3)(A).

[15] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires FINRA to give the Commission written notice of the FINRA's 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. FINRA has satisfied this requirement.

[16] 17 CFR 240.19b–4(f)(6).

[17] 17 CFR 240.19b–4(f)(6)(iii).

[18] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

also will be available for inspection and copying at the principal office of FINRA. 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–FINRA–2011–068 and should be submitted on or before December 21, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–30814 Filed 11–29–11; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65817; File No. SR–BYX–2011–029]

Self-Regulatory Organizations; BATS Y-Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Modify Exchange Rule 11.18 Relating to Trading Pauses Due to Extraordinary Market Volatility

November 23, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 22, 2011, BATS Y-Exchange, Inc. (the ''Exchange'' or ''BYX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing with the Commission a proposal to amend Rule 11.18, entitled ''Trading Halts Due to Extraordinary Market Volatility.''

The text of the proposed rule change is available at the Exchange's Web site at *http://www.batstrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 11.18 to exclude all rights and warrants from the single stock circuit breaker under the rule. On October 4, 2010, the Exchange filed an immediately effective filing to adopt various rule changes to bring BYX Rules up to date with the changes that had been made to the rules of BATS Exchange, Inc., the Exchange's affiliate, while BYX's Form 1 Application to register as a national securities exchange was pending approval. Such changes included changes to the Exchange's Rule 11.18, on a pilot basis, to provide for uniform market-wide trading pause standards for individual securities in the S&P 500® Index, the Russell 1000® Index and specified Exchange Traded Products that experience rapid price movement.[3] On June 23, 2011, the Commission approved proposed rule changes of the Exchanges to amend certain of their respective rules to expand the Pause Pilot to include all remaining NMS stocks (''Phase III Securities''), which included rights and warrants.[4] Unlike the original Pause Pilot securities, the amended Trading Pause Rule applies wider percentage price moves to the Phase III Securities before a trading pause is triggered.[5] The changes to the Trading Pause Rule became effective on August 8, 2011.

Over 25% of the trading pauses have occurred in rights and warrants since adoption of the Pause Pilot. Further, there has been a significant increase in trading pauses involving rights and warrants since the implementation of the Phase III Securities, with such pauses representing approximately 52% [sic] all trading pauses occurring through the end of August 2011. Rights and warrants trade on equity exchanges, but are closely related to call options. Rights and warrants entitle owners to purchase shares of stock at predetermined prices subject to various timing and other conditions. Like options, the price of rights and warrants are affected by the price of the underlying stock as well as other factors, particularly the volatility of the stock. As a consequence, the prices of rights and warrants may move more dramatically than the prices of the underlying stocks even when the rights and warrants (and the underlying stock) are trading in an orderly manner. This difference in trading behavior may result in a scenario whereby the rights and warrants trigger the circuit breaker under the Trading Pause Rule and are subject to a trading pause, even while the underlying stock continues to trade. This can be particularly true of rights and warrants that have low prices. Accordingly, the Exchange is proposing to exclude rights and warrants from the trading pause under the Trading Pause Rule.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[6] in general, and furthers the objectives of Section 6(b)(5),[7] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market

[19] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 63097 (October 13, 2010), 75 FR 64767 (October 20, 2010) (SR–BYX–2010–002). The Exchange subsequently submitted a proposed rule change to extend the operation of the Pause Pilot, which was set to expire on December 10, 2010, until April 11, 2011. Securities Exchange Act Release No. 63513 (December 9, 2010), 75 FR 78784 (December 16, 2010) (SR–BYX–2010–007). On March 31, 2011, the Exchange submitted a proposed rule change to further extend the Pause Pilot until the earlier of August 11, 2011 or the date on which a limit up/limit down mechanism to address extraordinary market volatility, if adopted, applies. Securities Exchange Act Release No. 64214 (April 6, 2011), 76 FR 20430 (April 12, 2011) (SR–BYX–2011–007).

[4] *See* Securities Exchange Act Release No. 64735 (June 23, 2011), 76 FR 38243 (June 29, 2011) (SR–BYX–2011–011, *et al.*).

[5] Under amended rules, a pause is triggered by a 30% or more price move in a Phase III Security priced at $1 or higher, and by a 50% or more price move to such a security priced less than $1. The price of a security is based on the closing price on the previous trading day, or, if no closing price exists, the last sale reported to the Consolidated Tape on the previous trading day.

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

and a national market system. The proposed rule change also is designed to support the principles of Section 11A(a)(1)[8] of the Act in that it seeks to ensure fair competition among brokers and dealers and among exchange markets. The Exchange believes that the proposed rule meets these requirements because it excludes certain securities from the rule's coverage that are prone to triggering pauses because of their unique characteristics. These securities are unique in that they may move more dramatically than the prices of the underlying stocks to which they are related even when both securities are trading in an orderly manner. As such, the securities that are subject to this proposal may trigger the circuit breaker under the Trading Pause Rule and be subject to a trading pause, even while the underlying security continues to trade. Although there is little benefit in pausing trading in these securities, such pauses sequester regulatory resources that are better applied to the review of trading pauses in other securities that have a greater impact on the national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change imposes any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[9] and Rule 19–4(f)(6) thereunder.[10] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[11] and Rule 19b–4(f)(6)(iii) thereunder.[12]

A proposed rule change filed under Rule 19b–4(f)(6)[13] normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii)[14] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Including rights and warrants in the pilot program which may trigger a circuit breaker and be subject to a trading pause, even while the underlying security continues to trade, provides little benefit and has the potential to create confusion among investors. Excluding rights and warrants from the pilot program should minimize investor confusion that could result from temporary trading pauses in these securities. For this reason, the Commission designates the proposed rule change as operative upon the date of this Notice.[15]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–BYX–2011–029 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–BYX–2011–029. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–BYX–2011–029 and should be submitted on or before December 21, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–30812 Filed 11–29–11; 8:45 am]

BILLING CODE 8011–01–P

[8] 15 U.S.C. 78k–1(a)(1).

[9] 15 U.S.C. 78s(b)(3)(A)(iii).

[10] 17 CFR 240.19b–4(f)(6).

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[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 also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65815; File No. SR–BX–2011–079]

Self-Regulatory Organizations; NASDAQ OMX BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Exclude All Rights and Warrants From the Pilot Rule for Trading Pauses Due to Extraordinary Market Volatility

November 23, 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, NASDAQ OMX BX, Inc. (''BX''), filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by BX. 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

BX proposes to exclude all rights and warrants from the pilot trading pause process under Rule 4120(a)(11) by amending IM–4120–3, which defines what is considered a ''Circuit Breaker Security'' under Rule 4120(a)(11).

The text of the proposed rule change is below. Proposed new language is italicized.

* * * * *

IM–4120–3. Circuit Breaker Securities Pilot

The provisions of paragraph (a)(11) of this Rule shall be in effect during a pilot set to end on January 31, 2012. During the pilot, the term ''Circuit Breaker Securities'' shall mean all NMS stocks *except rights and warrants.*

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, BX included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. BX has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

BX proposes to exclude all rights and warrants from the trading pause process described under Rule 4120(a)(11) by excluding them from the definition of ''Circuit Breaker Securities'' under IM–4120–3. The Commission approved Rule 4120(a)(11) and IM–4120–3 on a pilot basis on June 10, 2010, together with the analogous rules of other exchanges (collectively with BX, the ''Exchanges'') and FINRA, to provide for trading pauses in individual securities due to extraordinary market volatility in all securities included within the S&P 500 Index (''S&P 500'') (the ''Pause Pilot'').[3] The Exchanges and FINRA subsequently received approval to add to the Pause Pilot the securities included in the Russell 1000 Index (''Russell 1000'') and a specified list of Exchange Traded Products (''ETPs'').[4]

On June 23, 2011, the Commission approved proposed rule changes of the Exchanges and FINRA to amend their respective rules to expand the Pause Pilot to include all remaining NMS stocks (''Phase III Securities''), which includes rights and warrants.[5] Unlike the original Pause Pilot securities, the amended Pause Pilot applies wider percentage price moves to the Phase III Securities before a trading pause is triggered.[6] The changes to the Pause Pilot became effective on August 8, 2011.

The Exchanges and FINRA have analyzed the nature of trading pauses triggered since adoption of the Pause Pilot and found that over 25% of such pauses have occurred in rights and warrants. Further, the Exchanges and FINRA have experienced a significant increase in trading pauses involving rights and warrants since the implementation of the Phase III Securities, with such pauses representing approximately 52% [sic] all trading pauses occurring through the end of August 2011. Rights and warrants trade on equity exchanges, but are closely related to call options. Rights and warrants entitle owners to purchase shares of stock at predetermined prices subject to various timing and other conditions. Like options, the price of rights and warrants are affected by the price of the underlying stock as well as other factors, particularly the volatility of the stock. As a consequence, the prices of rights and warrants may move more dramatically than the prices of the underlying stocks even when the rights and warrants (and the underlying stock) are trading in an orderly manner. This difference in trading behavior may result in rights and warrants triggering the circuit breaker under the Pause Pilot and being subject to a trading pause, even while the underlying stock continues to trade. This can be particularly true of rights and warrants that have low prices. As such, the Exchanges and FINRA have determined to exclude rights and warrants from the Pause Pilot, and accordingly, BX is proposing to amend IM–4120–3 to exclude rights and warrants from the Pause Pilot under Rule 4120(a)(11).

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[7] in general, and furthers the objectives of

[3] The Commission approved the Pause Pilot for all equities exchanges and FINRA. *See* Securities Exchange Act Release No. 62252 (June 10, 2010), 75 FR 34186 (June 16, 2010) (File Nos. SR–BATS–2010–014; SR–EDGA–2010–01; SR–EDGX–2010–01; SR–BX–2010–037; SR–ISE–2010–48; SR–NYSE–2010–39; SR–NYSEAmex–2010–46; SR–NYSEArca–2010–41; SR–NASDAQ–2010–061; SR–CHX–2010–10; SR–NSX–2010–05; and SR–CBOE–2010–047), and Securities Exchange Act Release No. 62251 (June 10, 2010), 75 FR 34183 (June 16, 2010) (SR–FINRA–2010–025).

[4] The Commission approved the addition to the Pause Pilot of the securities included in the Russell 1000 and ETPs, where applicable, for all equities exchanges and FINRA. *See* Securities Exchange Act Release No. 62884 (September 10, 2010), 75 FR 56618 (September 16, 2010) (File Nos. SR–BATS–2010–018; SR–BX–2010–044; SR–CBOE–2010–065; SR–CHX–2010–14; SR–EDGA–2010–05; SR–EDGX–2010–05; SR–ISE–2010–66; SR–NASDAQ–2010–079; SR–NYSE–2010–49; SR–NYSEAmex–2010–63; SR–NYSEArca–2010–61; and SR–NSX–2010–08, and Securities Exchange Act Release No. 62883 (September 10, 2010), 75 FR 56608 (September 16, 2010) (SR–FINRA–2010–033). BX submitted a proposed rule change shortly after the addition of the Russell 1000 securities and ETPs to extend the operation of the Pause Pilot, which was set to expire on December 10, 2010, until April 11, 2011. *See* Securities Exchange Act Release No. 63527 (December 10, 2010), 75 FR 78781 (December 16, 2010) (SR–BX–2010–088). On March 31, 2011, BX submitted a proposed rule change to further extend the Pause Pilot until the earlier of August 11, 2011 or the date on which a limit up/limit down mechanism to address extraordinary market volatility, if adopted, applies. *See* Securities Exchange Act Release No. 64176 (April 4, 2011), 76 FR 19821 (April 8, 2011) (SR–BX–2011–018). On August 8, 2011, BX submitted a proposed rule change to further extend the Pause Pilot until January 31, 2012. *See* Securities Exchange Act Release No. 65093 (August 10, 2011), 76 FR 50781 (August 16, 2011) (SR–BX–2011–055).

[5] *See* Securities Exchange Act Release No. 64735 (June 23, 2011), 76 FR 38243 (June 29, 2011) (SR–BX–2011–025, *et al.*).

[6] Under the amended Pause Pilot, a pause is triggered by a 30% or more price move in a Phase III Security priced at $1 or higher, and by a 50% or more price move to such a security priced less than $1. The price of a security is based on the closing price on the previous trading day, or, if no closing price exists, the last sale reported to the Consolidated Tape on the previous trading day.

[7] 15 U.S.C. 78f(b).

Section 6(b)(5),[8] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system. The proposed rule change also is designed to support the principles of Section 11A(a)(1)[9] of the Act in that it seeks to ensure fair competition among brokers and dealers and among exchange markets. BX believes that the proposed rule meets these requirements because it excludes certain securities from the rule's coverage that are prone to triggering pauses because of their unique characteristics. These securities are unique in that they may move more dramatically than the prices of the underlying stocks to which they are related even when both securities are trading in an orderly manner. As such, the securities that are subject to this proposal may trigger a Pause Pilot circuit breaker and be subject to a trading pause, even while the underlying security continues to trade. Although there is little benefit in pausing trading in these securities, such pauses sequester regulatory resources that are better applied to the review of trading pauses in other securities that have a greater impact on the national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

BX does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[10] and Rule 19b–(f)(6) thereunder.[11] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[12] and Rule 19b–4(f)(6)(iii) thereunder.[13]

A proposed rule change filed under Rule 19b–4(f)(6)[14] normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii)[15] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Including rights and warrants in the pilot program which may trigger a circuit breaker and be subject to a trading pause, even while the underlying security continues to trade, provides little benefit and has the potential to create confusion among investors. Excluding rights and warrants from the pilot program should minimize investor confusion that could result from temporary trading pauses in these securities. For this reason, the Commission designates the proposed rule change as operative upon the date of this Notice.[16]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–BX–2011–079 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–BX–2011–079. 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 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 No. SR–BX–2011–079 and should be submitted on or before December 21, 2011.

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78k–1(a)(1).

[10] 15 U.S.C. 78s(b)(3)(A)(iii).

[11] 17 CFR 240.19b–4(f)(6).

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[14] 17 CFR 240.19b–4(f)(6).

[15] 17 CFR 240.19b–4(f)(6)(iii).

[16] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–30810 Filed 11–29–11; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65824; File No. SR–CBOE–2011–111]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Related to the Individual Stock Trading Pause Pilot Program

November 23, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 23, 2011, the Chicago Board Options Exchange, Incorporated (''Exchange'' or ''CBOE'') 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 Substance of the Proposed Rule Change

The Exchange is proposing to amend CBOE Stock Exchange, LLC's (''CBSX'', the CBOE's stock trading facility) rules to exclude all rights and warrants from the individual stock trading pause pilot and to include a conforming amendment to CBOE's options trading halt provisions. The text of the proposed rule change is available on the Exchange's Web site (*http://www.cboe.org/Legal*), at the Exchange's Office of the Secretary and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 6.3C to exclude all rights and warrants from the single stock circuit breaker under the rule. The Commission approved Rule 6.3C on a pilot basis on June 10, 2010 to provide for trading pauses in individual securities due to extraordinary market volatility (''Trading Pause'') in all securities included within the S&P 500 ® Index (''S&P 500'') (''Pause Pilot'').[5] The Exchange subsequently received approval to add to the Pause Pilot the securities included in the Russell 1000® Index (''Russell 1000'') and a specified list of Exchange Traded Products (''ETPs'').[6]

On June 23, 2011, the Commission approved proposed rule changes to expand the Pause Pilot to include all remaining NMS stocks (''Phase III Securities''), which included rights and warrants.[7] Unlike the original Pause Pilot securities, amended Rule 6.3C applies wider percentage price moves to the Phase III Securities before a trading pause is triggered.[8] The changes to Rule 6.3C became effective on August 8, 2011.[9]

Analysis of the nature of the trading pauses triggered since adoption of the Pause Pilot notes that over 25% of such pauses have occurred in rights and warrants. Further, there has been a significant increase in trading pauses involving rights and warrants since the implementation of the Phase III Securities, with such pauses representing approximately 52% [sic] all trading pauses occurring through the end of August 2011. Rights and warrants trade on equity exchanges, but are closely related to call options. Rights and warrants entitle owners to purchase shares of stock at predetermined prices subject to various timing and other conditions. Like options, the price of rights and warrants are affected by the price of the underlying stock as well as other factors, particularly the volatility of the stock. As a consequence, the prices of rights and warrants may move more dramatically than the prices of the underlying stocks even when the rights and warrants (and the underlying stock) are trading in an orderly manner. This difference in trading behavior may result in a scenario whereby the rights and warrants trigger the circuit breaker under Rule 6.3C and are subject to a trading pause, even while the underlying stock continues to trade. This can be particularly true of rights and warrants that have low prices. Accordingly, the Exchange is proposing to exclude rights and warrants from the trading pause under Rule 6.3C.

[17] 17 CFR 200.30–3(a)(12).

[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] The Commission approved the Pause Pilot for all equities exchanges and FINRA. *See* Securities Exchange Act Release No. 62252 (June 10, 2010), 75 FR 34186 (June 16, 2010) (File Nos. SR–BATS–2010–014; SR–EDGA–2010–01; SR–EDGX–2010–01; SR–BX–2010–037; SR–ISE–2010–48; SR–NYSE–2010–39; SR–NYSEAmex–2010–46; SR–NYSEArca–2010–41; SR–NASDAQ–2010–061; SR–CHX–2010–10; SR–NSX–2010–05; and SR–CBOE–2010–047) and Securities Exchange Act Release No. 62251 (June 10, 2010), 75 FR 34183 (June 16, 2010) (SR–FINRA–2010–025).

[6] The Commission approved the addition to the Pause Pilot of the securities included in the Russell 1000 and ETPs, where applicable, for all equities exchanges and FINRA *See* Securities Exchange Act Release No. 62884 (September 10, 2010), 75 FR 56618 (September 16, 2010) (File Nos. SR–BATS–2010–018; SR–BX–2010–044; SR–CBOE–2010–065; SR–CHX–2010–14; SR–EDGA–2010–05; SR–EDGX–2010–05; SR–ISE–2010–66; SR–NASDAQ–2010–079; SR–NYSE–2010–49; SR–NYSEAmex–2010–63; SR–NYSEArca–2010–61; and SR–NSX–2010–08 and Securities Exchange Act Release No. 62883 (September 10, 2010), 75 FR 56608 (September 16, 2010) (SR–FINRA–2010–033). The Pause Pilot, which was originally set to expire on December 10, 2010, has been extended and is currently set to expire on January 31, 2012. *See* Securities Exchange Act Release Nos. 63502 (December 9, 2010), 75 FR 78306 (December 15, 2010) (SR–CBOE–2010–112) (extension of Pilot through April 11, 2011); 64194 (April 5, 2011), 76 FR 20389 (April 12, 2011)(SR–CBOE–2011–031)(extension of Pilot through the earlier of August 11, 2011 or the date on which a limit up-limit down mechanism to address extraordinary market volatility, if adopted, applies to the pilot stocks) and 65070 (August 9, 2011), 76 FR 50516 (August 15, 2011)(SR–CBOE–2011–076).

[7] *See* Securities Exchange Act Release No. 64735 (June 23, 2011), 76 FR 38243 (June 29, 2011) (SR–NASDAQ–2011–067, *et al.*).

[8] Under amended Rule 6.3C, a pause is triggered by a 30% or more price move in a Phase III Security priced at $1 or higher, and by a 50% or more price move to such a security priced less than $1. The price of a security is based on the closing price on the previous trading day, or, if no closing price exists, the last sale reported to the Consolidated Tape on the previous trading day.

[9] The Exchange notes that CBSX is not currently the primary listing market for any stocks, and thus, will not be issuing any trading pauses pursuant to its rules.

Finally, the Exchange is proposing a conforming amendment to Rule 6.3.06, which pertains to trading halts on CBOE. In relevant part, Rule 6.3.06 currently provides that, if the primary listing market issues an individual stock trading pause in an underlying NMS stock, then CBOE will halt trading in the options on that stock until trading has resumed in the stock. Given the proposed exclusion of rights and warrants from the Pause Pilot, the Exchange is proposing to replace a reference in Rule 6.2.06 to ''an underlying NMS stock'' with a conforming reference to ''an underlying eligible NMS stock'' and to define the term ''eligible NMS stocks'' to mean NMS stocks, other than rights and warrants.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Section 6(b)(5),[11] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system. The proposed rule change also is designed to support the principles of Section 11A(a)(1)[12] of the Act in that it seeks to ensure fair competition among brokers and dealers and among exchange markets. The Exchange believes that the proposed rule meets these requirements because it excludes certain securities from Rule 6.3C's coverage that are prone to triggering pauses because of their unique characteristics. These securities are unique in that they may move more dramatically than the prices of the underlying stocks to which they are related even when both securities are trading in an orderly manner. As such, the securities that are subject to this proposal may trigger the circuit breaker under Rule 6.3C and be subject to a trading pause, even while the underlying security continues to trade. Although there is little benefit in pausing trading in these securities, such pauses sequester regulatory resources that are better applied to the review of trading pauses in other securities that have a greater impact on the national market system.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

[12] 15 U.S.C. 78k–1(a)(1).

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

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[13] and Rule 19b–4(f)(6) thereunder.[14] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[15] and Rule 19b–4(f)(6)(iii) thereunder.[16]

A proposed rule change filed under Rule 19b–4(f)(6)[17] normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii)[18] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Including rights and warrants in the pilot program which may trigger a circuit breaker and be subject to a trading pause, even while the underlying security continues to trade, provides little benefit and has the potential to create confusion among investors. Excluding rights and warrants from the pilot program should minimize investor confusion that could result from temporary trading pauses in these securities. For this reason, the Commission designates the proposed rule change as operative upon the date of this Notice.[19]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File No. SR–CBOE–2011–111 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–CBOE–2011–111. 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

[13] 15 U.S.C. 78s(b)(3)(A)(iii).

[14] 17 CFR 240.19b–4(f)(6).

[15] 15 U.S.C. 78s(b)(3)(A).

[16] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[17] 17 CFR 240.19b–4(f)(6).

[18] 17 CFR 240.19b–4(f)(6)(iii).

[19] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–CBOE–2011–111 and should be submitted on or before December 21, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–30819 Filed 11–29–11; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65813; File No. SR–Phlx–2011–158]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Exclude All Rights and Warrants From the Pilot Rule for Trading Pauses Due to Extraordinary Market Volatility

November 23, 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, NASDAQ OMX PHLX LLC (''PHLX''), filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by PHLX. 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

PHLX proposes to exclude all rights and warrants from the pilot trading pause process under Rule 3100(a)(4).

The text of the proposed rule change is below. Proposed new language is italicized.

* * * * *

Rule 3100. Trading Halts on PSX

(a) Authority to Initiate Trading Halts or Pauses

In circumstances in which the Exchange deems it necessary to protect investors and the public interest, and pursuant to the procedures set forth in paragraph (c):

(1)–(3) No change.

(4) If a primary listing market issues an individual stock trading pause in any of the Circuit Breaker Securities, as defined herein, the Exchange will pause trading in that security until trading has resumed on the primary listing market. If, however, trading has not resumed on the primary listing market and ten minutes have passed since the individual stock trading pause message has been received from the responsible single plan processor, the Exchange may resume trading in such stock. The provisions of this paragraph (a)(4) shall be in effect during a pilot set to end on January 31, 2012. During the pilot, the term ''Circuit Breaker Securities'' shall mean any NMS stock *except rights and warrants.*

(b)–(c) No change.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, PHLX included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. PHLX has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

PHLX proposes to exclude all rights and warrants from the single stock circuit breaker under Rule 3100(a)(4). On June 10, 2010, the Commission approved the proposed rules of the other equity exchanges and FINRA to provide for trading pauses in individual securities due to extraordinary market volatility in all securities included within the S&P 500 Index (''S&P 500'') (the ''Pause Pilot'').[3] The other equity exchanges and FINRA subsequently received approval to add to the Pause Pilot the securities included in the Russell 1000 Index (''Russell 1000'') and a specified list of Exchange Traded Products (''ETPs'').[4] In connection with its resumption of trading of NMS Stocks through the NASDAQ OMX PSX system, PHLX adopted Rule 3100(a)(4) so that it could participate in the pilot program.[5] On September 29, 2010, PHLX amended Rule 3100(a)(4) to include stocks comprising the Russell 1000 and specified ETPs.[6]

On June 23, 2011, the Commission approved proposed rule changes of PHLX and the other equity exchanges (collectively, the ''Exchanges''), and FINRA to amend their respective rules to expand the Pause Pilot to include all remaining NMS stocks (''Phase III Securities''), which includes rights and warrants.[7] Unlike the original Pause Pilot securities, the amended Pause Pilot applies wider percentage price moves to the Phase III Securities before

[20] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Commission approved the Pause Pilot for all equities exchanges and FINRA. *See* Securities Exchange Act Release No. 62252 (June 10, 2010), 75 FR 34186 (June 16, 2010) (File Nos. SR–BATS–2010–014; SR–EDGA–2010–01; SR–EDGX–2010–01; SR–BX–2010–037; SR–ISE–2010–48; SR–NYSE–2010–39; SR–NYSEAmex–2010–46; SR–NYSEArca–2010–41; SR–NASDAQ–2010–061; SR–CHX–2010–10; SR–NSX–2010–05; and SR–CBOE–2010–047), and Securities Exchange Act Release No. 62251 (June 10, 2010), 75 FR 34183 (June 16, 2010) (SR–FINRA–2010–025).

[4] The Commission approved the addition to the Pause Pilot of the securities included in the Russell 1000 and ETPs, where applicable, for all equities exchanges and FINRA. *See* Securities Exchange Act Release No. 62884 (September 10, 2010), 75 FR 56618 (September 16, 2010) (File Nos. SR–BATS–2010–018; SR–BX–2010–044; SR–CBOE–2010–065; SR–CHX–2010–14; SR–EDGA–2010–05; SR–EDGX–2010–05; SR–ISE–2010–66; SR–NASDAQ–2010–079; SR–NYSE–2010–49; SR–NYSEAmex–2010–63; SR–NYSEArca–2010–61; and SR–NSX–2010–08, and Securities Exchange Act Release No. 62883 (September 10, 2010), 75 FR 56608 (September 16, 2010) (SR–FINRA–2010–033).

[5] *See* Securities Exchange Act Release No. 62877 (September 9, 2010), 75 FR 56633 (September 16, 2010) (SR–Phlx–2010–79).

[6] Securities Exchange Act Release No. 63004 (September 29, 2010), 75 FR 61547 (October 5, 2010) (SR–Phlx–2010–126). PHLX submitted a proposed rule change shortly after the addition of the Russell 1000 securities and ETPs to extend the operation of the Pause Pilot, which was set to expire on December 10, 2010, until April 11, 2011. *See* Securities Exchange Act Release No. 63504 (December 9, 2010), 75 FR 78304 (December 15, 2010) (SR–Phlx–2010–174). On March 31, 2011, PHLX submitted a proposed rule change to further extend the Pause Pilot until the earlier of August 11, 2011 or the date on which a limit up/limit down mechanism to address extraordinary market volatility, if adopted, applies. *See* Securities Exchange Act Release No. 64175 (April 4, 2011), 76 FR 19823 (April 8, 2011) (SR–Phlx–2011–44). On August 8, 2011, PHLX submitted a proposed rule change to further extend the Pause Pilot until January 31, 2012. *See* Securities Exchange Act Release No. 65083 (August 10, 2011), 76 FR 50801 (August 16, 2011) (SR–Phlx–2011–113).

[7] *See* Securities Exchange Act Release No. 64735 (June 23, 2011), 76 FR 38243 (June 29, 2011) (SR–Phlx–2011–64, *et al.*).

a trading pause is triggered.[8] The changes to the Pause Pilot became effective on August 8, 2011.

The Exchanges and FINRA have analyzed the nature of trading pauses triggered since adoption of the Pause Pilot and found that over 25% of such pauses have occurred in rights and warrants. Further, the Exchanges and FINRA have experienced a significant increase in trading pauses involving rights and warrants since the implementation of the Phase III Securities, with such pauses representing approximately 52% [sic] all trading pauses occurring through the end of August 2011. Rights and warrants trade on equity exchanges, but are closely related to call options. Rights and warrants entitle owners to purchase shares of stock at predetermined prices subject to various timing and other conditions. Like options, the price of rights and warrants are affected by the price of the underlying stock as well as other factors, particularly the volatility of the stock. As a consequence, the prices of rights and warrants may move more dramatically than the prices of the underlying stocks even when the rights and warrants (and the underlying stock) are trading in an orderly manner. This difference in trading behavior may result in rights and warrants triggering the circuit breaker under the Pause Pilot and being subject to a trading pause, even while the underlying stock continues to trade. This can be particularly true of rights and warrants that have low prices. As such, the Exchanges and FINRA have determined to exclude rights and warrants from the Pause Pilot, and accordingly, PHLX is proposing to amend Rule 3100(a)(4) to exclude rights and warrants from the Pause Pilot.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Section 6(b)(5),[10] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system. The proposed rule change also is designed to support the principles of Section 11A(a)(1)[11] of the Act in that it seeks to ensure fair competition among brokers and dealers and among exchange markets. PHLX believes that the proposed rule meets these requirements because it excludes certain securities from the rule's coverage that are prone to triggering pauses because of their unique characteristics. These securities are unique in that they may move more dramatically than the prices of the underlying stocks to which they are related even when both securities are trading in an orderly manner. As such, the securities that are subject to this proposal may trigger a Pause Pilot circuit breaker and be subject to a trading pause, even while the underlying security continues to trade. Although there is little benefit in pausing trading in these securities, such pauses sequester regulatory resources that are better applied to the review of trading pauses in other securities that have a greater impact on the national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

PHLX does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[12] and Rule 19b–4(f)(6) thereunder.[13] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[14] and Rule 19b–4(f)(6)(iii) thereunder.[15]

A proposed rule change filed under Rule 19b–4(f)(6)[16] normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii)[17] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Including rights and warrants in the pilot program which may trigger a circuit breaker and be subject to a trading pause, even while the underlying security continues to trade, provides little benefit and has the potential to create confusion among investors. Excluding rights and warrants from the pilot program should minimize investor confusion that could result from temporary trading pauses in these securities. For this reason, the Commission designates the proposed rule change as operative upon the date of this Notice.[18]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

[8] Under the amended Pause Pilot, a pause is triggered by a 30% or more price move in a Phase III Security priced at $1 or higher, and by a 50% or more price move to such a security priced less than $1. The price of a security is based on the closing price on the previous trading day, or, if no closing price exists, the last sale reported to the Consolidated Tape on the previous trading day.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] 15 U.S.C. 78k–1(a)(1).

[12] 15 U.S.C. 78s(b)(3)(A)(iii).

[13] 17 CFR 240.19b–4(f)(6).

[14] 15 U.S.C. 78s(b)(3)(A).

[15] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[16] 17 CFR 240.19b–4(f)(6).

[17] 17 CFR 240.19b–4(f)(6)(iii).

[18] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

Electronic Comments

• Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or

• Send an email to *rule-comments@sec.gov*. Please include File No. SR–Phlx–2011–158 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–Phlx–2011–158. 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 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 No. SR–Phlx–2011–158 and should be submitted on or before December 21, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–30808 Filed 11–29–11; 8:45 am]

BILLING CODE 8011–01–P

[19] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #12932 and #12933]

Connecticut Disaster # CT–00026

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 Connecticut (FEMA—4046—DR), dated 11/17/2011.

Incident: Severe storm.

Incident Period: 10/29/2011 through 10/30/2011.

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: Fairfield, Hartford, Litchfield, Middlesex, New Haven, Tolland, Windham.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations With Credit Available Elsewhere	3.125.
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 12932B and for economic injury is 12933B.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2011–30498 Filed 11–29–11; 8:45 am]

BILLING CODE M

SMALL BUSINESS ADMINISTRATION

[License No. 09/79–0454]

Emergence Capital Partners SBIC, L.P.; Notice Seeking Exemption Under Section 312 of the Small Business Investment Act, Conflicts of Interest

Notice is hereby given that Emergence Capital Partners SBIC, L.P., 160 Bovet Road, Suite 300, San Mateo, CA 94402 a Federal Licensee under the Small Business Investment Act of 1958, as amended (''the Act''), in connection with the financing of a small concern, has sought an exemption under Section 312 of the Act and Section 107.730, Financings which Constitute Conflicts of Interest of the Small Business Administration (''SBA'') Rules and Regulations (13 CFR 107.730). Emergence Capital Partners SBIC, L.P. proposes to provide equity security financing to Bill.com, Inc., 3250 Ash Street, Palo Alto, CA 94306.

The financing is brought within the purview of § 107.730(a)(1) of the Regulations because Emergence Capital Partners, L.P. and Emergence Capital Associates, L.P., both Associates of Emergence Capital Partners SBIC, L.P., own in the aggregate more than ten percent of Bill.com, Inc, and therefore this transaction is considered a financing of an Associate requiring prior SBA approval.

Notice is hereby given that any interested person may submit written comments on the transaction, within fifteen days of the date of this publication, to the Associate Administrator for Investment, U.S. Small Business Administration, 409 Third Street, SW., Washington, DC 20416.

Dated: November 15, 2011.

Sean J. Greene,

Associate Administrator for Investment.

[FR Doc. 2011–30604 Filed 11–29–11; 8:45 am]

BILLING CODE M

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35569]

Alabama & Florida Railway Co., Inc. d/b/a Ripley & New Albany Railroad Co.—Acquisition and Operation Exemption—Mississippi Tennessee Holdings, LLC and Mississippi Tennessee Railroad, LLC

Alabama & Florida Railway Co., Inc. d/b/a Ripley & New Albany Railroad Co. (RNA), a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1150.41 [1] to acquire and operate a portion of rail line owned by Mississippi Tennessee Holdings, LLC (MTH) (currently operated by Mississippi Tennessee Railroad, LLC (MTR)), between milepost 325.56 at New Albany, and milepost 348.1 at Ripley, a distance of 22.54 miles in Union and Tippah Counties, Miss. RNA states that it proposes to acquire all of MTH's title and interest in the right-of-way, track and structures, as well as MTR's leasehold interest in the property.

RNA certifies that its projected annual revenues as a result of this transaction will not result in RNA's becoming a Class II or Class I rail carrier and will not exceed $5 million.

The proposed transaction may not be consummated before December 14, 2011, the effective date of the exemption (30 days after the amended exemption was filed).

If the verified notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Stay petitions must be filed no later than December 7, 2011 (at least 7 days before the amended exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35569, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Daniel A. LaKemper, 1318 S. Johanson Rd., Peoria, IL 61607.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov.*

Decided: November 25, 2011.

[1] The notice of exemption was filed on November 10, 2011, and an amended notice was filed on November 14, 2011.

By the Board, Joseph H. Dettmar, Acting Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2011–30840 Filed 11–29–11; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 1127A

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 1127A, Application for Extension of Time for Payment of Tax Due to Undue Hardship.

DATES: Written comments should be received on or before January 30, 2012 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette B. Lawrence, Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Elaine Christophe, (202) 622–3179, at Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the Internet at *Elaine.H.Christophe@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Application for Extension of Time for Payment of Tax Due to Undue Hardship.

OMB Number: 1545–2131.

Form Number: 1127A.

Abstract: Under IRC 6161, individual taxpayers are allowed to request an extension of time for payment of tax shown or required to be shown on a return or for a tax due on a notice of deficiency for 2011 not to exceed 6 months from the date fixed for payment thereof. In order to be granted this extension, they must file Form 1127A, self-certifying hardship due to the current economic downturn. 1127A is for 2011 tax only and can only be filed for 1040 taxes and for individuals only.

Current Actions: This is a new form. This form is being submitted for OMB approval.

Type of Review: New Information Collection.

Affected Public: Individuals and Households.

Estimated Number of Respondents: 1,000.

Estimated Time Per Respondent: 5 hours, 9 minutes.

Estimated Total Annual Burden Hours: 5,150.

The following paragraph applies to all of the collections of information covered by this notice:

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

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

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 21, 2011.

Yvette B. Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2011–30800 Filed 11–29–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 4810

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 4810, Request for Prompt Assessment Under Internal Revenue Code Section 6501(d).

DATES: Written comments should be received on or before January 30, 2012 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette B. Lawrence, Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Elaine Christophe, at (202) 622–3179, or at Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the Internet, at *Elaine.H.Christophe@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Request for Prompt Assessment Under Internal Revenue Code Section 6501(d).

OMB Number: 1545–0430.

Form Number: 4810.

Abstract: Fiduciaries representing a dissolving corporation or a decedent's estate may request a prompt assessment of tax under Internal Revenue Code section 6501(d). Form 4810 is used to help locate the return and expedite the processing of the taxpayer's request.

Current Actions: There is no change in the paperwork burden previously approved by OMB. This form is being submitted for renewal purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households, business or other for-profit organizations, farms, and the Federal government.

Estimated Number of Respondents: 4,000.

Estimated Time Per Respondent: 30 minutes.

Estimated Total Annual Burden Hours: 24,800.

The following paragraph applies to all of the collections of information covered by this notice:

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

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

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 10, 2011.

Yvette B. Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2011–30799 Filed 11–29–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13(44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Inspection of Applications for Tax Exemption and Applications for Determination Letters for Pension and Other Plans.

DATES: Written comments should be received on or before January 30, 2012 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette B. Lawrence, Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulations should be directed to Elaine Christophe at Internal Revenue Service, Room 6512, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 622–3179, or through the Internet at *(Elaine.H.Christophe@irs.gov).*

SUPPLEMENTARY INFORMATION:

Title: Inspection of Applications for Tax Exemption and Applications for Determination Letters for Pension and Other Plans.

OMB Number: 1545–0817.

Regulation Project Number: EE–28–78 (TD 7845).

Abstract: Internal Revenue Code section 6104 requires applications for tax exempt status, annual reports of private foundations, and certain portions of returns to be open for public inspection. Some information may be withheld from disclosure. The Internal Revenue Service needs the required information to comply with requests for public inspection.

Current Actions: There is no change to this existing information collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households, business or other for-profit organizations, not-for-profit institutions, Federal Government, and state, local or tribal government.

Estimated Number of Respondents: 42,370.

Estimated Time per Respondent: 12 minutes.

Estimated Total Annual Burden Hours: 8,538.

The following paragraph applies to all of the collections of information covered by this notice:

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

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

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 14, 2011.

Yvette B. Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2011–30797 Filed 11–29–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Revenue Procedure 97–15

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Section 103—Remedial Payment Closing Agreement Program.

DATES: Written comments should be received on or before January 30, 2012 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette B. Lawrence, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulations should be directed to Elaine Christophe at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 622–3179, or through the Internet at *(Elaine.H.Christophe@irs.gov).*

SUPPLEMENTARY INFORMATION:

Title: Section 103–Remedial Payment Closing Agreement Program.

OMB Number: 1545–1528.

Revenue Procedure Number: Revenue Procedure 97–15.

Abstract: This information is required by the Internal Revenue Service to verify compliance with sections 57, 103, 142, 144, 145, and 147 of the Internal Revenue Code of 1986, as applicable (including any corresponding provision, if any, of the Internal Revenue Code of 1954). This information will be used by the Service to enter into a closing agreement with the issuer of certain state or local bonds to establish the closing agreement amount.

Current Actions: There are no changes being made to the information collection at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: State, local or tribal government, and not-for-profit institutions.

Estimated Number of Respondents: 50.

Estimated Time per Respondent: 1 hour, 30 minutes.

Estimated Total Annual Burden Hours: 75.

The following paragraph applies to all the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 14, 2011.

Yvette B. Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2011–30791 Filed 11–29–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Excise Tax Under Section 4980B, 4980D, 4980E & 4980G.

DATES: Written comments should be received on or before January 30, 2012 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette B. Lawrence, Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this regulation should be directed to Elaine Christophe, (202) 622–3179, Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the Internet at *Elaine.H.Christophe@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Excise Tax Under Section 4980B, 4980D, 4980E & 4980G.

OMB Number: 1545–2146.

Regulation Project Number: REG–120476–07.

Abstract: This regulation provide the requirement for filing of the return and the time for filing a return for the payment of the excise taxes under section 4980B, 4980D, 4980E, and 4980G.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, not-for-profit organizations, and individuals.

Estimated Number of Respondents: 5,000.

Estimated Time per Respondent: .50 hours.

Estimated Total Annual Burden Hours: 2,500.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 10, 2011.

Yvette B. Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2011–30801 Filed 11–29–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Qualified Electing Fund Elections.

DATES: Written comments should be received on or before January 30, 2012 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette B. Lawrence, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this regulation should be directed to Elaine Christophe, (202) 622–3179, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the Internet at *Elaine.H.Christophe@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Qualified Electing Fund Elections.

OMB Number: 1545–1514.

Regulation Project Number: REG–209040–88.

Abstract: This regulation permits certain shareholders to make a special election under Internal Revenue Code section 1295 with respect to certain preferred shares of a passive foreign investment company. This special election operates in lieu of the regular section 1295 election and requires less annual reporting. Electing preferred shareholders must account for dividend income under the special rules of the regulation, rather than under the general income inclusion rules of section 1293.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, not-for-profit organizations, and individuals.

Estimated Number of Respondents: 1,030.

Estimated Time per Respondent: .58 hours.

Estimated Total Annual Burden Hours: 600.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 10, 2011.

Yvette B. Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2011–30802 Filed 11–29–11; 8:45 am]

BILLING CODE 4830–01–P

FEDERAL REGISTER

Vol. 76 Wednesday,
No. 230 November 30, 2011

Part II

Department of Health and Human Services

Centers for Medicare and Medicaid Services

42 CFR Parts 410, 411, 416 et al.
Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment; Ambulatory Surgical Center Payment; Hospital Value-Based Purchasing Program; Physician Self-Referral; and Patient Notification Requirements in Provider Agreements; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 411, 416, 419, 489, and 495

[CMS–1525–FC]

RIN 0938–AQ26

Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment; Ambulatory Surgical Center Payment; Hospital Value-Based Purchasing Program; Physician Self-Referral; and Patient Notification Requirements in Provider Agreements

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period revises the Medicare hospital outpatient prospective payment system (OPPS) for CY 2012 to implement applicable statutory requirements and changes arising from our continuing experience with this system. In this final rule with comment period, we describe the changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the OPPS.

In addition, this final rule with comment period updates the revised Medicare ambulatory surgical center (ASC) payment system to implement applicable statutory requirements and changes arising from our continuing experience with this system. In this final rule with comment period, we set forth the relative payment weights and payment amounts for services furnished in ASCs, specific HCPCS codes to which these changes apply, and other ratesetting information for the CY 2012 ASC payment system.

We are revising the requirements for the Hospital Outpatient Quality Reporting (OQR) Program, adding new requirements for ASC Quality Reporting System, and making additional changes to provisions of the Hospital Inpatient Value-Based Purchasing (VBP) Program.

We also are allowing eligible hospitals and CAHs participating in the Medicare Electronic Health Record (EHR) Incentive Program to meet the clinical quality measure reporting requirement of the EHR Incentive Program for payment year 2012 by participating in the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot.

Finally, we are making changes to the rules governing the whole hospital and rural provider exceptions to the physician self-referral prohibition for expansion of facility capacity and changes to provider agreement regulations on patient notification requirements.

DATES: *Effective Date:* This final rule with comment period is effective on January 1, 2012.

Comment Period: To be assured consideration, comments on the payment classifications assigned to HCPCS codes identified in Addenda B, AA, and BB of this final rule with comment period with the ''NI'' comment indicator and on other areas specified throughout this final rule with comment period, and comments on the suspension of the effective dates of the Hospital-Acquired Condition (HAC), Agency for Healthcare Research and Quality (AHRQ), and Medicare spending per beneficiary measures discussed in section XVI.A.2. of this final rule with comment period, must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on January 3, 2012.

Application Deadline—New Class of New Technology Intraocular Lenses: Requests for review of applications for a new class of new technology intraocular lenses must be received by 5 p.m. EST on March 2, 2012, at the following address: ASC/NTOL, Division of Outpatient Care, Mailstop C4–05–17, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

ADDRESSES: In commenting, please refer to file code CMS–1525–FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may (and we encourage you to) submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the ''submit a comment'' tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1525–FC, P.O. Box 8013, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments via express or overnight mail to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1525–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 the telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Marjorie Baldo, (410) 786–4617, Hospital outpatient prospective payment issues.

Char Thompson, (410) 786–2300, Ambulatory surgical center issues.

Michele Franklin, (410) 786–4533, and Jana Lindquist, (410) 786–4533, Partial hospitalization and community mental health center issues.

James Poyer, (410) 786–2261, Reporting of Hospital Outpatient Quality Reporting (OQR) and ASC Quality Reporting Program issues.

Teresa Schell, (410) 786–8651, Physician Ownership and Investment in Hospitals issues.

Georganne Kuberski, (410) 786–0799, Patient Notification Requirements issues.

James Poyer, (410) 786–2261, and Ernessa Brawley (410) 786–2075, Hospital Value-Based Purchasing (VBP) Program issues.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection, generally beginning approximately 3 weeks after publication of the rule, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244, on Monday through Friday of each week from 8:30 a.m. to 4 p.m. EST. To schedule an appointment to view public comments, phone 1–(800) 743–3951.

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through Federal Digital System (FDsys), a service of the U.S. Government Printing Office. This database can be accessed via the internet at *http://www.gpo.gov/fdsys/*.

Addenda Available Only Through the Internet on the CMS Web Site

In the past, a majority of the Addenda referred to throughout the preamble of our OPPS/ASC proposed and final rules were published in the **Federal Register** as part of the annual rulemakings. However, beginning with the CY 2012 proposed rule, all of the Addenda will no longer appear in the **Federal Register** as part of the annual OPPS/ASC proposed and final rules to decrease administrative burden and reduce costs associated with publishing lengthy tables. Instead, these Addenda will be published and available only on the CMS Web site. The Addenda relating to the OPPS are available at: *http://www.cms.gov/HospitalOutpatientPPS*. The Addenda relating to the ASC payment system are available at: *http://www.cms.gov/ASCPayment/*. For complete details on the availability of the Addenda referenced in this final rule with comment period, we refer readers to section XVII. Readers who experience any problems accessing any of the Addenda that are posted on the CMS Web site identified above should contact Charles Braver at (410) 786–0378.

Alphabetical List of Acronyms Appearing in This Federal Register Document

ACEP American College of Emergency Physicians
AHA American Hospital Association
AHIMA American Health Information Management Association
AHRQ Agency for Healthcare Research and Quality
AMA American Medical Association
AMP Average Manufacturer Price
AOA American Osteopathic Association
APC Ambulatory Payment Classification
ARRA American Recovery and Reinvestment Act of 2009, Public Law 111–5
ASC Ambulatory Surgical Center
ASP Average Sales Price
AWP Average Wholesale Price
BBA Balanced Budget Act of 1997, Public Law 105–33
BBRA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, Public Law 106–113
BIPA Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Public Law 106–554
BLS Bureau of Labor Statistics
CAH Critical Access Hospital
CAP Competitive Acquisition Program
CBSA Core-Based Statistical Area
CCN CMS Certification Number
CCR Cost-to-Charge Ratio
CDC Centers for Disease Control
CERT Comprehensive Error Rate Testing
CLFS Clinical Laboratory Fee Schedule
CMHC Community Mental Health Center
CMS Centers for Medicare & Medicaid Services
CPT Current Procedural Terminology (copyrighted by the American Medical Association)
CQM Clinical Quality Measure
CR Cardiac Rehabilitation
CY Calendar Year
DFO Designated Federal Official
DHS Designated Health Service
DRA Deficit Reduction Act of 2005, Public Law 109–171
DSH Disproportionate Share Hospital
EACH Essential Access Community Hospital
E/M Evaluation and Management
EHR Electronic Health Record
ESRD End-Stage Renal Disease
FACA Federal Advisory Committee Act, Public Law 92–463
FAR Federal Acquisition Regulations
FDA Food and Drug Administration
FFS Fee-for-Service
FSS Federal Supply Schedule
FY Fiscal Year
GAO Government Accountability Office
HAC Hospital-Acquired Condition
HAI Healthcare-Associated Infection
HCAHPS Hospital Consumer Assessment of Healthcare Providers and Systems
HCERA Health Care and Education Reconciliation Act of 2010, Public Law 111–152
HCP Healthcare Personnel
HCPCS Healthcare Common Procedure Coding System
HCRIS Hospital Cost Report Information System
HHA Home Health Agency
HIPAA Health Insurance Portability and Accountability Act of 1996, Public Law 104–191
HOPD Hospital Outpatient Department
Hospital OQR Hospital Outpatient Quality Reporting
ICR Intensive Cardiac Rehabilitation
IDE Investigational Device Exemption
IHS Indian Health Service
IQR Inpatient Quality Reporting
I/OCE Integrated Outpatient Code Editor
IOL Intraocular Lens
IPPS [Hospital] Inpatient Prospective Payment System
MAC Medicare Administrative Contractor
MedPAC Medicare Payment Advisory Commission
MIEA–TRHCA Medicare Improvements and Extension Act under Division B, Title I of the Tax Relief Health Care Act of 2006, Public Law 109–432
MIPPA Medicare Improvements for Patients and Providers Act of 2008, Public Law 110–275
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173
MMEA Medicare and Medicaid Extenders Act of 2010, Public Law 111–309
MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007, Public Law 110–173
MPFS Medicare Physician Fee Schedule
MSA Metropolitan Statistical Area
NCCI National Correct Coding Initiative
NHSN National Healthcare Safety Network
NCD National Coverage Determination
NPP Nonphysician practitioner
NQF National Quality Forum
NTIOL New Technology Intraocular Lens
OIG [HHS] Office of the Inspector General
OMB Office of Management and Budget
OPD [Hospital] Outpatient Department
OPPS [Hospital] Outpatient Prospective Payment System
OQR Outpatient Quality Reporting
PBD Provider-Based Department
PHP Partial Hospitalization Program
PPI Producer Price Index
PPS Prospective Payment System
PR Pulmonary Rehabilitation
PRA Paperwork Reduction Act
QAPI Quality Assessment and Performance Improvement
QIO Quality Improvement Organization
RAC Recovery Audit Contractor
RFA Regulatory Flexibility Act
RHHI Regional Home Health Intermediary
SBA Small Business Administration
SCH Sole Community Hospital
SDP Single Drug Pricer
SI Status Indicator
TEP Technical Expert Panel
TOPs Transitional Outpatient Payments
VBP Value-Based Purchasing
WAC Wholesale Acquisition Cost

In this document, we address two payment systems under the Medicare program: the OPPS and the ASC payment system. In addition, we are making changes to the rules governing limitations on certain physician referrals to hospitals in which

physicians have an ownership or investment interest, the provider agreement regulations on patient notification requirements, and the rules governing the Hospital Inpatient Value-Based Purchasing (VBP) Program. The provisions relating to the OPPS are included in sections I. through XII., section XIV., and sections XVII. through XXI. of this final rule with comment period. Addenda A, B, C, D1, D2, E, L, M, and N, which relate to the OPPS, are referenced in section XVII. of this final rule with comment period and are available via the Internet on the CMS Web site at the URL indicated in section XVII. The provisions related to the ASC payment system are included in sections XIII., XIV., and XVII. through XXI. of this final rule with comment period. Addenda AA, BB, DD1, DD2, and EE, which relate to the ASC payment system, are referenced in section XVII. of this final rule with comment period and are available via the Internet on the CMS Web site at the URL indicated in section XVII. The provisions relating to physician referrals to hospitals in which physicians have an ownership or investment interest and to the provider agreement regulations on patient notification requirements are included in section XV., and the provisions relating to the Hospital Inpatient VBP Program are included in section XVI. of this final rule with comment period.

Table of Contents

I. Background and Summary of the CY 2012 OPPS/ASC Proposed Rule and This Final Rule With Comment Period
A. Legislative and Regulatory Authority for the Hospital Outpatient Perspective Payment System
B. Excluded OPPS Services and Hospitals
C. Prior Rulemaking
D. Advisory Panel on Ambulatory Payment Classification (APC) Groups
1. Authority of the APC Panel
2. Establishment of the APC Panel
3. APC Panel Meetings and Organizational Structure
E. Summary of the Major Contents of the CY 2012 OPPS/ASC Proposed Rule
1. Updates Affecting OPPS Payments
2. OPPS Ambulatory Payment Classification (APC) Group Policies
3. OPPS Payment for Devices
4. OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals
5. Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices
6. OPPS Payment for Hospital Outpatient Visits
7. Payment for Partial Hospitalization Services
8. Procedures That Would Be Paid Only as Inpatient Procedures
9. Policies on Supervision Standards for Outpatient Services in Hospitals and CAHs
10. OPPS Payment Status and Comment Indicators
11. OPPS Policy and Payment Recommendations
12. Updates to the Ambulatory Surgical Center (ASC) Payment System
13. Reporting Quality Data for Annual Payment Rate Updates
14. Changes to EHR Incentive Program for Eligible Hospitals and CAHs Regarding Electronic Submission of Clinical Quality Measures (CQMs)
15. Changes to Provisions Relating to Physician Self-Referral Prohibition and Provider Agreement Regulations on Patient Notification Requirements
16. Additional Changes to the Hospital Inpatient VBP Program
17. Economic and Federalism Analyses
F. Public Comments Received in Response to the CY 2012 OPPS/ASC Proposed Rule
G. Public Comments Received on the CY 2011 OPPS/ASC Final Rule With Comment Period
II. Updates Affecting OPPS Payments
A. Recalibration of APC Relative Weights
1. Database Construction
a. Database Source and Methodology
b. Use of Single and Multiple Procedure Claims
c. Calculation and Use of Cost-to-Charge Ratios (CCRs)
2. Data Development Process and Calculation of Median Costs
a. Claims Preparation
b. Splitting Claims and Creation of ''Pseudo'' Single Procedure Claims
(1) Splitting Claims
(2) Creation of ''Pseudo'' Single Procedure Claims
c. Completion of Claim Records and Median Cost Calculations
d. Calculation of Single Procedure APC Criteria-Based Median Costs
(1) Device-Dependent APCs
(2) Blood and Blood Products
(3) Allergy Tests (APCs 0370 and 0381)
(4) Hyperbaric Oxygen Therapy (APC 0659)
(5) Payment for Ancillary Outpatient Services When Patient Expires (APC 0375)
(6) Endovascular Revascularization of the Lower Extremity (APCs 0083, 0229, and 0319)
(7) Non-Congenital Cardiac Catheterization (APC 0080)
(8) Cranial Neurostimulator and Electrodes (APC 0318)
(9) Brachytherapy Sources
e. Calculation of Composite APC Criteria-Based Median Costs
(1) Extended Assessment and Management Composite APCs (APCs 8002 and 8003)
(2) Low Dose Rate (LDR) Prostate Brachytherapy Composite APC (APC 8001)
(3) Cardiac Electrophysiologic Evaluation and Ablation Composite APC (APC 8000)
(4) Mental Health Services Composite APC (APC 0034)
(5) Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)
(6) Cardiac Resynchronization Therapy Composite APC (APCs 0108, 0418, 0655, and 8009)
3. Changes to Packaged Services
a. Background
b. Packaging Issues
(1) CMS Presentation of Findings Regarding Expanded Packaging at the February 28–March 1, 2011 and August 10–12, 2011 APC Panel Meetings
(2) Packaging Recommendations of the APC Panel at Its February 28–March 1, 2011 Meeting
(3) Packaging Recommendations of the APC Panel at Its August 2011 Meeting
(4) Other Packaging Proposals and Policies for CY 2012
4. Calculation of OPPS Scaled Payment Weights
B. Conversion Factor Update
C. Wage Index Changes
D. Statewide Average Default CCRs
E. OPPS Payment to Certain Rural and Other Hospitals
1. Hold Harmless Transitional Payment Changes
2. Adjustment for Rural SCHs and EACHs Under Section 1833(t)(13)(B) of the Act
F. OPPS Payments to Certain Cancer Hospitals Described by Section 1886(d)(1)(B)(v) of the Act
1. Background
2. Study of Cancer Hospital Costs Relative to Other Hospitals
3. CY 2011 Proposed Payment Adjustment for Certain Cancer Hospitals
4. Proposed CY 2011 Cancer Hospital Payment Adjustment That Was Not Finalized
5. Payment Adjustment for Certain Cancer Hospitals for CY 2012
G. Hospital Outpatient Outlier Payments
1. Background
2. Proposed Outlier Calculation
3. Final Outlier Calculation
4. Outlier Reconciliation
H. Calculation of an Adjusted Medicare Payment From the National Unadjusted Medicare Payment
I. Beneficiary Copayments
1. Background
2. OPPS Copayment Policy
3. Calculation of an Adjusted Copayment Amount for an APC Group
III. OPPS Ambulatory Payment Classification (APC) Group Policies
A. OPPS Treatment of New CPT and Level II HCPCS Codes
1. Treatment of New Level II HCPCS Codes and Category I CPT Vaccine Codes and Category III CPT Codes for Which We Solicited Public Comments in the CY 2012 Proposed Rule
2. Process for New Level II HCPCS Codes and Category I and Category III CPT Codes for Which We Are Soliciting Public Comments on This CY 2012 OPPS/ASC Final Rule With Comment Period
B. OPPS Changes—Variations Within APCs
1. Background
2. Application of the 2 Times Rule
3. Exceptions to the 2 Times Rule
C. New Technology APCs
1. Background
2. Movement of Procedures From New Technology APCs to Clinical APCs

D. OPPS APC-Specific Policies
1. Cardiovascular Services
a. Cardiovascular Computed Tomography (CCT) (APCs 0340 and 0383)
b. Cardiac Imaging (APC 377)
c. Insertion/Replacement/Repair of AICD Leads, Generator, and Pacing Electrodes (APC 0108)
d. Implantable Loop Recorder Monitoring (APC 0690)
e. Echocardiography (APCs 0128, 0269, 0270, and 0697)
2. Gastrointestinal Services
a. Upper Gastrointestinal (GI) Services (APCs 0141, 0419, and 0422)
b. Gastrointestinal Transit and Pressure Measurement (APC 0361)
3. Genitourinary Services
a. Laser Lithotripsy (APC 0163)
b. Percutaneous Renal Cryoablation (APC 0423)
4. Nervous System Services
a. Revision/Removal of Neurotransmitter Electrodes (APCs 0040 and 0687)
b. Magnetoencephalography (MEG) (APCs 0065, 0066, and 0067)
c. Transcranial Magnetic Stimulation Therapy (TMS) (APC 0218)
5. Ocular and Ophthalmic Services
a. Placement of Amniotic Membrane (APCs 0233 and 0244)
b. Insertion of Anterior Segment Aqueous Drainage Device (APC 0673)
c. Scanning Ophthalmic Diagnostic Imaging (APC 0230)
d. Intraocular Laser Endoscopy (APC 0233)
6. Orthopedic and Musculoskeletal Services
a. Percutaneous Laminotomy/Laminectormy (APC 0208)
b. Level II Arthroscopy (APC 0042)
c. Closed Treatment Fracture of Finger, Toe, and Trunk (APCs 0129, 0138, and 0139)
d. Level I and II Strapping and Cast Application (APCs 0058 and 0426)
7. Radiology Services
a. Proton Beam Therapy (APCs 0664 and 0667)
b. Stereotactic Radiosurgery (SRS) Treatment Delivery Services (APCs 0065, 0066, 0067, and 0127)
c. Adrenal Imaging (APC 0408)
d. Positron Emission Tomography (PET) Imaging (APC 0308) (Created From Myocardial Positron Emission Tomography (PET) Imaging (APC 0307) and Nonmyocardial Positron Emission Tomography (PET) Imaging (APC 0308))
e. Device Construction for Intensity Modulated Radiation Therapy (IMRT) (APC 0305)
f. Computed Tomography of Abdomen/Pelvic (APCs 0331 and 0334)
g. Complex Interstitial Radiation Source Application (APC 0651)
h. Radioelement Applications (APC 0312)
8. Respiratory Services
a. Pulmonary Rehabilitation (APC 0102)
b. Bronchial Thermoplasty (APC 0415)
c. Insertion of Bronchial Valve (APC 0415)
9. Other Services
a. Skin Repair (APCs 0133, 0134, and 0135)
b. Nasal Sinus Endoscopy (APC 0075)
c. Bioimpedance Spectroscopy (APC 0097)
d. Autologous Blood Salvage (APC 0345)
IV. OPPS Payment for Devices
A. Pass-Through Payments for Devices
1. Expiration of Transitional Pass-Through Payments for Certain Devices
a. Background
b. CY 2012 Policy
2. Provisions for Reducing Transitional Pass-Through Payments To Offset Costs Packaged Into APC Groups
a. Background
b. CY 2012 Policy
B. Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices
1. Background
2. APCs and Devices Subject to the Adjustment Policy
V. OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals
A. OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals
1. Background
2. Drugs and Biologicals With Expiring Pass-Through Status in CY 2011
3. Drugs, Biologicals, and Radiopharmaceuticals With New or Continuing Pass-Through Status in CY 2012
4. Provisions for Reducing Transitional Pass-Through Payments for Diagnostic Radiopharmaceuticals and Contrast Agents To Offset Costs Packaged Into APC Groups
a. Background
b. Payment Offset Policy for Diagnostic Radiopharmaceuticals
c. Payment Offset Policy for Contrast Agents
B. OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status
1. Background
2. Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals
a. Background
b. Cost Threshold for Packaging of Payment for HCPCS Codes That Describe Certain Drugs, Nonimplantable Biologicals, and Therapeutic Radiopharmaceuticals (''Threshold-Packaged Drugs'')
c. Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological But Different Dosages
d. Packaging of Payment for Diagnostic Radiopharmaceuticals, Contrast Agents, and Implantable Biologicals (''Policy-Packaged'' Drugs and Devices)
3. Payment for Drugs and Biologicals Without Pass-Through Status That Are Not Packaged
a. Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable and Packaged Drugs and Biologicals
b. CY 2012 Payment Policy
c. Payment Policy for Therapeutic Radiopharmaceuticals
4. Payment for Blood Clotting Factors
5. Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes, But Without OPPS Hospital Claims Data
VI. Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices
A. Background
B. Estimate of Pass-Through Spending
VII. OPPS Payment for Hospital Outpatient Visits
A. Background
B. Policies for Hospital Outpatient Visits
1. Clinic Visits: New and Established Patient Visits
2. Emergency Department Visits
3. Visit Reporting Guidelines
VIII. Payment for Partial Hospitalization Services
A. Background
B. PHP APC Update for CY 2012
C. Separate Threshold for Outlier Payments to CMHCs
IX. Procedures That Will Be Paid Only as Inpatient Procedures
A. Background
B. Changes to the Inpatient List
X. Policies for the Supervision of Outpatient Services in Hospitals and CAHs
A. Background
B. Issues Regarding the Supervision of Hospital Outpatient Therapeutic Services Raised by Hospitals and Other Stakeholders
1. Independent Review Process
a. Selection of Review Entity
b. Review Process
c. Evaluation Criteria
2. Conditions of Payment and Hospital Outpatient Therapeutic Services Described by Different Benefit Categories
3. Technical Corrections to the Supervision Standards for Hospital Outpatient Therapeutic Services Furnished in Hospitals or CAHs
C. Summary of CY 2012 Final Policies on Supervision Standards for Outpatient Therapeutic Services in Hospitals and CAHs
1. Independent Review Process
2. Conditions of Payment and Hospital Outpatient Therapeutic Services Described by Different Benefit Categories
3. Technical Corrections
XI. Final CY 2012 OPPS Payment Status and Comment Indicators
A. Final CY 2012 OPPS Payment Status Indicator Definitions
1. Payment Status Indicators To Designate Services That Are Paid Under the OPPS
2. Payment Status Indicators To Designate Services That Are Paid Under a Payment System Other Than the OPPS
3. Payment Status Indicators to Designate Services That Are Not Recognized Under the OPPS But That May Be Recognized by Other Institutional Providers
4. Payment Status Indicators To Designate Services That Are Not Payable by Medicare on Outpatient Claims
B. Final CY 2012 Comment Indicator Definitions
XII. OPPS Policy and Payment Recommendations
A. MedPAC Recommendations
B. APC Panel Recommendations
C. OIG Recommendations
XIII. Updates to the Ambulatory Surgical Center (ASC) Payment System
A. Background
1. Legislative Authority for the ASC Payment System
2. Prior Rulemaking

3. Policies Governing Changes to the Lists of Codes and Payment Rates for ASC Covered Surgical Procedures and Covered Ancillary Services
B. Treatment of New Codes
1. Process for Recognizing New Category I and Category III CPT Codes and Level II HCPCS Codes
2. Treatment of New Level II HCPCS Codes and Category III CPT Codes Implemented in April and July 2011 for Which We Solicited Public Comments in the CY 2012 OPPS/ASC Proposed Rule
3. Process for New Level II HCPCS Codes and Category I and Category III CPT Codes for Which We Are Soliciting Public Comments in This CY 2012 OPPS/ASC Final Rule With Comment Period
C. Update to the Lists of ASC Covered Surgical Procedures and Covered Ancillary Services
1. Covered Surgical Procedures
a. Additions to the List of ASC Covered Surgical Procedures
b. Covered Surgical Procedures Designated as Office-Based
(1) Background
(2) Changes for CY 2012 to Covered Surgical Procedures Designated as Office-Based
c. ASC Covered Surgical Procedures Designated as Device-Intensive
(1) Background
(2) Changes to List of Covered Surgical Procedures Designated as Device-Intensive for CY 2012
d. ASC Treatment of Surgical Procedures Removed From the OPPS Inpatient List for CY 2012
2. Covered Ancillary Services
D. ASC Payment for Covered Surgical Procedures and Covered Ancillary Services
1. Payment for Covered Surgical Procedures
a. Background
b. Update to ASC-Covered Surgical Procedure Payment Rates for CY 2012
c. Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices
d. Waiver of Coinsurance and Deductible for Certain Preventive Services
e. Payment for the Cardiac Resynchronization Therapy Composite
2. Payment for Covered Ancillary Services
a. Background
b. Payment for Covered Ancillary Services for CY 2012
E. New Technology Intraocular Lenses (NTIOLs)
1. NTIOL Cycle and Evaluation Criteria
2. NTIOL Application Process for Payment Adjustment
3. Requests To Establish New NTIOL Classes for CY 2012
4. Payment Adjustment
5. Announcement of CY 2012 Deadline for Submitting Requests for CMS Review of Appropriateness of ASC Payment for Insertion of an NTIOL Following Cataract Surgery
F. ASC Payment and Comment Indicators
1. Background
2. ASC Payment and Comment Indicators
G. ASC Policy and Payment Recommendations
H. Calculation of the ASC Conversion Factor and the ASC Payment Rates
1. Background
2. Calculation of the ASC Payment Rates
a. Updating the ASC Relative Payment Weights for CY 2012 and Future Years
b. Updating the ASC Conversion Factor
3. Display of CY 2012 ASC Payment Rates
XIV. Hospital Outpatient Quality Reporting Program Updates and ASC Quality Reporting
A. Background
1. Overview
2. Statutory History of Hospital Outpatient Quality Reporting (Hospital OQR) Program
3. Technical Specification Updates and Data Publication
a. Maintenance of Technical Specifications for Quality Measures
b. Publication of Hospital OQR Program Data
B. Revision to Measures Previously Adopted for the Hospital OQR Program for the CY 2013 and CY 2014 Payment Determinations
1. Background
2. Revision to OP–22 Left Without Being Seen
C. New Quality Measures for the CY 2014 and CY 2015 Payment Determinations
1. Considerations in Expanding and Updating Quality Measures Under Hospital OQR Program
2. New Hospital OQR Program Quality Measures for the CY 2014 Payment Determination
a. New National Healthcare Safety Network (NHSN) Healthcare Associated Infection (HAI) Measure for the CY 2014 Payment Determination: Surgical Site Infection (NQF #0299)
b. New Chart-Abstracted Measures for the CY 2014 Payment Determination
c. New Structural Measures
(1) Safe Surgery Checklist Use Measure
(2) Hospital Outpatient Department Volume for Selected Outpatient Surgical Procedures Measure
3. Hospital OQR Program Measures for the CY 2015 Payment Determination
a. Retention of CY 2014 Hospital OQR Measures for the CY 2015 Payment Determination
b. New NHSN HAI Measure for the CY 2015 Payment Determination
D. Possible Quality Measures Under Consideration for Future Inclusion in the Hospital OQR Program
E. Payment Reduction for Hospitals That Fail To Meet the Hospital OQR Requirements for the CY 2012 Payment Update
1. Background
2. Reporting Ratio Application and Associated Adjustment Policy for CY 2012
F. Extraordinary Circumstances Extension or Waiver for CY 2012 and Subsequent Years
G. Requirements for Reporting of Hospital OQR Data for CY 2013 and Subsequent Years
1. Administrative Requirements for CY 2013 and Subsequent Years
2. Form, Manner, and Timing of Data Submission for CY 2013 and Subsequent Years
a. CY 2013 and CY 2014 Data Submission Requirements for Chart-Abstracted Measure Data Submitted Directly to CMS
b. Eligibility to Voluntarily Sample and Data Submission Exception for Low Patient Volume for CY 2013 and Subsequent Years
c. Population and Sampling Data Requirements Beginning With the CY 2013 Payment Determination and for Subsequent Years
d. Claims-Based Measure Data Requirements for the CY 2013 and CY 2014 Payment Determinations
e. Structural Measure Data Requirements for the CY 2013 and CY 2014 Payment Determinations
f. Data Submission Deadlines for the NHSN HAI Surgical Site Infection Measure for the CY 2014 Payment Determination
g. Data Submission Requirements for OP–22: ED-Patient Left Before Being Seen for the CY 2013 and CY 2014 Payment Determinations
3. Hospital OQR Validation Requirements for Chart-Abstracted Measure Data Submitted Directly to CMS: Data Validation Approach for the CY 2013 Payment Determination
a. Randomly Selected Hospitals
b. Use of Targeting Criteria for Data Validation Selection for CY 2013
(1) Background
(2) Targeting Criteria for Data Validation Selection for CY 2013
c. Encounter Selection
d. Validation Score Calculation
4. Additional Data Validation Conditions Under Consideration for CY 2014 and Subsequent Years
H. Hospital OQR Reconsideration and Appeals Procedures for CY 2013 and Subsequent Years
I. Electronic Health Records (EHRs)
J. 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Hospitals and CAHs
1. Background
2. Electronic Reporting Pilot
3. CQM Reporting Under the Electronic Reporting Pilot
K. ASC Quality Reporting Program
1. Background
2. ASC Quality Reporting Program Measure Selection
a. Timetable for Selecting ASC Quality Measures
b. Considerations in the Selection of Measures for the ASC Quality Reporting Program
3. ASC Quality Measures for the CY 2014 Payment Determination
a. Claims-Based Measures Requiring Submission of Quality Data Codes (QDCs) Beginning January 1, 2012
(1) Patient Burns (NQF #0263)
(2) Patient Falls (NQF #0266)
(3) Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267)
(4) Hospital Transfer/Admission (NQF #0265)
(5) Prophylactic Intravenous (IV) Antibiotic Timing (NQF #0264)

(6) Ambulatory Patient With Appropriate Method of Surgical Hair Removal (NQF #0515)
(7) Selection of Prophylactic Antibiotic: First OR Second Generation Cephalosporin (NQF #0268)
b. Surgical Site Infection Rate (NQF #0299)
4. ASC Quality Measures for the CY 2015 Payment Determination
a. Retention of Measures Adopted for the CY 2014 Payment Determination in the CY 2015 Payment Determination
b. Structural Measures for the CY 2015 Payment Determination
(1) Safe Surgery Checklist Use
(2) ASC Facility Volume Data on Selected ASC Surgical Procedures
5. ASC Quality Measures for the CY 2016 Payment Determination
a. Retention of Measures Adopted for the CY 2015 Payment Determination in the CY 2016 Payment Determination
b. HAI Measure: Influenza Vaccination Coverage Among Healthcare Personnel (HCP) (NQF #0431)
6. ASC Measure Topics for Future Consideration
7. Technical Specification Updates and Data Publication for the CY 2014 Payment Determination
a. Maintenance of Technical Specifications for Quality Measures
b. Publication of ASC Quality Reporting Program Data
8. Requirements for Reporting of ASC Quality Data for the CY 2014 Payment Determination
a. Data Collection and Submission Requirements for the Claims-Based Measures
b. Data Submission Deadlines for the Surgical Site Infection Rate Measure
XV. Changes to Whole Hospital and Rural Provider Exceptions to the Physician Self-Referral Prohibition: Exception for Expansion of Facility Capacity; and Changes to Provider Agreement Regulations on Patient Notification Requirements
A. Background
B. Changes Made by the Affordable Care Act
1. Provisions Relating to Exception to Ownership and Investment Prohibition (Section 6001(a) of the Affordable Care Act)
2. Provisions of Section 6001(a)(3) of the Affordable Care Act
C. Process for Requesting an Exception to the Prohibition on Expansion of Facility Capacity
1. General Comments
2. Applicable Hospital
a. Percentage Increase in Population
b. Inpatient Admissions
c. Nondiscrimination
d. Bed Capacity
e. Bed Occupancy
3. High Medicaid Facility
a. Number of Hospitals in County
b. Inpatient Admissions
c. Nondiscrimination
4. Procedures for Submitting a Request
5. Community Input
6. Permitted Increase
a. Amount of Permitted Increase
b. Location of Permitted Increase
7. Decisions
8. Limitation on Review
9. Frequency of Request
D. Changes Related to Provider Agreement Regulations on Patient Notification Requirements
XVI. Additional Hospital Value-Based Purchasing (Hospital VBP) Program Policies
A. Hospital VBP Program
1. Legislative Background
2. Overview of the Hospital Inpatient VBP Program Final Rule
3. Additional FY 2014 Hospital VBP Program Measures
4. Minimum Number of Cases and Measures for the Outcome Domain for the FY 2014 Hospital VBP Program
a. Background
b. Minimum Number of Cases for Mortality Measures, AHRQ Composite Measures, and HAC Measures
c. Minimum Number of Measures for Outcome Domain
5. Performance Periods and Baseline Periods for FY 2014 Measures
a. Clinical Process of Care Domain and Patient Experience of Care Domain Performance Period and Baseline Period
b. Outcome Domain Performance Periods and Baseline Periods
6. Performance Standards for the FY 2014 Hospital VBP Program
a. Background
b. Mortality Measures
c. Clinical Process of Care and Patient Experience of Care FY 2014 Performance Standards
d. AHRQ Measures
e. HAC Measures
7. FY 2014 Hospital VBP Program Scoring Methodology
a. FY 2014 Domain Scoring Methodology
b. HAC Measures Scoring Methodology
8. Ensuring HAC Reporting Accuracy
9. Domain Weighting for FY 2014 Hospital VBP Program
B. Review and Correction Process Under the Hospital VBP Program
1. Background
2. Review and Correction of Data Submitted to the QIO Clinical Warehouse on Chart-Abstracted Process of Care Measures and Measure Rates
3. Review and Correction Process for Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Data
a. Phase One: Review and Correction of HCAHPS Data Submitted to the QIO Clinical Warehouse
b. Phase Two: Review and Correction of the HCAHPS Scores for the Hospital VBP Program
XVII. Files Available to the Public via the Internet
A. Information in Addenda Related to the Final CY 2012 Hospital OPPS
B. Information in Addenda Related to the Final CY 2012 ASC Payment System
XVIII. Collection of Information Requirements
A. Legislative Requirements for Solicitation of Comments
B. Requirements in Regulation Text
1. ICRs Regarding Basic Commitments of Providers (§ 489.20)
2. ICRs Regarding Exceptions Process Related to the Prohibition of Expansion of Facility Capacity (§ 411.362)
C. Associated Information Collections Not Specified in Regulatory Text
1. Hospital Outpatient Quality Reporting (Hospital OQR) Program
2. Hospital OQR Program Measures for the CY 2012, CY 2013, CY 2014, and CY 2015 Payment Determinations
a. Previously Adopted Hospital OQR Program Measures for the CY 2012, CY 2013, and CY 2014 Payment Determinations
b. Additional Hospital OQR Program Measures for CY 2014
c. Hospital OQR Program Measures for CY 2015
3. Hospital OQR Program Validation Requirements for CY 2013
4. Hospital OQR Program Reconsideration and Appeals Procedures
5. ASC Quality Reporting Program
6. 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Hospitals and CAHs
7. Additional Topics
XIX. Response to Comments
XX. Economic Analyses
A. Regulatory Impact Analysis
1. Introduction
2. Statement of Need
3. Overall Impacts for OPPS and ASC Provisions
4. Detailed Economic Analyses
a. Effects of OPPS Changes in This Final Rule With Comment Period
(1) Limitations of Our Analysis
(2) Estimated Effects of This Final Rule With Comment Period on Hospitals
(3) Estimated Effects of This Final Rule With Comment Period on CMHCs
(4) Estimated Effect of This Final Rule With Comment Period on Beneficiaries
(5) Effects on Other Providers
(6) Effects on the Medicare and Medicaid Programs
(7) Alternatives Considered
b. Effects of ASC Payment System Changes in This Final Rule With Comment Period
(1) Limitations of Our Analysis
(2) Estimated Effects of This Final Rule With Comment Period on Payments to ASCs
(3) Estimated Effects of This Final Rule With Comment Period on Beneficiaries
(4) Alternatives Considered
c. Accounting Statements and Tables
d. Effects of Requirements for the Hospital Outpatient Quality Reporting (OQR) Program
e. Effects of Changes to Physician Self-Referral Regulations
f. Effects of Changes to Provider Agreement Regulations on Patient Notification Requirements
g. Effects of Additional Hospital VBP Program Requirements
h. Effects of the 2012 Electronic Reporting Pilot
B. Regulatory Flexibility Act (RFA) Analysis
C. Unfunded Mandates Reform Act Analysis

D. Conclusion
XXI. Federalism Analysis
Regulation Text

I. Background and Summary of the CY 2012 OPPS/ASC Proposed Rule and This Final Rule With Comment Period

A. Legislative and Regulatory Authority for the Hospital Outpatient Prospective Payment System

When Title XVIII of the Social Security Act (the Act) was enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs. In an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care, the Congress mandated replacement of the reasonable cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) added section 1833(t) to the Act authorizing implementation of a PPS for hospital outpatient services. The OPPS was first implemented for services furnished on or after August 1, 2000. Implementing regulations for the OPPS are located at 42 CFR Part 419.

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) made major changes in the hospital OPPS. The following Acts made additional changes to the OPPS: the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554); the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173); the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171), enacted on February 8, 2006; the Medicare Improvements and Extension Act under Division B of Title I of the Tax Relief and Health Care Act of 2006 (MIEA–TRHCA) (Pub. L. 109–432), enacted on December 20, 2006; the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110–173), enacted on December 29, 2007; the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275), enacted on July 15, 2008; the Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), enacted on March 30, 2010 (These two public laws are collectively known as the Affordable Care Act.); and most recently the Medicare and Medicaid Extenders Act of 2010 (MMEA, Pub. L. 111–309).

Under the OPPS, we pay for hospital outpatient services on a rate-per-service basis that varies according to the ambulatory payment classification (APC) group to which the service is assigned. We use the Healthcare Common Procedure Coding System (HCPCS) (which includes certain Current Procedural Terminology (CPT) codes) to identify and group the services within each APC group. The OPPS includes payment for most hospital outpatient services, except those identified in section I.B. of this final rule with comment period. Section 1833(t)(1)(B) of the Act provides for payment under the OPPS for hospital outpatient services designated by the Secretary (which includes partial hospitalization services furnished by community mental health centers (CMHCs)) and hospital outpatient services that are furnished to inpatients who have exhausted their Part A benefits, or who are otherwise not in a covered Part A stay.

The OPPS rate is an unadjusted national payment amount that includes the Medicare payment and the beneficiary copayment. This rate is divided into a labor-related amount and a nonlabor-related amount. The labor-related amount is adjusted for area wage differences using the hospital inpatient wage index value for the locality in which the hospital or CMHC is located.

All services and items within an APC group are comparable clinically and with respect to resource use (section 1833(t)(2)(B) of the Act). In accordance with section 1833(t)(2) of the Act, subject to certain exceptions, items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service in the APC group is more than 2 times greater than the lowest median cost for an item or service within the same APC group (referred to as the ''2 times rule''). In implementing this provision, we generally use the median cost of the item or service assigned to an APC group.

For new technology items and services, special payments under the OPPS may be made in one of two ways. Section 1833(t)(6) of the Act provides for temporary additional payments, which we refer to as ''transitional pass-through payments,'' for at least 2 but not more than 3 years for certain drugs, biological agents, brachytherapy devices used for the treatment of cancer, and categories of other medical devices. For new technology services that are not eligible for transitional pass-through payments, and for which we lack sufficient data to appropriately assign them to a clinical APC group, we have established special APC groups based on costs, which we refer to as New Technology APCs. These New Technology APCs are designated by cost bands which allow us to provide appropriate and consistent payment for designated new procedures that are not yet reflected in our claims data. Similar to pass-through payments, an assignment to a New Technology APC is temporary; that is, we retain a service within a New Technology APC until we acquire sufficient data to assign it to a clinically appropriate APC group.

B. Excluded OPPS Services and Hospitals

Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. While most hospital outpatient services are payable under the OPPS, section 1833(t)(1)(B)(iv) of the Act excludes payment for ambulance, physical and occupational therapy, and speech-language pathology services, for which payment is made under a fee schedule. It also excludes screening mammography, diagnostic mammography, and effective January 1, 2011, an annual wellness visit providing personalized prevention plan services. The Secretary exercised the authority granted under the statute to also exclude from the OPPS those services that are paid under fee schedules or other payment systems. Such excluded services include, for example, the professional services of physicians and nonphysician practitioners paid under the Medicare Physician Fee Schedule (MPFS); laboratory services paid under the Clinical Laboratory Fee Schedule (CLFS); services for beneficiaries with end-stage renal disease (ESRD) that are paid under the ESRD composite rate; and services and procedures that require an inpatient stay that are paid under the hospital inpatient prospective payment system (IPPS). We set forth the services that are excluded from payment under the OPPS in 42 CFR 419.22 of the regulations.

Under § 419.20(b) of the regulations, we specify the types of hospitals and entities that are excluded from payment under the OPPS. These excluded entities include: Maryland hospitals, but only for services that are paid under a cost containment waiver in accordance with section 1814(b)(3) of the Act; critical access hospitals (CAHs); hospitals located outside of the 50 States, the District of Columbia, and Puerto Rico; and Indian Health Service (IHS) hospitals.

C. Prior Rulemaking

On April 7, 2000, we published in the **Federal Register** a final rule with comment period (65 FR 18434) to implement a prospective payment system for hospital outpatient services. The hospital OPPS was first implemented for services furnished on or after August 1, 2000. Section 1833(t)(9) of the Act requires the Secretary to review certain components of the OPPS, not less often than annually, and to revise the groups, relative payment weights, and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors.

Since initially implementing the OPPS, we have published final rules in the **Federal Register** annually to implement statutory requirements and changes arising from our continuing experience with this system. These rules can be viewed on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS/*. The CY 2011 OPPS/ASC final rule with comment period appears in the November 24, 2010 **Federal Register** (75 FR 71800). In that final rule with comment period, we revised the OPPS to update the payment weights and conversion factor for services payable under the CY 2011 OPPS on the basis of claims data from January 1, 2009, through December 31, 2009, and to implement certain provisions of the Affordable Care Act. In addition, we responded to public comments received on the provisions of the CY 2010 final rule with comment period (74 FR 60316) pertaining to the APC assignment of HCPCS codes identified in Addendum B to that rule with the new interim (''NI'') comment indicator, and public comments received on the August 3, 2010 OPPS/ASC proposed rule for CY 2011 (75 FR 46170).

On July 18, 2011, the CY 2012 OPPS/ASC proposed rule appeared in the **Federal Register** (76 FR 42170). This proposed rule, with a 60-day comment period that ended on August 30, 2011, proposed to revise the Medicare OPPS and the ASC payment system to implement applicable statutory requirements and changes arising from our continuing experience with these systems.

D. Advisory Panel on Ambulatory Payment Classification (APC) Groups

1. Authority of the Advisory Panel on Ambulatory Payment Classification (APC) Groups (the APC Panel)

Section 1833(t)(9)(A) of the Act, as amended by section 201(h) of Public Law 106–113, and redesignated by section 202(a)(2) of Public Law 106–113, requires that we consult with an outside panel of experts to review the clinical integrity of the payment groups and their weights under the OPPS. The Act further specifies that the panel will act in an advisory capacity. The APC Panel, discussed under section I.D.2. of this final rule, fulfills these requirements. The APC Panel is not restricted to using data compiled by CMS, and it may use data collected or developed by organizations outside the Department in conducting its review.

2. Establishment of the APC Panel

On November 21, 2000, the Secretary signed the initial charter establishing the APC Panel. This expert panel, which may be composed of up to 15 representatives of providers (currently employed full-time, not as consultants, in their respective areas of expertise) subject to the OPPS, reviews clinical data and advises CMS about the clinical integrity of the APC groups and their payment weights. The APC Panel is technical in nature, and it is governed by the provisions of the Federal Advisory Committee Act (FACA). Since its initial chartering, the Secretary has renewed the APC Panel's charter five times: on November 1, 2002; on November 1, 2004; on November 21, 2006; on November 2, 2008 and November 12, 2010. The current charter specifies, among other requirements, that: the APC Panel continues to be technical in nature; is governed by the provisions of the FACA; may convene up to three meetings per year; has a Designated Federal Official (DFO); and is chaired by a Federal Official designated by the Secretary.

The current APC Panel membership and other information pertaining to the APC Panel, including its charter, **Federal Register** notices, membership, meeting dates, agenda topics, and meeting reports, can be viewed on the CMS Web site at: *http://www.cms.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp#TopOfPage*.

3. APC Panel Meetings and Organizational Structure

The APC Panel first met on February 27 through March 1, 2001. Since the initial meeting, the APC Panel has held multiple meetings, with the last meeting taking place on August 10–12, 2011. Prior to each meeting, we publish a notice in the **Federal Register** to announce the meeting and, when necessary, to solicit nominations for APC Panel membership and to announce new members.

The APC Panel has established an operational structure that, in part, currently includes the use of three subcommittees to facilitate its required APC review process. The three current subcommittees are the Data Subcommittee, the Visits and Observation Subcommittee, and the Subcommittee for APC Groups and Status Indicator (SI) Assignments (previously known as the Packaging Subcommittee).

The Data Subcommittee is responsible for studying the data issues confronting the APC Panel and for recommending options for resolving them. The Visits and Observation Subcommittee reviews and makes recommendations to the APC Panel on all technical issues pertaining to observation services and hospital outpatient visits paid under the OPPS (for example, APC configurations and APC payment weights). The Subcommittee for APC Groups and SI Assignments advises the Panel on the following issues: the appropriate SIs to be assigned to HCPCS codes, including but not limited to whether a HCPCS code or a category of codes should be packaged or separately paid; and the appropriate APCs to be assigned to HCPCS codes regarding services for which separate payment is made.

Each of these subcommittees was established by a majority vote from the full APC Panel during a scheduled APC Panel meeting, and the APC Panel recommended that the subcommittees continue at the August 2011 APC Panel meeting. We accept those recommendations of the APC Panel. All subcommittee recommendations are discussed and voted upon by the full APC Panel.

Discussions of the other recommendations made by the APC Panel at the February/March 2011 and August 2011 APC Panel meetings are included in the sections of this final rule with comment period that are specific to each recommendation. For discussions of earlier APC Panel meetings and recommendations, we refer readers to previously published hospital OPPS/ASC proposed and final rules, the CMS Web site mentioned earlier in this section, and the FACA database at: *http://fido.gov/facadatabase/public.asp*.

E. Summary of the Major Contents of the CY 2012 OPPS/ASC Proposed Rule

In the CY 2012 OPPS/ASC proposed rule that appeared in the **Federal Register** on July 18, 2011 (76 FR 42170), we set forth proposed changes to the Medicare hospital OPPS for CY 2012 to implement statutory requirements and changes arising from our continuing

experience with the system. In addition, we set forth proposed changes to the revised Medicare ASC payment system for CY 2012, including proposed updated payment weights, covered surgical procedures, and covered ancillary items and services based on the proposed OPPS update. In addition, we proposed to make changes to the rules governing limitations on certain physician referrals to hospitals in which physicians have an ownership or investment interest, provider agreement regulations on patient notification requirements, and the rules governing the Hospital Inpatient Value-Based Purchasing (VBP) Program.

The following is a summary of the major changes that we proposed to make for CY 2012:

1. Updates Affecting OPPS Payments

In section II. of the proposed rule, we set forth—

- The methodology used to recalibrate the proposed APC relative payment weights.
- The proposed changes to packaged services.
- The proposed update to the conversion factor used to determine payment rates under the OPPS. In this section, we proposed changes in the amounts and factors for calculating the full annual update increase to the conversion factor.
- The proposed consideration of adopting a policy that would address situations where IPPS wage index adjustments result in significant fluctuations in the wage index.
- The proposed update of statewide average default CCRs.
- The proposed application of hold harmless transitional outpatient payments (TOPs) for certain small rural hospitals, extended by section 3121 of the Affordable Care Act.
- The proposed payment adjustment for rural SCHs.
- The proposed payment adjustment for cancer hospitals.
- The proposed calculation of the hospital outpatient outlier payment.
- The calculation of the proposed national unadjusted Medicare OPPS payment.
- The proposed beneficiary copayments for OPPS services.

2. OPPS Ambulatory Payment Classification (APC) Group Policies

In section III. of the proposed rule, we discussed—

- The proposed additions of new HCPCS codes to APCs.
- The proposed establishment of a number of new APCs.
- Our analyses of Medicare claims data and certain recommendations of the APC Panel.
- The application of the 2 times rule and proposed exceptions to it.
- The proposed changes to specific APCs.
- The proposed movement of procedures from New Technology APCs to clinical APCs.

3. OPPS Payment for Devices

In section IV. of the proposed rule, we discussed the proposed pass-through payment for specific categories of devices and the proposed adjustment for devices furnished at no cost or with partial or full credit.

4. OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

In section V. of the proposed rule, we discussed the proposed CY 2012 OPPS payment for drugs, biologicals, and radiopharmaceuticals, including the proposed payment for drugs, biologicals, and radiopharmaceuticals with and without pass-through status.

5. Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

In section VI. of the proposed rule, we discussed the estimate of CY 2012 OPPS transitional pass-through spending for drugs, biologicals, and devices.

6. OPPS Payment for Hospital Outpatient Visits

In section VII. of the proposed rule, we set forth our proposed policies for the payment of clinic and emergency department visits and critical care services based on claims data.

7. Payment for Partial Hospitalization Services

In section VIII. of the proposed rule, we set forth our proposed payment for partial hospitalization services, including the proposed separate threshold for outlier payments for CMHCs.

8. Procedures That Would Be Paid Only as Inpatient Procedures

In section IX. of the proposed rule, we discussed the procedures that we proposed to remove from the inpatient list and assign to APCs for payment under the OPPS.

9. Policies on Supervision Standards for Outpatient Services in Hospitals and CAHs

In section X. of the proposed rule, we discussed proposed policy changes relating to the supervision of outpatient services furnished in hospitals and CAHs.

10. OPPS Payment Status and Comment Indicators

In section XI. of the proposed rule, we discussed our proposed changes to the definitions of status indicators assigned to APCs and presented our proposed comment indicators.

11. OPPS Policy and Payment Recommendations

In section XII. of the proposed rule, we addressed recommendations made by the Medicare Payment Advisory Commission (MedPAC) in its March 2011 report to Congress, by the Office of Inspector General (OIG), and by the APC Panel regarding the OPPS for CY 2012.

12. Updates to the Ambulatory Surgical Center (ASC) Payment System

In section XIII. of the proposed rule, we discussed the proposed updates of the revised ASC payment system and payment rates for CY 2012.

13. Reporting Quality Data for Annual Payment Rate Updates

In section XIV. of the proposed rule, we discussed the proposed measures for reporting hospital outpatient quality data for the OPD fee schedule increase factor for CY 2013 and subsequent calendar years; set forth the requirements for data collection and submission; and discuss the reduction to the OPPS OPD fee schedule increase factor for hospitals that fail to meet the Hospital OQR Program requirements. We also discussed proposed measures for reporting ASC quality data for the annual payment update factor for CYs 2014, 2015, and 2016; and set forth the requirements for data collection and submission for the annual payment update.

14. Changes to EHR Incentive Program for Eligible Hospitals and CAHs Regarding Electronic Submission of Clinical Quality Measures (CQMs)

In section XIV.J. of the proposed rule, we proposed to allow eligible hospitals and CAHs participating in the Medicare EHR Incentive Program to meet the CQM reporting requirement of the EHR Incentive Program for payment year 2012 by participating in the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot.

15. Changes to Provisions Relating to Physician Self-Referral Prohibition and Provider Agreement Regulations on Patient Notification Requirements

In section XV. of the proposed rule, we presented our proposed exception

process for expansion of facility capacity under the whole hospital and rural provider exceptions to the physician self-referral law, and proposed changes to the provider agreement regulations on patient notification requirements.

16. Additional Changes Relating to the Hospital Inpatient VBP Program

In section XVI. of the proposed rule, we presented our proposed requirements for the FY 2014 Hospital Inpatient VBP Program.

17. Economic and Federalism Analyses

In sections XX. and XXI. of the proposed rule, we set forth an analysis of the regulatory and federalism impacts that the proposed changes would have on affected entities and beneficiaries.

F. Public Comments Received in Response to the CY 2012 OPPS/ASC Proposed Rule

We received approximately 1,356 timely pieces of correspondence containing multiple comments on the CY 2012 OPPS/ASC proposed rule that appeared in the **Federal Register** on July 18, 2011. We note that we received some public comments that were outside the scope of the CY 2012 OPPS/ASC proposed rule. Out of scope public comments are not addressed in this CY 2012 OPPS/ASC final rule with comment period. Summaries of the public comments that are within the scope of the proposed rule and our responses are set forth in the various sections of this final rule with comment period under the appropriate headings.

G. Public Comments Received on the CY 2011 OPPS/ASC Final Rule With Comment Period

We received approximately 43 timely pieces of correspondence on the CY 2011 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on November 24, 2010 (75 FR 71800), some of which contained multiple comments on the interim APC assignments and/or status indicators of HCPCS codes identified with comment indicator ''NI'' in Addendum B to that final rule with comment period. Summaries of those public comments on topics open to comment in the CY 2012 OPPS/ASC final rule with comment period and our responses to them are set forth in various sections of this final rule with comment period under the appropriate headings.

II. Updates Affecting OPPS Payments

A. Recalibration of APC Relative Weights

1. Database Construction

a. Database Source and Methodology

Section 1833(t)(9)(A) of the Act requires that the Secretary review not less often than annually and revise the relative payment weights for APCs. In the April 7, 2000 OPPS final rule with comment period (65 FR 18482), we explained in detail how we calculated the relative payment weights that were implemented on August 1, 2000 for each APC group.

In the CY 2012 OPPS/ASC proposed rule (76 FR 42179), for the CY 2012 OPPS, we proposed to recalibrate the APC relative payment weights for services furnished on or after January 1, 2012, and before January 1, 2013 (CY 2012), using the same basic methodology that we described in the CY 2011 OPPS/ASC final rule with comment period. That is, we proposed to recalibrate the relative payment weights for each APC based on claims and cost report data for hospital outpatient department (HOPD) services, using the most recent available data to construct a database for calculating APC group weights. Therefore, for the purpose of recalibrating the proposed APC relative payment weights for CY 2012, we used approximately 138 million final action claims (claims for which all disputes and adjustments have been resolved and payment has been made) for hospital outpatient department services furnished on or after January 1, 2010, and before January 1, 2011. For this final rule with comment period, for the purpose of recalibrating the final APC relative payment weights for CY 2012, we used approximately 148 million final action claims (claims for which all disputes and adjustments have been resolved and payment has been made) for hospital outpatient department services furnished on or after January 1, 2010, and before January 1, 2011. (For exact counts of claims used, we refer readers to the claims accounting narrative under supporting documentation for the proposed rule and this final rule with comment period on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS/HORD/*.)

Of the 148 million final action claims for services provided in hospital outpatient settings used to calculate the final CY 2012 OPPS payment rates for this final rule with comment period, approximately 112 million claims were the type of bill potentially appropriate for use in setting rates for OPPS services (but did not necessarily contain services payable under the OPPS). Of the 112 million claims, approximately 3 million claims were not for services paid under the OPPS or were excluded as not appropriate for use (for example, erroneous cost-to-charge ratios (CCRs) or no HCPCS codes reported on the claim). From the remaining approximately 109 million claims, we created approximately 110 million single records, of which approximately 75 million were ''pseudo'' single or ''single session'' claims (created from approximately 25 million multiple procedure claims using the process we discuss later in this section). Approximately 888,000 claims were trimmed out on cost or units in excess of +/−3 standard deviations from the geometric mean, yielding approximately 108 million single bills for median setting. As described in section II.A.2. of this final rule with comment period, our data development process is designed with the goal of using appropriate cost information in setting the APC relative weights. The bypass process is described in section II.A.1.b. of this final rule with comment period. This section discusses how we develop ''pseudo'' single procedure claims (as defined below), with the intention of using more appropriate data from the available claims. In some cases, the bypass process allows us to use some portion of the submitted claim for cost estimation purposes, while the remaining information on the claim continues to be unusable. Consistent with the goal of using appropriate information in our data development process, we only use claims (or portions of each claim) that are appropriate for ratesetting purposes. Ultimately, we were able to use for CY 2012 ratesetting some portion of approximately 94 percent of the CY 2010 claims containing services payable under the OPPS.

The final APC relative weights and payments for CY 2012 in Addenda A and B to this final rule with comment period (which are referenced in section XVII. of this final rule with comment period and available via the Internet on the CMS Web site) were calculated using claims from CY 2010 that were processed before July 1, 2011, and continue to be based on the median hospital costs for services in the APC groups. Under the methodology we are adopting in this final rule with comment period, we select claims for services paid under the OPPS and match these claims to the most recent cost report filed by the individual hospitals represented in our claims data.

We continue to believe that it is appropriate to use the most current full calendar year claims data and the most recently submitted cost reports to calculate the median costs underpinning the APC relative payment weights and the CY 2012 payment rates.

b. Use of Single and Multiple Procedure Claims

For CY 2012, in general, we proposed to continue to use single procedure claims to set the medians on which the APC relative payment weights would be based, with some exceptions as discussed below in this section. We generally use single procedure claims to set the median costs for APCs because we believe that the OPPS relative weights on which payment rates are based should be derived from the costs of furnishing one unit of one procedure and because, in many circumstances, we are unable to ensure that packaged costs can be appropriately allocated across multiple procedures performed on the same date of service.

It is generally desirable to use the data from as many claims as possible to recalibrate the APC relative payment weights, including those claims for multiple procedures. As we have for several years, we proposed to continue to use date of service stratification and a list of codes to be bypassed to convert multiple procedure claims to ''pseudo'' single procedure claims. Through bypassing specified codes that we believe do not have significant packaged costs, we are able to use more data from multiple procedure claims. In many cases, this enabled us to create multiple ''pseudo'' single procedure claims from claims that were submitted as multiple procedure claims spanning multiple dates of service, or claims that contained numerous separately paid procedures reported on the same date on one claim. We refer to these newly created single procedure claims as ''pseudo'' single procedure claims. The history of our use of a bypass list to generate ''pseudo'' single procedure claims is well documented, most recently in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71811 through 71822). In addition, for CY 2008, we increased packaging and created the first composite APCs. We have continued our packaging policies and the creation of composite APCs for CYs 2009, 2010, and 2011, and we proposed to continue them for CY 2012. Increased packaging and creation of composite APCs also increased the number of bills that we were able to use for median calculation by enabling us to use claims that contained multiple major procedures that previously would not have been usable. Further, for CY 2009, we expanded the composite APC model to one additional clinical area, multiple imaging services (73 FR 68559 through 68569), which also increased the number of bills we were able to use to calculate APC median costs. We have continued the composite APCs for multiple imaging services for CYs 2010 and 2011, and we proposed to continue to create them for CY 2012. We refer readers to section II.A.2.e. of the proposed rule and this final rule with comment period for a discussion of the use of claims to establish median costs for composite APCs.

We proposed to continue to apply these processes to enable us to use as much claims data as possible for ratesetting for the CY 2012 OPPS. This methodology enabled us to create, for the proposed rule, approximately 67 million ''pseudo'' single procedure claims, including multiple imaging composite ''single session'' bills (we refer readers to section II.A.2.e.(5) of the proposed rule for further discussion), to add to the approximately 33 million ''natural'' single procedure claims. For the proposed rule, ''pseudo'' single procedure and ''single session'' procedure bills represented approximately 67 percent of all single procedure bills used to calculate median costs.

For CY 2012, we proposed to bypass 460 HCPCS codes for CY 2012 that were identified in Addendum N to the proposed rule (which is available via the Internet on the CMS Web site). Since the inception of the bypass list, which is the list of codes to be bypassed to convert multiple procedure claims to ''pseudo'' single procedure claims, we have calculated the percent of ''natural'' single bills that contained packaging for each HCPCS code and the amount of packaging on each ''natural'' single bill for each code. Each year, we generally retain the codes on the previous year's bypass list and use the updated year's data (for CY 2012, data available for the February 28–March 1, 2011 APC Panel meeting from CY 2010 claims processed through September 30, 2010, and CY 2009 claims data processed through June 30, 2010, used to model the payment rates for CY 2011) to determine whether it would be appropriate to propose to add additional codes to the previous year's bypass list. For CY 2012, we proposed to continue to bypass all of the HCPCS codes on the CY 2011 OPPS bypass list. We updated HCPCS codes on the CY 2011 bypass list that were mapped to new HCPCS codes for CY 2012 ratesetting by evaluating data for the replacement codes under the empirical criteria described below and also removing the HCPCS codes that we proposed to be deleted for CY 2012, which were listed in Table 1 of the proposed rule. We also proposed to remove HCPCS codes that were not separately paid under the OPPS because the purpose of the bypass list is to obtain more data for those codes relevant to ratesetting. None of these deleted codes were ''overlap bypass codes'' (those HCPCS codes that are both on the bypass list and are members of the multiple imaging composite APCs). We also proposed to add to the bypass list for CY 2012 all HCPCS codes not on the CY 2011 bypass list that, using either the CY 2011 final rule data (CY 2009 claims) or the February 28–March 1, 2011 APC Panel data (first 9 months of CY 2010 claims), met the empirical criteria for the bypass list that are summarized below. The entire list proposed for CY 2012 (including the codes that remain on the bypass list from prior years) was open to public comment. Because we must make some assumptions about packaging in the multiple procedure claims in order to assess a HCPCS code for addition to the bypass list, we assumed that the representation of packaging on ''natural'' single procedure claims for any given code is comparable to packaging for that code in the multiple procedure claims. The proposed criteria for the bypass list were:

- There are 100 or more ''natural'' single procedure claims for the code. This number of single procedure claims ensures that observed outcomes are sufficiently representative of packaging that might occur in the multiple claims.
- Five percent or fewer of the ''natural'' single procedure claims for the code have packaged costs on that single procedure claim for the code. This criterion results in limiting the amount of packaging being redistributed to the separately payable procedures remaining on the claim after the bypass code is removed and ensures that the costs associated with the bypass code represent the cost of the bypassed service.
- The median cost of packaging observed in the ''natural'' single procedure claims is equal to or less than $55. This criterion also limits the amount of error in redistributed costs. During the assessment of claims against the bypass criteria, we do not know the dollar value of the packaged cost that should be appropriately attributed to the other procedures on the claim. Therefore, ensuring that redistributed costs associated with a bypass code are small in amount and volume protects the validity of cost estimates for low

cost services billed with the bypassed service.

In response to comments to the CY 2010 OPPS/ASC proposed rule requesting that the packaged cost threshold be updated, we considered whether it would be appropriate to update the $50 packaged cost threshold for inflation when examining potential bypass list additions. As discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60328), the real value of this packaged cost threshold criterion has declined due to inflation, making the packaged cost threshold more restrictive over time when considering additions to the bypass list. Therefore, adjusting the threshold by the market basket increase would prevent continuing decline in the threshold's real value. For CY 2011, based on CY 2009 claims data, we proposed to apply the final market basket increase of 3.6 percent published in the CY 2009 OPPS/ASC final rule with comment period (73 FR 26584) to the $50 packaged cost threshold used in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60325). This calculation led us to a proposed packaged cost threshold for bypass list additions for CY 2011 of $50 ($51.80 rounded to $50). We stated that we believe that applying the market basket increase from the year of claims data to the packaged cost threshold, rounded to the nearest $5 increment, would appropriately account for the effects of inflation when considering additions to the bypass list because the market basket increase reflects the extent to which the price of inputs for hospital services is expected to increase compared to the price of inputs for hospital services in the prior year. We proposed for CY 2012, based on the same rationale described for the CY 2011 OPPS/ASC final rule with comment period (75 CFR 71812), to continue to update the packaged cost threshold by the market basket increase. By applying the final CY 2011 market basket increase of 1.85 percent to the prior non-rounded dollar threshold of $51.80 (75 FR 71812), we determined that the threshold increases for CY 2012 to $55 ($52.76 rounded to $55, the nearest $5 increment). Therefore, we proposed to set the median packaged cost threshold on the CY 2010 claims at $55 for a code to be considered for addition to the CY 2012 OPPS bypass list.

- The code is not a code for an unlisted service.

In addition, we proposed to continue to include, on the bypass list, HCPCS codes that CMS medical advisors believe have minimal associated packaging based on their clinical assessment of the complete CY 2012 OPPS proposal. Some of these codes were identified by CMS medical advisors and some were identified in prior years by commenters with specialized knowledge of the packaging associated with specific services. We also proposed to continue to include on the bypass list certain HCPCS codes in order to purposefully direct the assignment of packaged costs to a companion code where services always appear together and where there would otherwise be few single procedure claims available for ratesetting. For example, we have previously discussed our reasoning for adding HCPCS code G0390 (Trauma response team associated with hospital critical care service) and the CPT codes for additional hours of drug administration to the bypass list (73 FR 68513 and 71 FR 68117 through 68118).

As a result of the multiple imaging composite APCs that we established in CY 2009, the program logic for creating ''pseudo'' single procedure claims from bypassed codes that are also members of multiple imaging composite APCs changed. When creating the set of ''pseudo'' single procedure claims, claims that contain ''overlap bypass codes'' (those HCPCS codes that are both on the bypass list and are members of the multiple imaging composite APCs) were identified first. These HCPCS codes were then processed to create multiple imaging composite ''single session'' bills, that is, claims containing HCPCS codes from only one imaging family, thus suppressing the initial use of these codes as bypass codes. However, these ''overlap bypass codes'' were retained on the bypass list because, at the end of the ''pseudo'' single processing logic, we reassessed the claims without suppression of the ''overlap bypass codes'' under our longstanding ''pseudo'' single process to determine whether we could convert additional claims to ''pseudo'' single procedure claims. (We refer readers to section II.A.2.b. of the proposed rule and this final rule with comment period for further discussion of the treatment of ''overlap bypass codes.'') This process also created multiple imaging composite ''single session'' bills that could be used for calculating composite APC median costs. ''Overlap bypass codes'' that are members of the proposed multiple imaging composite APCs were identified by asterisks (*) in Addendum N to the proposed rule (which is available via the Internet on the CMS Web site).

Addendum N to the proposed rule included the proposed list of bypass codes for CY 2012. The list of bypass codes contains codes that were reported on claims for services in CY 2010 and, therefore, includes codes that were in effect in 2010 and used for billing but were deleted for CY 2011. We retained these deleted bypass codes on the proposed CY 2012 bypass list because these codes existed in CY 2010 and were covered OPD services in that period, and CY 2010 claims data are used to calculate CY 2012 payment rates. Keeping these deleted bypass codes on the bypass list potentially allowed us to create more ''pseudo'' single procedure claims for ratesetting purposes. ''Overlap bypass codes'' that were members of the proposed multiple imaging composite APCs were identified by asterisks (*) in the third column of Addendum N to the proposed rule. HCPCS codes that we proposed to add for CY 2012 were identified by asterisks (*) in the fourth column of Addendum N.

Comment: One commenter recommended that CMS add CPT code 77332 (Treatment devices, design and construction; simple (simple block, simple bolus)) to the bypass list in order to yield additional claims for ratesetting for composite APC 8001 (LDR Prostate Brachytherapy Composite). The commenter's analysis showed that bypassing the code would yield a significant increase in the number of claims to set the composite rate.

Response: As discussed above, we perform an analysis on the natural single major claims to determine possible additions to the bypass list. In doing so, we apply a set of empirical criteria to identify codes that would be appropriate for addition to the bypass list, based on how well they represent the clinical use of the service as well as the limited packaging impact of bypassing those codes. These criteria are consistent with the goal of using appropriate data for ratesetting. The commenter suggested that bypassing the code would be appropriate because it would yield additional claims without a discussion of the impact of bypassing the code. In the APC Panel 2012 data used to create the bypass list proposal, the code failed to meet the empirical criteria. Of the 134 available natural single major claims, 117 (87 percent) of those claims contained packaging, which exceeds the 5 percent limit for a code to be placed on the bypass list. Additionally, the median cost of packaging on those claims was $200.23, which exceeds the $55 limit for the code to be placed on the bypass list. These data suggest that bypassing the code may potentially and relatively often, distribute packaged costs, where it

might not be appropriate. For example, where CPT code 77332 is furnished on the day on which a visit was the only other payable service, if CPT code 77332 were on the bypass list, the packaging would be associated with the visit, not with CPT code 77332, because we use the line-item costs for codes on the bypass list without their attendant packaging to establish the median cost for the bypass code. This would inappropriately reduce the median cost for CPT code 77332. While we seek to use as much available information as possible that is available in the OPPS claims data set, we do so with the goal of using appropriate cost information in setting the APC relative weights. In this case, we believe that adding the CPT code 77332 to the bypass list would create considerable risk in assigning packaging that rightfully should be associated with CPT code 77332 to other services. Therefore we are not adding CPT code 77332 to the bypass list for CY 2012.

Comment: One commenter recommended that CMS continue to explore additional methodologies to increase the number of procedure claims used for rate setting, including expanding the criteria for inclusion on the bypass list.

Response: We are always seeking additional methodologies that would enable us to increase the number of procedure claims used for rate setting. However, it is important to us that we ensure that any new methodology or change to current methodology or criteria would not result in costs that are appropriately packaged into a service being inappropriately assigned to another service, as, for example, we believe would be the case if we were to place CPT code 77332 on the bypass list.

After consideration of the public comments we received, we are adopting as final the proposed ''pseudo'' single claims process and the final CY 2012 bypass list of 460 HCPCS codes, as displayed in Addendum N of this final rule with comment period (available via the Internet on the CMS Web site). Table 1 below contains the list of codes that we are removing from the CY 2012 bypass list because these codes were either deleted from the HCPCS before CY 2010 (and therefore were not covered OPD services in CY 2010) or were not separately payable codes under the CY 2012 OPPS because these codes are not used for ratesetting (and therefore would not need to be bypassed). None of these deleted codes were ''overlap bypass'' codes.

TABLE 1.—HCPCS CODES REMOVED FROM THE CY 2012 BYPASS LIST

HCPCS Code	HCPCS Short Descriptor
29220	Strapping of low back
78350	Bone mineral, single photon
90816	Psytx, hosp, 20-30 min
90818	Psytx, hosp, 45-50 min
90826	Intac psytx, hosp, 45-50 min
99241	Office consultation
99242	Office consultation
99243	Office consultation
99244	Office consultation
99245	Office consultation
0144T	CT heart wo dye; qual calc

c. Calculation and Use of Cost-to-Charge Ratios (CCRs)

In the CY 2012 OPPS/ASC proposed rule (76 FR 42181), for CY 2012, we proposed to continue to use the hospital-specific overall ancillary and departmental CCRs to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk. To calculate the APC median costs on which the proposed CY 2012 APC payment rates were based, we calculated hospital-specific overall ancillary CCRs and hospital-specific departmental CCRs for each hospital for which we had CY 2010 claims data from the most recent available hospital cost reports, in most cases, cost reports beginning in CY 2009. For the CY 2012 OPPS proposed rates, we used the set of claims processed during CY 2010. We applied the hospital-specific CCR to the hospital's charges at the most detailed level possible, based on a revenue code-to-cost center crosswalk that contains a hierarchy of CCRs used to estimate costs from charges for each revenue code. That crosswalk is available for review and continuous comment on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS/03_crosswalk.asp#TopOfPage*.

To ensure the completeness of the revenue code-to-cost center crosswalk, we reviewed changes to the list of revenue codes for CY 2010 (the year of the claims data we used to calculate the proposed CY 2012 OPPS payment rates). For CY 2010, the National Uniform Billing Committee added revenue codes 860 (Magnetoencephalography (MEG); general classification) and 861 (Magnetoencephalography (MEG)). For purposes of applying a CCR to charges reported under revenue codes 860 and 861, we proposed to use nonstandard Medicare cost report cost center 3280 (Electrocardiogram (EKG) and Electroencephalography (EEG)) as the primary cost center and to use standard cost center 5400 (Electroencephalography (EEG)) as the secondary cost center. We believe that MEG, which evaluates brain activity, is

similar to EEG, which also evaluates brain activity, and that the few hospitals that furnish MEG are likely to furnish it in the same department of the hospital in which they furnish EEG services. Therefore, we believe that the CCRs that we apply to the EEG revenue codes are more likely to result in a more accurate estimated cost for MEG than would the application of the hospital-specific overall ancillary CCR. For hospitals that report charges under revenue code 860 or 861 but do not report costs on their cost report under cost center 3280 or 5400, we proposed to apply the hospital-specific overall CCR to the charges reported under revenue code 860 or 861 for purposes of estimating the cost of these services. We discuss MEG, including the issue of the CCR to be applied to charges for MEG, in section III.D. of this final rule with comment period. We note that revenue codes with effective dates in CY 2011 are not relevant to this process because these new revenue codes were not applicable to claims for services furnished during CY 2010.

In accordance with our longstanding policy, we calculated CCRs for the standard and nonstandard cost centers accepted by the electronic cost report database. In general, the most detailed level at which we calculated CCRs was the hospital-specific departmental level. For a discussion of the hospital-specific overall ancillary CCR calculation, we refer readers to the CY 2007 OPPS/ASC final rule with comment period (71 FR 67983 through 67985). One longstanding exception to this general methodology for calculation of CCRs used for converting charges to costs on each claim is the calculation of median blood costs, as discussed in section II.A.2.d.(2) of the proposed rule and this final rule with comment period and which has been our standard policy since the CY 2005 OPPS.

For the CCR calculation process, we used the same general approach that we used in developing the final APC rates for CY 2007 and thereafter, using the revised CCR calculation that excluded the costs of paramedical education programs and weighted the outpatient charges by the volume of outpatient services furnished by the hospital. We refer readers to the CY 2007 OPPS/ASC final rule with comment period for more information (71 FR 67983 through 67985). We first limited the population of cost reports to only those for hospitals that filed outpatient claims in CY 2010 before determining whether the CCRs for such hospitals were valid.

We then calculated the CCRs for each cost center and the overall ancillary CCR for each hospital for which we had claims data. We did this using hospital-specific data from the Hospital Cost Report Information System (HCRIS). We used the most recent available cost report data, in most cases, cost reports with cost reporting periods beginning in CY 2009. For the proposed rule, we used the most recently submitted cost reports to calculate the CCRs to be used to calculate median costs for the proposed CY 2012 OPPS payment rates. If the most recent available cost report was submitted but not settled, we looked at the last settled cost report to determine the ratio of submitted to settled cost using the overall ancillary CCR, and we then adjusted the most recent available submitted, but not settled, cost report using that ratio. We then calculated both an overall ancillary CCR and cost center-specific CCRs for each hospital. We used the overall ancillary CCR referenced in section II.A.1.c. of the proposed rule for all purposes that require use of an overall ancillary CCR. We proposed to continue this longstanding methodology for the calculation of median costs for CY 2012.

Since the implementation of the OPPS, some commenters have raised concerns about potential bias in the OPPS cost-based weights due to ''charge compression,'' which is the practice of applying a lower charge markup to higher cost services and a higher charge markup to lower cost services. As a result, the cost-based weights may reflect some aggregation bias, undervaluing high-cost items and overvaluing low-cost items when an estimate of average markup, embodied in a single CCR, is applied to items of widely varying costs in the same cost center.

To explore this issue, in August 2006, we awarded a contract to RTI International (RTI) to study the effects of charge compression in calculating the IPPS cost-based relative weights, particularly with regard to the impact on inpatient diagnosis-related group (DRG) payments, and to consider methods to better capture the variation in cost and charges for individual services when calculating costs for the IPPS relative weights across services in the same cost center. RTI issued a report in March 2007 with its findings on charge compression, which is available on the CMS Web site at: *http://www.cms.gov/reports/downloads/Dalton.pdf*. Although this report was focused largely on charge compression in the context of the IPPS cost-based relative weights, because several of the findings were relevant to the OPPS, we discussed that report in the CY 2008 OPPS/ASC proposed rule (72 FR 42641 through 42643) and discussed those findings again in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66599 through 66602).

In August 2007, we contracted with RTI to evaluate the cost estimation process for the OPPS relative weights because its 2007 report had concentrated on IPPS DRG cost-based relative weights. The results of RTI's analyses had implications for both the OPPS APC cost-based relative weights and the IPPS MS–DRG (Medicare severity) cost-based relative weights. The RTI final report can be found on RTI's Web site at: *http://www.rti.org/reports/cms/HHSM–500–2005–0029I/PDF/Refining_Cost_to_Charge_Ratios_200807_Final.pdf*. For a complete discussion of the RTI recommendations, public comments, and our responses, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68519 through 68527).

We addressed the RTI finding that there was aggregation bias in both the IPPS and the OPPS cost estimation of expensive and inexpensive medical supplies in the FY 2009 IPPS final rule. Specifically, we finalized our proposal for both the OPPS and IPPS to create one cost center for ''Medical Supplies Charged to Patients'' and one cost center for ''Implantable Devices Charged to Patients,'' essentially splitting the then current CCR for ''Medical Supplies and Equipment'' into one CCR for low-cost medical supplies and another CCR for high-cost implantable devices in order to mitigate some of the effects of charge compression. Accordingly, in Transmittal 20 of the Provider Reimbursement Manual, Part II (PRM–II), Chapter 36, Form CMS–2552–96, which was issued in July 2009, we created a new subscripted Line 55.01 on Worksheet A for the ''Implantable Devices Charged to Patients'' cost center. This new subscripted cost center, placed under the standard line for ''Medical Supplies Charged to Patients,'' is available for use for cost reporting periods beginning on or after May 1, 2009. A subscripted cost center is the addition of a separate new cost center line and description which bears a logical relationship to the standard cost center line and is located immediately following a standard cost center line. Subscripting a cost center line adds flexibility and cost center expansion capability to the cost report. For example, Line 55 of Worksheet A on Form CMS 2552–96 (the Medicare hospital cost report) is ''Medical Supplies Charged to Patients.'' The additional cost center, which isolates the costs of ''Implantable Medical Supplies Charged to Patients'', was created by adding subscripted Line

55.01 to Worksheet A and is defined as capturing the costs and charges billed with the following UB–04 revenue codes: 0275 (Pacemaker); 0276 (Intraocular lens); 0278 (other implants); and 0624 (FDA investigations devices) (73 FR 48458).

In preparation for the FY 2012 IPPS proposed rule and the CY 2012 OPPS proposed rule, we assessed the availability of data in the ''Implantable Devices Charged to Patients'' cost center. In order to develop a robust analysis regarding the use of cost data from the ''Implantable Devices Charged to Patients'' cost center, we believe that it is necessary to have a critical mass of cost reports filed with data in this cost center. The cost center for ''Implantable Devices Charged to Patients'' is effective for cost reporting periods beginning on or after May 1, 2009. We checked the availability of CY 2009 cost reports in the December 31, 2010 quarter ending update of HCRIS, which is the latest upload of CY 2009 cost report data that we could use for the proposed rule. We determined that there were only 437 hospitals that had completed the ''Implantable Devices Charged to Patients'' cost center (out of approximately 3,500 IPPS hospitals). We stated in the proposed rule that we do not believe this is a sufficient amount of data from which to generate a meaningful analysis. Therefore, we did not propose to use data from the ''Implantable Devices Charged to Patients'' cost center to create a distinct CCR for Implantable Devices Charged to Patients for use in calculating the OPPS relative weights for CY 2012. We stated that we would reassess the availability of data for the ''Implantable Devices Charged to Patients'' cost center for the CY 2013 OPPS rulemaking cycle. Because there is approximately a 3-year lag in the availability of cost report data for IPPS and OPPS ratesetting purposes in a given calendar year, we believe we may be able to use data from the revised Medicare hospital cost report form to estimate costs from charges for implantable devices for the CY 2013 OPPS relative weights. For a complete discussion of the rationale for the creation of the new cost center for ''Implantable Devices Charged to Patients,'' public comments, and our responses, we refer readers to the FY 2009 IPPS final rule (73 FR 48458 through 45467).

In the CY 2009 OPPS/ASC final rule with comment period, we indicated that we would be making some other OPPS-specific changes in response to the RTI report recommendations. Specifically, these changes included modifications to the cost reporting software and the addition of three new nonstandard cost centers. With regard to modifying the cost reporting preparation software in order to offer additional descriptions for nonstandard cost centers to improve the accuracy of reporting for nonstandard cost centers, we indicated that the change would be made for the next release of the cost report software. These changes have been made to the cost reporting software with the implementation of CMS Transmittal 21, under Chapter 36 of the PRM–II, available on the CMS Web site at: *http://www.cms.gov/Manuals/PBM/*, which is effective for cost reporting periods ending on or after October 1, 2009.

We also indicated that we intended to add new nonstandard cost centers for ''Cardiac Rehabilitation,'' ''Hyperbaric Oxygen Therapy,'' and ''Lithotripsy.'' We note that, in January 2010, CMS issued Transmittal 21 which updated the PRM–II, Chapter 36, Form CMS–2552–96. One of the updates in this transmittal established nonstandard cost centers for ''Cardiac Rehabilitation,'' ''Hyperbaric Oxygen Therapy,'' and ''Lithotripsy'' for use on Worksheet A. These three new nonstandard cost centers became available for cost reporting periods ending on or after October 1, 2009, and are included in the revenue code to cost center crosswalk we proposed to use for calculating payment rates for the CY 2012 OPPS (76 FR 42183). Specifically, the nonstandard cost centers are: 3120 (Cardiac Catheterization Laboratory); 3230 (CAT Scan); 3430 (Magnetic Resonance Imaging (MRI)). The revenue code to cost center crosswalk that we proposed to use for purposes of estimating the median costs of items and services for the CY 2012 OPPS is available for review and continuous comment (outside of comment on this final rule with comment period) on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS/03_crosswalk.asp#TopOfPage*.

Furthermore, in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080), we finalized our proposal to create new standard cost centers for ''Computed Tomography (CT),'' ''Magnetic Resonance Imaging (MRI),'' and ''Cardiac Catheterization,'' and to require that hospitals report the costs and charges for these services under new cost centers on the revised Medicare cost report Form CMS 2552–10. As we discussed in the FY 2009 IPPS/LTCH PPS and CY 2009 OPPS/ASC proposed and final rules, RTI found that the costs and charges of CT scans, MRI, and cardiac catheterization differ significantly from the costs and charges of other services included in the standard associated cost center. RTI also concluded that both the IPPS and OPPS relative weights would better estimate the costs of those services if CMS were to add standard costs centers for CT scans, MRI, and cardiac catheterization in order for hospitals to report separately the costs and charges for those services and in order for CMS to calculate unique CCRs to estimate the cost from charges on claims data. (We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080) for a more detailed discussion on the reasons for the creation of standard cost centers for CT scans, MRI, and cardiac catheterization.) The new standard cost centers for MRI, CT scans, and cardiac catheterization are effective for cost report periods beginning on or after May 1, 2010, on the revised cost report Form CMS–2552–10. CMS issued the new hospital cost report Form CMS–2552–10 on December 30, 2010. The new cost report form can be accessed at the CMS Web site at: *https://www.cms.gov/Manuals/PBM/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS021935&intNumPerPage=10*. Once at this Web site, users should double click on ''Chapter 40.''

We believe that improved cost report software, the incorporation of new standard and nonstandard cost centers, and the elimination of outdated requirements will improve the accuracy of the cost data contained in the electronic cost report data files and, therefore, the accuracy of our cost estimation processes for the OPPS relative weights. We will continue our standard practice of examining ways in which we can improve the accuracy of our cost estimation processes.

Comment: Commenters requested that CMS reconsider its position to not use the data from the implantable device cost center to calculate the APC relative weights for CY 2012. Commenters noted that in the FY 2012 IPPS proposed rule, CMS found that only 437 hospitals out of approximately 3,500 IPPS hospitals reported data in the ''Implantable Devices Charged to Patients'' cost center of the Medicare hospital cost report based on the December 2010 update of FY 2009 HCRIS. Several commenters said that an analysis by their contractor identified nearly 800 hospitals using the new cost center in the April 2011 HCRIS update and estimated that 1000 hospitals would be using the new cost center by August 2011. Therefore, the commenters believed there is now a sufficient amount of data to use the implantable device CCR to calculate the relative weights and improve the

accuracy of the payment rates. Commenters also suggested that because the IPPS and OPPS use CCRs calculated at different levels, the analysis of robustness for the new cost center is less significant in the OPPS than in the IPPS, and should not be necessary before adopting the CCRs from the Implantable Device cost center. One commenter suggested that the only justifiable reason to not implement the new CCR would be for issues related to suspect data, and that the limited use of the cost center should not delay implementation of the new Implantable Medical Device cost center CCR. One commenter suggested that, should the available data be deemed insufficient, CMS should provide additional analysis justifying why that data were insufficient, provide data on the representativeness of the hospitals reporting under the implantable medical device cost center and explore other alternatives in addressing charge compression.

Response: In the CY 2012 OPPS/ASC proposed rule, we indicated that we did not have sufficient cost report data to develop the kind of robust analysis that we assured the public we would provide prior to implementing a new CCR for implantable medical devices. Therefore, we stated that we would reassess the availability of data for CY 2013. We have reviewed the availability of FY 2009 cost reports in the June 30, 2011 quarter ending update of HCRIS, which is the latest upload of FY 2009 cost report data that we currently have available. We have determined that, for cost reporting periods beginning on or after May 1, 2009, the effective date of line 55.30 (Implantable Devices Charged to Patients), there were 363 hospitals paid under the OPPS whose claims were used for the calculation of median costs in the CY 2012 OPPS/ASC proposed rule (out of approximately 4,000 OPPS hospitals) that have completed the ''Implantable Devices Charged to Patients'' cost center in the HCRIS data for the quarter ending December 31, 2010. In contrast, we found that there were 1,689 OPPS hospitals that reported costs in the implantable device cost center in the HCRIS data for the quarter ending June 30, 2011, that were used to calculate the median costs that are the basis for the CY 2012 payment rates established in this final rule with public comment period.

We agree that there are differences between the OPPS and IPPS in the calculation of the CCRs and their use in establishing estimated costs. However, we believe that it is important to analyze the CCRs used for calculation of the median costs for procedures that use implantable devices and the impact of changes in these median costs on payments for all services before the new CCRs for implantable devices are adopted. Such analysis is important because it allows the opportunity for the public to provide comment on the impact of the adoption of those CCRs on payment for services that do not use implantable devices. In a budget neutral payment system, payment for services that do not require implantable devices would be reduced as a result of increases in payment for services that use implantable devices. Quarterly HCRIS updates and the commenters themselves indicate that hundreds of hospitals would report cost report data for the new implantable device cost center in the HCRIS data used for this final rule with comment period, although such data was not available for the proposed rule. This would create the possibility that changes to payments for services that include implantable devices that appear in the final rule with comment period could be vastly different from the proposed payments for those services in the CY 2012 proposed rule. Similarly, if we were to use the CCRs for implantable devices in the calculation of the median costs for this final rule with comment period, the public would not have had an opportunity to comment on the impact of their use on payments for services that do not use implantable devices.

We are not finalizing relative payment weights based on the new CCR for implantable devices charged to patients for CY 2012 because we believe that the transition in reporting charges and costs for implantable medical devices from the general medical supplies cost centers to a highly specialized cost center for high cost items means that the final rule relative weights would otherwise be very different from the proposed rule relative weights. In the proposed rule cost report data, 363 hospitals reported approximately $4.9 billion in costs in the implantable medical device cost center in Worksheet A. In the final rule cost report data, 1,689 hospitals reported approximately $20.7 billion in costs in the implantable medical device cost center on Worksheet A. Therefore, it was not possible to calculate proposed payment rates that would reflect the same use of the implantable medical device CCR as would be used for the final rule due to the transition. To the extent that the use of a CCR for implantable medical devices in the final rule might create median costs for services that require high cost implantable medical devices that differ significantly from those we estimated for the proposed rule, the public would not have had an opportunity to comment on the unexpected changes to payments for all other services that would occur as a result of using the CCR for implantable medical devices.

We believe that it is more appropriate to wait until CY 2013, when we expect to provide an impact analysis that enables the public to assess the full impact of the use of the new CCR that is specific to implantable devices on payments for all services. Therefore, we are not using the CCRs that are specific to implantable devices in calculating the APC relative weights for CY 2012.

Comment: Commenters urged CMS to increase education efforts to encourage faster hospital adoption of the use of the implantable medical device cost center. One commenter suggested that more widespread use of the implantable device cost center would improve the validity of payment weights based on those estimated costs.

Response: We agree that it is important that hospitals understand how to accurately report data in the ''Implantable Devices Charged to Patients'' cost center, and we have worked to add more clarity to the cost report instructions. In addition, we also believe that the December 31, 2010 update of HCRIS reflected relatively few entries for this cost center because the corresponding cost center line was only available for use for cost reporting periods beginning on or after May 1, 2009. This timing of this effective date meant that hospital data for this cost center line would not be evident to CMS until the March 31, 2011 HCRIS update. However, this update occurred after the December 31, 2010 HCRIS update we used when we prepared the proposed rule.

Comment: Commenters suggested that CMS monitor the accuracy of the data reported in the implantable device cost center on the Medicare hospital cost report. Commenters urged CMS to impress upon the Medicare Administrative Contractors (MACs) the importance of establishing a mechanism to audit the implantable device cost center to ensure that the costs and charges are appropriately reported. In addition, one commenter suggested that the cost reporting software be modified to create a level 1 error in the case where no data is reported on line 55.30 (Implantable Devices Charged to Patients) to compel hospitals to report that information.

Response: We agree with the commenters that the cost reporting lines, whether they are for implantable devices charged to patients, MRI, CT scans, cardiac catheterization, or any

others, should be subject to greater audit scrutiny from the Medicare contractors. The new Medicare cost report form CMS–2552–10, on line 121 of Worksheet S–2, Part I, asks ''Did this facility incur and report costs for implantable devices charged to a patient? Enter in column 1 'Y' for yes or 'N' for no.'' All hospital types, including non-IPPS hospitals, CAHs, and Maryland inpatient short-term acute hospitals, are required to properly report their costs and charges, and if the answer to this question is ''Y'' for any type of hospital, then line 72, column 26, of Worksheet B, Part I must be greater than 0, with an accurate amount that reflects the hospital's costs for implantable devices charged to patients. In addition, we note that a Level 1 edit on the CMS–2552–10 form already exists that ensures that line 72, column 26, of Worksheet B, Part I (Implantable Devices Charged to Patients on Worksheet A of the CMS–2552–10 form) is greater than 0 if Worksheet S–2, Part I, line 121 is ''Y.'' The edit is also set up for the reverse scenario; that is, if there is an amount on Worksheet B, Part I, line 72, column 26, then the response on Worksheet S–2, Part I, line 121 must be ''Y.'' We do not agree with commenters that a level 1 error should be established to force hospitals to report costs on line 55.30 because it is possible that some hospitals do not provide services for which charges are reported in the revenue codes that correspond to the costs that are to be reported on line 55.30 (for example, psychiatric hospitals).

Comment: One commenter believed that the standard cost centers for Computed Tomography and Magnetic Resonance Imaging would be artificially low due to hospital allocation of capital costs across the hospital rather than to particular cost centers, and suggested that payments based on these CCRs would not accurately reflect the resources used in providing those services. As a result, the commenter recommended that CMS exercise a similar degree of caution as that in the approach for the new ''Implantable Devices Charged to Patients'' cost center CCRs before using any data based on the new CT and MRI cost centers.

Response: We provided background on the creation of the new standard cost centers in the proposed rule and will reassess the availability of data for the ''Implantable Devices Charged to Patients'' cost center, and the ''MRI, CT Scans, and Cardiac Catheterization'' cost centers, for the CY 2013 OPPS rulemaking cycle. If appropriate, we will propose to create distinct CCRs for these cost centers at that time.

Comment: Commenters asked that CMS create a new cost center exclusively for the costs of MEG so that the calculation of the median cost for MEG would more accurately reflect the expense of the equipment, maintenance contract and dedicated staff necessary to furnish the service. Several commenters suggested that cost center 5400 should be the primary cost center assignment and 3280 should be the secondary cost center assignment for revenue codes 0860 (Magnetoencephalography (MEG)—General Classification) and 0861 Magnoetoecnephalography (MEG). This would reverse the current cost center assignments for these revenue codes. Some commenters asked that CMS adopt the non-standard subscripted cost center assignment that one MAC had allowed for its hospitals that furnish MEG.

Response: In the absence of recommendations for use of other existing cost center's CCRs, we continue to believe that for revenue codes 0860 and 0861 nonstandard cost center 3280 ''EKG and EEG'' is an appropriate primary cost center mapping and cost center 5400 ''Electroencephalography'' is an appropriate secondary cost center mapping. We welcome recommendations on more suitable currently existing standard or nonstandard cost center CCRs. We will also discuss the issue with the APC Panel.

With regard to the request to create a new cost center exclusive to the costs of MEG, as we stated in the CY 2011 OPPS/ASC final rule with comment period, we do not believe a new cost center is needed to capture the costs of MEG. Over the past several years, we have either proposed or discussed potential new standard and nonstandard cost centers for the Medicare hospital cost report in our 2008, 2009, 2010, 2011 hospital inpatient and outpatient final rules. All of the potential cost centers that we have discussed for addition to the cost report, whether standard or nonstandard, have demonstrated volume in the electronic hospital cost report data. In its July 2008 report on using cost report data to estimate costs for both the IPPS and OPPS (*http://www.rti.org/reports/cms/*), RTI International examined the electronic hospital cost report database and recommended new standard and nonstandard cost centers on the basis of reporting volume across hospitals. RTI International typically identified no fewer than 200 institutions reporting a specific service category, such as cardiac catheterization or cardiac rehabilitation, in subscripted or other lines for the new nonstandard and standard cost centers. Historically, our rationale for adding an official nonstandard cost center to the cost report has been at the request of Medicare contractors experiencing a significant volume of requests for a cost center for a specific type of service.

In contrast, the volume of MEG services has been and continues to be extremely low. In the hospital outpatient CY 2010 OPPS claims data, hospitals reported 150 units of MEG spread among the three CPT codes for MEG: 75 units of CPT code 95965 (Magnetoencephalography (MEG), recording and analysis; for spontaneous brain magnetic activity (e.g. epileptic cerebral cortex localization)); 38 units of CPT code 95966 (Magnetoencephalography (MEG), recording and analysis; for spontaneous brain magnetic activity (e.g. epileptic cerebral cortex localization) for evoked magnetic fields, single modality (e.g. sensory, motor, language or visual cortex localization)); and 37 units of CPT code 95967 (Magnetoencephalography (MEG), recording and analysis; for spontaneous brain magnetic activity (e.g. epileptic cerebral cortex localization), for evoked magnetic fields, each additional modality (e.g. sensory, motor language, or visual cortex localization (List separately in addition to code for primary procedure))). This continues the pattern of very low volumes of the total of the 3 MEG codes that have been reported in the outpatient setting since the creation of the codes in CY 2005 (39 units in CY 2005, 75 units in CY 2006, 102 units in CY 2007, 75 units in 2008, 131 units in 2009, and 150 units in CY 2010). Therefore, we continue to believe that a specific cost center is not appropriate for MEG, given the longstanding low volume of this service.

For a discussion of the APC Panel recommendation on the final payment policy for MEG, we refer readers to section III.D. of this final rule with comment period.

Comment: Commenters requested that CMS outline a method by which more discrete cost center lines could be requested for capital-expensive services having their own NUBC revenue codes.

Response: The process by which a hospital may request permission to use a subscripted line on a cost report is found in the Provider Reimbursement Manual, Part II (PRM–II), Chapter 40. Contractor approval is not necessary to subscript lines on the cost report for use in reporting nonstandard cost centers, as long as hospitals follow the Medicare guidelines in the PRM. However, as discussed above with regard to creation of national cost centers, we have either

proposed or discussed potential new standard and nonstandard cost centers for the Medicare hospital cost report in cases where doing so would provide more accurate information that would justify the resources and costs associated with doing so. For example, we have proposed and finalized nonstandard cost centers such as those for Cardiac Rehabilitation, Hyperbaric Oxygen Therapy, and Lithotripsy (74 FR 60344) as well as standard cost centers for Implantable Medical Devices Charged to Patients, Cardiac Catheterization, Computed Tomography, and Magnetic Resonance Imaging through the annual rulemaking process.

Comment: Several commenters requested that CMS modify the revenue code-to-cost center crosswalk to include data on the number of providers billing using each revenue code in the claims data whose cost reports contain the associated cost center under each mapping.

Response: All of the data that are required to perform this analysis is available to the public. The HCRIS data, which include information from the hospital cost reports, are available on the CMS Web site at *http://www.cms.gov/CostReports/CostReportsFY/list.asp#TopOfPage*, while our CMS Web site, *http://www.cms.gov/HospitalOutpatientPPS*, includes information about purchasing the ''OPPS Limited Data Set''. The HCRIS data can be used to extract the cost center information the commenters request while the claims data in the OPPS Limited Data Set include the revenue codes and HCPCS on the claims billed by each OPPS provider.

2. Data Development Process and Calculation of Median Costs

In this section of this final rule with comment period, we discuss the use of claims to calculate OPPS payment rates for CY 2012. The hospital OPPS page on the CMS Web site on which this final rule with comment period is posted provides an accounting of claims used in the development of the final payment rates at: *http://www.cms.gov/HospitalOutpatientPPS*. The accounting of claims used in the development of this final rule with comment period is included on the CMS Web site under supplemental materials for this CY 2012 OPPS/ASC final rule with comment period. That accounting provides additional detail regarding the number of claims derived at each stage of the process. In addition, below in this section we discuss the file of claims that comprises the data set that is available for purchase under a CMS data use agreement. Our CMS Web site, *http://www.cms.gov/HospitalOutpatientPPS*, includes information about purchasing the ''OPPS Limited Data Set,'' which now includes the additional variables previously available only in the OPPS Identifiable Data Set, including ICD–9–CM diagnosis codes and revenue code payment amounts. This file is derived from the CY 2010 claims that were used to calculate the proposed and final payment rates for the CY 2012 OPPS.

We used the methodology described in sections II.A.2.a. through II.A.2.e. of this final rule with comment period to calculate the median costs we use to establish the relative weights used in calculating the OPPS payment rates for CY 2012 shown in Addenda A and B to the this rule with comment period (which are available via the Internet on the CMS Web site). We refer readers to section II.A.4. of the proposed rule and this final rule with comment period for a discussion of the conversion of APC median costs to scaled payment weights.

Comment: Commenters expressed concern with respect to the volatility of the OPPS payment rates from year to year. One commenter suggested a ''stability policy'' that the median costs from claims be adjusted to limit changes from year to year and asked that CMS limit any decreases in payment compared to the prior year to no more than a 5-percent decline.

Response: As previously discussed in the CY 2011 OPPS/ASC final rule with comment period (FR 75 71833), there are a number of factors that contribute to median costs fluctuations from one year to the next including (but not limited to) hospital behavior in adjusting mix of services, hospital costs and charges changes each year resulting in changes to the CCRs, reassignments of HCPCS codes, changes to OPPS payment policy (for example, changes to packaging), and implementation of composite APCs. We cannot stabilize hospital-driven fundamental inputs to the calculation of OPPS payment rates. However, we have strived to resolve some of the other potential reasons for instability from year to year. Specifically, we continue to seek ways to use more claims data so that we have fewer APCs for which there are small numbers of single bills used to set the APC median costs. Moreover, we have tried to eliminate APCs with very small numbers of single bills where we could do so. We recognize that changes to payment policies, such as the packaging of payment for ancillary and supportive services and the implementation of composite APCs, may contribute to volatility in payment rates in the short term. However, we believe that larger payment packages and bundles should help to stabilize payments in the long term by enabling us to use more claims data and by establishing payments for larger groups of services. Further, in seeking to mitigate fluctuations in the OPPS, implementing such a system would make payments less reflective of the true service costs. Limiting decreases to payments across all APCs in a budget neutral payment system could unfairly reduce the payments for other services due to the effects of the scaling that is necessary to maintain budget neutrality and would distort the relativity of payment that is based on the cost of all services.

Comment: Several commenters expressed concerns over the payment reductions for device-dependent APCs, blood and blood products, multiple imaging composites, and packaged services citing impact to beneficiary access to necessary procedures and patient safety. The commenters were also concerned that payments do not accurately reflect the costs of providing the procedures.

Response: We discuss the public comments we received on the payment for particular services throughout this final rule with comment period. However, in general, we believe that our methodology for calculating the payments made for services furnished in hospital outpatient departments comports with the statutory requirements and results in payments that reflect the relative cost of these services within the statutory constraints of a budget neutral system. Indeed, our data show significant increase in payment as a percentage of cost since the inception of the OPPS.

a. Claims Preparation

For this final rule with comment period, we used the CY 2010 hospital outpatient claims processed before July 1, 2011, to calculate the median costs of APCs that underpin the relative weights for CY 2012. To begin the calculation of the relative weights for CY 2012, we pulled all claims for outpatient services furnished in CY 2010 from the national claims history file. This is not the population of claims paid under the OPPS, but all outpatient claims (including, for example, critical access hospital (CAH) claims and hospital claims for clinical laboratory services for persons who are neither inpatients nor outpatients of the hospital).

We then excluded claims with condition codes 04, 20, 21, and 77 because these are claims that providers submitted to Medicare knowing that no payment would be made. For example,

providers submit claims with a condition code 21 to elicit an official denial notice from Medicare and document that a service is not covered. We then excluded claims for services furnished in Maryland, Guam, the U.S. Virgin Islands, American Samoa, and the Northern Mariana Islands because hospitals in those geographic areas are not paid under the OPPS, and, therefore, we do not use claims for services furnished in these areas in ratesetting.

We divided the remaining claims into the three groups shown below. Groups 2 and 3 comprise the 112 million claims that contain hospital bill types paid under the OPPS.

1. Claims that were not bill types 12X (Hospital Inpatient (Medicare Part B only)), 13X (Hospital Outpatient), 14x (Hospital—Laboratory Services Provided to Nonpatients), or 76X (Clinic—Community Mental Health Center). Other bill types are not paid under the OPPS; therefore, these claims were not used to set OPPS payment.

2. Claims that were bill types 12X, 13X or 14X. Claims with bill types 12X and 13X are hospital outpatient claims. Claims with bill type 14X are laboratory specimen claims, of which we use a subset for the limited number of services in these claims that are paid under the OPPS.

3. Claims that were bill type 76X (CMHC).

To convert charges on the claims to estimated cost, we multiplied the charges on each claim by the appropriate hospital-specific CCR associated with the revenue code for the charge as discussed in section II.A.1.c. of this final rule with comment period. We then flagged and excluded CAH claims (which are not paid under the OPPS) and claims from hospitals with invalid CCRs. The latter included claims from hospitals without a CCR; those from hospitals paid an all-inclusive rate; those from hospitals with obviously erroneous CCRs (greater than 90 or less than 0.0001); and those from hospitals with overall ancillary CCRs that were identified as outliers (that exceeded +/− 3 standard deviations from the geometric mean after removing error CCRs). In addition, we trimmed the CCRs at the cost center (that is, departmental) level by removing the CCRs for each cost center as outliers if they exceeded +/− 3 standard deviations from the geometric mean. We used a four-tiered hierarchy of cost center CCRs, which is the revenue code-to-cost center crosswalk, to match a cost center to every possible revenue code appearing in the outpatient claims that is relevant to OPPS services, with the top tier being the most common cost center and the last tier being the default CCR. If a hospital's cost center CCR was deleted by trimming, we set the CCR for that cost center to ''missing'' so that another cost center CCR in the revenue center hierarchy could apply. If no other cost center CCR could apply to the revenue code on the claim, we used the hospital's overall ancillary CCR for the revenue code in question as the default CCR. For example, if a visit was reported under the clinic revenue code but the hospital did not have a clinic cost center, we mapped the hospital-specific overall ancillary CCR to the clinic revenue code. The revenue code-to-cost center crosswalk is available for inspection and comment on the CMS Web site: *http://www.cms.gov/HospitalOutpatientPPS*. Revenue codes that we do not use to set medians or to model impacts are identified with an ''N'' in the revenue code-to-cost center crosswalk.

We applied the CCRs as described above to claims with bill type 12X, 13X, or 14X, excluding all claims from CAHs and hospitals in Maryland, Guam, the U.S. Virgin Islands, American Samoa, and the Northern Mariana Islands and claims from all hospitals for which CCRs were flagged as invalid.

We identified claims with condition code 41 as partial hospitalization services of hospitals and moved them to another file. We note that the separate file containing partial hospitalization claims is included in the files that are available for purchase as discussed above.

We then excluded claims without a HCPCS code. We moved to another file claims that contained nothing but influenza and pneumococcal pneumonia (PPV) vaccines. Influenza and PPV vaccines are paid at reasonable cost and, therefore, these claims are not used to set OPPS rates.

We next copied line-item costs for drugs, blood, and brachytherapy sources to a separate file (the lines stay on the claim, but are copied onto another file). No claims were deleted when we copied these lines onto another file. These line-items are used to calculate a per unit mean and median cost and a per day mean and median cost for drugs and nonimplantable biologicals, therapeutic radiopharmaceutical agents, and brachytherapy sources, as well as other information used to set payment rates, such as a unit-to-day ratio for drugs.

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60517), we first adopted a policy to redistribute some portion of total cost of packaged drugs and biologicals to the separately payable drugs and biologicals as acquisition and pharmacy overhead and handling costs. As discussed further in section V.B.3. of this final rule with comment, as we proposed, we are continuing this policy for CY 2012. Therefore, we used the line-item cost data for drugs and biologicals for which we had a HCPCS code with ASP pricing information to calculate the ASP+X values, first for all drugs and biologicals with HCPCS codes, whether separately paid or packaged, and then for separately payable drugs and biologicals and for packaged drugs and biologicals, respectively, by taking the ratio of total claim cost for each group relative to total ASP dollars (per unit of each drug or biological HCPCS code's July 2011 ASP amount multiplied by total units for each drug or biological in the CY 2010 claims data). These values are ASP+9 percent (for all drugs and biologicals with HCPCS codes, whether separately paid or packaged), ASP–2 percent (for drugs and biologicals that are separately paid), and ASP+192 percent (for drugs and biologicals that have HCPCS codes and that are packaged), respectively. As we discuss in section V.B.3. of this final rule with comment period, and as we proposed, we are redistributing $169 million of the total cost in our claims data for coded packaged drugs and biologicals with an ASP to payment for separately payable drugs and biologicals. We also are redistributing an additional $71.3 million from the cost of uncoded packaged drugs billed under pharmacy revenue code series 025X (Pharmacy) and 026X (IV Therapy). This total excludes the cost of diagnostic and therapeutic radiopharmaceuticals because they are not reported under pharmacy revenue codes or under the pharmacy cost center on the hospital cost report. Our CY 2012 redistribution of $240.3 million in estimated costs from coded and uncoded packaged drugs to separately payable drugs represents the $200 million in total packaged drug costs redistributed from the CY 2011 OPPS/ASC final rule with comment period (75 FR 71967), updated by the PPI for Pharmaceuticals for Human Use, to derive a proportion of redistributed costs to total costs. We then updated our analysis for this CY 2012 OPPS/ASC final rule with comment period, holding the proportion of redistributed pharmacy overhead and handling cost constant, both for packaged coded drugs (35 percent) and for packaged uncoded drugs (10.7 percent), constant between the proposed rule and the final rule with comment period. This allowed us to keep the proportion of redistributed costs (and

thus the ASP+X percent) stable between the proposed rule and the final rule with comment period. Redistributing a total of $240.3 million in pharmacy overhead cost from packaged drugs and biologicals reduces the $1.4 billion cost of packaged drugs and biologicals with HCPCS codes and ASPs to $1.16 billion, approximately a 17-percent reduction. Redistributing $71.3 million from the cost of uncoded packaged drugs and biologicals reduces the $666 million cost of uncoded drugs and biologicals to $594.7 million, approximately an 11-percent reduction. To implement our CY 2012 policy to redistribute $169 million from the pharmacy overhead cost of coded packaged drugs and biologicals to separately payable drugs and biologicals and $71.3 million from the cost of uncoded packaged drugs, we multiplied the cost of each packaged drug or biological with a HCPCS code and ASP pricing information in our CY 2010 claims data by 0.77, and we multiplied all uncoded packaged pharmacy drug costs in our CY 2010 claims data, excluding those for diagnostic radiopharmaceuticals, by 0.89. We also added the redistributed $240.3 million to the total cost of separately payable drugs and biologicals in our CY 2010 claims data, which increased the relationship between the total cost for separately payable drugs and biologicals and ASP dollars for the same drugs and biologicals from ASP–2 percent to ASP+4 percent. We refer readers to section V.B.3. of this final rule with comment period for a complete discussion of our policy to pay for separately paid drugs and biologicals and pharmacy overhead for CY 2012.

We then removed line-items that were not paid during claim processing, presumably for a line-item rejection or denial. The number of edits for valid OPPS payment in the Integrated Outpatient Code Editor (I/OCE) and elsewhere has grown significantly in the past few years, especially with the implementation of the full spectrum of National Correct Coding Initiative (NCCI) edits. To ensure that we are using valid claims that represent the cost of payable services to set payment rates, we removed line-items with an OPPS status indicator that were not paid during claims processing in the claim year, but have a status indicator of ''S,'' ''T,'' ''V,'' or ''X'' in the prospective year's payment system. This logic preserves charges for services that would not have been paid in the claim year but for which some estimate of cost is needed for the prospective year, such as services newly proposed to come off the inpatient list for CY 2011 that were assigned status indicator ''C'' in the claim year. It also preserves charges for packaged services so that the costs can be included in the cost of the services with which they are reported, even if the CPT codes for the packaged services were not paid because the service is part of another service that was reported on the same claim or the code otherwise violates claims processing edits.

For CY 2012, we proposed to continue the policy we implemented for CY 2011 to exclude line-item data for pass-through drugs and biologicals (status indicator ''G'' for CY 2010) and nonpass-through drugs and biologicals (status indicator ''K'' for CY 2010) where the charges reported on the claim for the line were either denied or rejected during claims processing. Removing lines that were eligible for payment but were not paid ensures that we are using appropriate data. The trim avoids using cost data on lines that we believe were defective or invalid because those rejected or denied lines did not meet the Medicare requirements for payment. For example, edits may reject a line for a separately paid drug because the number of units billed exceeded the number of units that would be reasonable and, therefore, is likely a billing error (for example, a line reporting 55 units of a drug for which 5 units is known to be a fatal dose). As with our trimming in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71828) of line-items with a status indicator of ''S,'' ''T,'' ''V,'' or ''X,'' we believe that unpaid line-items represent services that are invalidly reported and, therefore, should not be used for ratesetting. We believe that removing lines with valid status indicators that were edited and not paid during claims processing increases the accuracy of the single bills used to determine the mean unit costs for use in the ASP+X calculation described in section V.B.3. of this final rule with comment period.

b. Splitting Claims and Creation of ''Pseudo'' Single Procedure Claims

(1) Splitting Claims

As we proposed, for this CY 2012 final rule with comment period, we then split the remaining claims into five groups: single majors; multiple majors; single minors; multiple minors; and other claims. (Specific definitions of these groups follow below.) For CY 2012, we proposed to continue our current policy of defining major procedures as any HCPCS code having a status indicator of ''S,'' ''T,'' ''V,'' or ''X;'' defining minor procedures as any code having a status indicator of ''F,'' ''G,'' ''H,'' ''K,'' ''L,'' ''R,'' ''U,'' or ''N,'' and classifying ''other'' procedures as any code having a status indicator other than one that we have classified as major or minor. For CY 2012, we proposed to continue assigning status indicator ''R'' to blood and blood products; status indicator ''U'' to brachytherapy sources; status indicator ''Q1'' to all ''STVX-packaged codes;'' status indicator ''Q2'' to all ''T-packaged codes;'' and status indicator ''Q3'' to all codes that may be paid through a composite APC based on composite-specific criteria or paid separately through single code APCs when the criteria are not met. As discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68709), we established status indicators ''Q1,'' ''Q2,'' and ''Q3'' to facilitate identification of the different categories of codes. We proposed to treat these codes in the same manner for data purposes for CY 2012 as we have treated them since CY 2008. Specifically, we proposed to continue to evaluate whether the criteria for separate payment of codes with status indicator ''Q1'' or ''Q2'' are met in determining whether they are treated as major or minor codes. Codes with status indicator ''Q1'' or ''Q2'' are carried through the data either with status indicator ''N'' as packaged or, if they meet the criteria for separate payment, they are given the status indicator of the APC to which they are assigned and are considered as ''pseudo'' single procedure claims for major codes. Codes assigned status indicator ''Q3'' are paid under individual APCs unless they occur in the combinations that qualify for payment as composite APCs and, therefore, they carry the status indicator of the individual APC to which they are assigned through the data process and are treated as major codes during both the split and ''pseudo'' single creation process. The calculation of the median costs for composite APCs from multiple procedure major claims is discussed in section II.A.2.e. of this final rule with comment period.

Specifically, we divided the remaining claims into the following five groups:

1. *Single Procedure Major Claims:* Claims with a single separately payable procedure (that is, status indicator ''S,'' ''T,'' ''V,'' or ''X,'' which includes codes with status indicator ''Q3''); claims with one unit of a status indicator ''Q1'' code (''STVX-packaged'') where there was no code with status indicator ''S,'' ''T,'' ''V,'' or ''X'' on the same claim on the same date; or claims with one unit of a status indicator ''Q2'' code (''T-packaged'') where there was no code

with a status indicator ''T'' on the same claim on the same date.

2. *Multiple Procedure Major Claims:* Claims with more than one separately payable procedure (that is, status indicator ''S,'' ''T,'' ''V,'' or ''X,'' which includes codes with status indicator ''Q3''), or multiple units of one payable procedure. These claims include those codes with a status indicator ''Q2'' code (''T-packaged'') where there was no procedure with a status indicator ''T'' on the same claim on the same date of service but where there was another separately paid procedure on the same claim with the same date of service (that is, another code with status indicator ''S,'' ''V,'' or ''X''). We also include, in this set, claims that contained one unit of one code when the bilateral modifier was appended to the code and the code was conditionally or independently bilateral. In these cases, the claims represented more than one unit of the service described by the code, notwithstanding that only one unit was billed.

3. *Single Procedure Minor Claims:* Claims with a single HCPCS code that was assigned status indicator ''F,'' ''G,'' ''H,'' ''K,'' ''L,'' ''R,'' ''U,'' or ''N'' and not status indicator ''Q1'' (''STVX-packaged'') or status indicator ''Q2'' (''T-packaged'') code.

4. *Multiple Procedure Minor Claims:* Claims with multiple HCPCS codes that are assigned status indicator ''F,'' ''G,'' ''H,'' ''K,'' ''L,'' ''R,'' ''U,'' or ''N;'' claims that contain more than one code with status indicator ''Q1'' (''STVX-packaged'') or more than one unit of a code with status indicator ''Q1'' but no codes with status indicator ''S,'' ''T,'' ''V,'' or ''X'' on the same date of service; or claims that contain more than one code with status indicator ''Q2'' (T-packaged), or ''Q2'' and ''Q1,'' or more than one unit of a code with status indicator ''Q2'' but no code with status indicator ''T'' on the same date of service.

5. *Non-OPPS Claims:* Claims that contain no services payable under the OPPS (that is, all status indicators other than those listed for major or minor status). These claims were excluded from the files used for the OPPS. Non-OPPS claims have codes paid under other fee schedules, for example, durable medical equipment or clinical laboratory tests, and do not contain a code for a separately payable or packaged OPPS service. Non-OPPS claims include claims for therapy services paid sometimes under the OPPS but billed, in these non-OPPS cases, with revenue codes indicating that the therapy services would be paid under the Medicare Physician Fee Schedule (MPFS).

The claims listed in numbers 1, 2, 3, and 4 above are included in the data file that can be purchased as described above. Claims that contain codes to which we have assigned status indicators ''Q1'' (''STVX-packaged'') and ''Q2'' (''T-packaged'') appear in the data for the single major file, the multiple major file, and the multiple minor file used for ratesetting. Claims that contain codes to which we have assigned status indicator ''Q3'' (composite APC members) appear in both the data of the single and multiple major files used in this final rule with comment period, depending on the specific composite calculation.

We did not receive any public comments on our proposed process of organizing claims by type. Therefore, for the reasons set forth in the proposed rule (76 FR 42185 through 41286), we are finalizing our CY 2012 proposal without modification. (2) Creation of ''Pseudo'' Single Procedure Claims

As we proposed, to develop ''pseudo'' single procedure claims for this final rule with comment period, we examined both the multiple procedure major claims and the multiple procedure minor claims. We first examined the multiple major procedure claims for dates of service to determine if we could break them into ''pseudo'' single procedure claims using the dates of service for all lines on the claim. If we could create claims with single major procedures by using dates of service, we created a single procedure claim record for each separately payable procedure on a different date of service (that is, a ''pseudo'' single).

As we proposed, for this final rule with comment period, we also used the bypass codes listed in Addendum N to this final rule with comment period (which is referenced in section XVII. of this final rule with comment period and available via the Internet on the CMS Web site) and discussed in section II.A.1.b. of this final rule with comment period to remove separately payable procedures which we determined contained limited or no packaged costs or that were otherwise suitable for inclusion on the bypass list from a multiple procedure bill. As discussed above, we ignore the ''overlap bypass codes,'' that is, those HCPCS codes that are both on the bypass list and are members of the multiple imaging composite APCs, in this initial assessment for ''pseudo'' single procedure claims. The CY 2012 ''overlap bypass codes'' are listed in Addendum N to this final rule with comment period (which is available via the Internet on the CMS Web site). When one of the two separately payable procedures on a multiple procedure claim was on the bypass list, we split the claim into two ''pseudo'' single procedure claim records. The single procedure claim record that contained the bypass code did not retain packaged services. The single procedure claim record that contained the other separately payable procedure (but no bypass code) retained the packaged revenue code charges and the packaged HCPCS code charges. We also removed lines that contained multiple units of codes on the bypass list and treated them as ''pseudo'' single procedure claims by dividing the cost for the multiple units by the number of units on the line. Where one unit of a single, separately payable procedure code remained on the claim after removal of the multiple units of the bypass code, we created a ''pseudo'' single procedure claim from that residual claim record, which retained the costs of packaged revenue codes and packaged HCPCS codes. This enabled us to use claims that would otherwise be multiple procedure claims and could not be used.

As we proposed, for this final rule with comment period, we then assessed the claims to determine if the criteria for the multiple imaging composite APCs, discussed in section II.A.2.e.(5) of this final rule with comment period, were met. Where the criteria for the imaging composite APCs were met, we created a ''single session'' claim for the applicable imaging composite service and determined whether we could use the claim in ratesetting. For HCPCS codes that are both conditionally packaged and are members of a multiple imaging composite APC, we first assessed whether the code would be packaged and, if so, the code ceased to be available for further assessment as part of the composite APC. Because the packaged code would not be a separately payable procedure, we considered it to be unavailable for use in setting the composite APC median cost. Having identified ''single session'' claims for the imaging composite APCs, we reassessed the claim to determine if, after removal of all lines for bypass codes, including the ''overlap bypass codes,'' a single unit of a single separately payable code remained on the claim. If so, we attributed the packaged costs on the claim to the single unit of the single remaining separately payable code other than the bypass code to create a ''pseudo'' single procedure claim. We also identified line-items of overlap bypass codes as a ''pseudo'' single procedure claim. This

allowed us to use more claims data for ratesetting purposes.

As we proposed, for this final rule with comment period, we also examined the multiple procedure minor claims to determine whether we could create ''pseudo'' single procedure claims. Specifically, where the claim contained multiple codes with status indicator ''Q1'' (''STVX-packaged'') on the same date of service or contained multiple units of a single code with status indicator ''Q1,'' we selected the status indicator ''Q1'' HCPCS code that had the highest CY 2011 relative weight, set the units to one on that HCPCS code to reflect our policy of paying only one unit of a code with a status indicator of ''Q1.'' We then packaged all costs for the following into a single cost for the ''Q1'' HCPCS code that had the highest CY 2011 relative weight to create a ''pseudo'' single procedure claim for that code: additional units of the status indicator ''Q1'' HCPCS code with the highest CY 2011 relative weight; other codes with status indicator ''Q1''; and all other packaged HCPCS codes and packaged revenue code costs. We changed the status indicator for the selected code from the data status indicator of ''N'' to the status indicator of the APC to which the selected procedure was assigned for further data processing and considered this claim as a major procedure claim. We used this claim in the calculation of the APC median cost for the status indicator ''Q1'' HCPCS code.

Similarly, as we proposed, for this final rule with comment period, where a multiple procedure minor claim contained multiple codes with status indicator ''Q2'' (''T-packaged'') or multiple units of a single code with status indicator ''Q2,'' we selected the status indicator ''Q2'' HCPCS code that had the highest CY 2011 relative weight, set the units to one on that HCPCS code to reflect our policy of paying only one unit of a code with a status indicator of ''Q2.'' We then packaged all costs for the following into a single cost for the ''Q2'' HCPCS code that had the highest CY 2011 relative weight to create a ''pseudo'' single procedure claim for that code: additional units of the status indicator ''Q2'' HCPCS code with the highest CY 2011 relative weight; other codes with status indicator ''Q2''; and other packaged HCPCS codes and packaged revenue code costs. We changed the status indicator for the selected code from a data status indicator of ''N'' to the status indicator of the APC to which the selected code was assigned, and we considered this claim as a major procedure claim.

As we proposed, for this final rule with comment period, where a multiple procedure minor claim contained multiple codes with status indicator ''Q2'' (''T-packaged'') and status indicator ''Q1'' (''STVX-packaged''), we selected the T-packaged status indicator ''Q2'' HCPCS code that had the highest relative weight for CY 2011 and set the units to one on that HCPCS code to reflect our policy of paying only one unit of a code with a status indicator of ''Q2.'' We then packaged all costs for the following into a single cost for the selected (''T packaged'') HCPCS code to create a ''pseudo'' single procedure claim for that code: additional units of the status indicator ''Q2'' HCPCS code with the highest CY 2011 relative weight; other codes with status indicator ''Q2''; codes with status indicator ''Q1'' (''STVX-packaged''); and other packaged HCPCS codes and packaged revenue code costs. We favor status indicator ''Q2'' over ''Q1'' HCPCS codes because ''Q2'' HCPCS codes have higher CY 2011 relative weights. If a status indicator ''Q1'' HCPCS code had a higher CY 2011 relative weight, it would become the primary code for the simulated single bill process. We changed the status indicator for the selected status indicator ''Q2'' (''T-packaged'') code from a data status indicator of ''N'' to the status indicator of the APC to which the selected code was assigned and we considered this claim as a major procedure claim.

We then applied our process for creating ''pseudo'' single procedure claims to the conditionally packaged codes that do not meet the criteria for packaging, which enabled us to create single procedure claims from them, where they meet the criteria for single procedure claims. Conditionally packaged codes are identified using status indicators ''Q1'' and ''Q2,'' and are described in section XI.A.1. of this final rule with comment period.

Lastly, as we proposed, for this final rule with comment period, we excluded those claims that we were not able to convert to single procedure claims even after applying all of the techniques for creation of ''pseudo'' single procedure claims to multiple procedure major claims and to multiple procedure minor claims. As has been our practice in recent years, we also excluded claims that contained codes that were viewed as independently or conditionally bilateral and that contained the bilateral modifier (Modifier 50 (Bilateral procedure)) because the line-item cost for the code represented the cost of two units of the procedure, notwithstanding that hospitals billed the code with a unit of one.

Comment: Commenters supported the proposed process for creating pseudo single procedure claims.

Response: We appreciate the commenters' support and will continue to look for ways to refine the process to secure more claims data for use in calculating median costs.

After consideration of the public comments we received, as we proposed, we are continuing to apply the proposed methodology described above for the purpose of creating pseudo single procedure claims for the CY 2012 OPPS.

c. Completion of Claim Records and Median Cost Calculations

(1) General Process

As we proposed, for this final rule with comment period, we then packaged the costs of packaged HCPCS codes (codes with status indicator ''N'' listed in Addendum B to this final rule with comment period (which is referenced in section XVII. of this final rule with comment period and available via the Internet on the CMS Web site) and the costs of those lines for codes with status indicator ''Q1'' or ''Q2'' when they are not separately paid), and the costs of the services reported under packaged revenue codes in Table 2 below that appeared on the claim without a HCPCS code into the cost of the single major procedure remaining on the claim.

As noted in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66606), for the CY 2008 OPPS, we adopted an APC Panel recommendation that CMS should review the final list of packaged revenue codes for consistency with OPPS policy and ensure that future versions of the I/OCE edit accordingly. As we have in the past, we will continue to compare the final list of packaged revenue codes that we adopt for CY 2012 to the revenue codes that the I/OCE will package for CY 2012 to ensure consistency.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68531), we replaced the NUBC standard abbreviations for the revenue codes listed in Table 2 of the CY 2009 OPPS/ASC proposed rule with the most current NUBC descriptions of the revenue code categories and subcategories to better articulate the meanings of the revenue codes without changing the proposed list of revenue codes. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60362 through 60363), we finalized changes to the packaged revenue code list based on our examination of the updated NUBC codes and public comment to the CY 2010 proposed list of packaged revenue

codes. For CY 2012, as we did for CY 2011, we reviewed the changes to revenue codes that were effective during CY 2010 for purposes of determining the charges reported with revenue codes but without HCPCS codes that we would propose to package for the CY 2012 OPPS. We believe that the charges reported under the revenue codes listed in Table 2 below continue to reflect ancillary and supportive services for which hospitals report charges without HCPCS codes. Therefore, for CY 2012, as we proposed, we are continuing to package the costs that we derive from the charges reported without HCPCS code under the revenue codes displayed in Table 2 below for purposes of calculating the median costs on which the CY 2012 OPPS are based.

We did not receive any public comments on our proposed list of packaged revenue codes. Therefore, for the reasons set forth in the proposed rule (76 FR 42187 through 42188), we are finalizing the proposed packaged revenue codes for CY 2012, without modification, which are identified in Table 2 below. We note that these revenue codes include only revenue codes that were in effect in CY 2010, the year of the claims data on which the CY 2012 OPPS payment rates are based.

BILLING CODE 4120–01–P

TABLE 2.—CY 2012 PACKAGED REVENUE CODES

Revenue Code	Description
0250	Pharmacy; General Classification
0251	Pharmacy; Generic Drugs
0252	Pharmacy; Non-Generic Drugs
0254	Pharmacy; Drugs Incident to Other Diagnostic Services
0255	Pharmacy; Drugs Incident to Radiology
0257	Pharmacy; Non-Prescription
0258	Pharmacy; IV Solutions
0259	Pharmacy; Other Pharmacy
0260	IV Therapy; General Classification
0261	IV Therapy; Infusion Pump
0262	IV Therapy; IV Therapy/Pharmacy Svcs
0263	IV Therapy; IV Therapy/Drug/Supply Delivery
0264	IV Therapy; IV Therapy/Supplies
0269	IV Therapy; Other IV Therapy
0270	Medical/Surgical Supplies and Devices; General Classification
0271	Medical/Surgical Supplies and Devices; Non-sterile Supply
0272	Medical/Surgical Supplies and Devices; Sterile Supply
0275	Medical/Surgical Supplies and Devices; Pacemaker
0276	Medical/Surgical Supplies and Devices; Intraocular Lens
0278	Medical/Surgical Supplies and Devices; Other Implants
0279	Medical/Surgical Supplies and Devices; Other Supplies/Devices
0280	Oncology; General Classification
0289	Oncology; Other Oncology
0343	Nuclear Medicine; Diagnostic Radiopharmaceuticals
0344	Nuclear Medicine; Therapeutic Radiopharmaceuticals
0370	Anesthesia; General Classification
0371	Anesthesia; Anesthesia Incident to Radiology
0372	Anesthesia; Anesthesia Incident to Other DX Services
0379	Anesthesia; Other Anesthesia
0390	Administration, Processing and Storage for Blood and Blood Components; General Classification
0392	Administration, Processing and Storage for Blood and Blood Components; Processing and Storage
0399	Administration, Processing and Storage for Blood and Blood Components; Other Blood Handling
0621	Medical Surgical Supplies – Extension of 027X; Supplies Incident to Radiology
0622	Medical Surgical Supplies – Extension of 027X; Supplies Incident to Other DX Services
0623	Medical Supplies – Extension of 027X, Surgical Dressings
0624	Medical Surgical Supplies – Extension of 027X; FDA Investigational Devices

Revenue Code	Description
0630	Pharmacy – Extension of 025X; Reserved
0631	Pharmacy – Extension of 025X; Single Source Drug
0632	Pharmacy – Extension of 025X; Multiple Source Drug
0633	Pharmacy – Extension of 025X; Restrictive Prescription
0681	Trauma Response; Level I Trauma
0682	Trauma Response; Level II Trauma
0683	Trauma Response; Level III Trauma
0684	Trauma Response; Level IV Trauma
0689	Trauma Response; Other
0700	Cast Room; General Classification
0710	Recovery Room; General Classification
0720	Labor Room/Delivery; General Classification
0721	Labor Room/Delivery; Labor
0732	EKG/ECG (Electrocardiogram); Telemetry
0762	Specialty services; Observation Hours
0801	Inpatient Renal Dialysis; Inpatient Hemodialysis
0802	Inpatient Renal Dialysis; Inpatient Peritoneal Dialysis (Non-CAPD)
0803	Inpatient Renal Dialysis; Inpatient Continuous Ambulatory Peritoneal Dialysis (CAPD)
0804	Inpatient Renal Dialysis; Inpatient Continuous Cycling Peritoneal Dialysis (CCPD)
0809	Inpatient Renal Dialysis; Other Inpatient Dialysis
0810	Acquisition of Body Components; General Classification
0819	Inpatient Renal Dialysis; Other Donor
0821	Hemodialysis-Outpatient or Home; Hemodialysis Composite or Other Rate
0824	Hemodialysis-Outpatient or Home; Maintenance – 100%
0825	Hemodialysis-Outpatient or Home; Support Services
0829	Hemodialysis-Outpatient or Home; Other OP Hemodialysis
0942	Other Therapeutic Services (also see 095X, an extension of 094x); Education/Training
0943	Other Therapeutic Services (also see 095X, an extension of 094X), Cardiac Rehabilitation
0948	Other Therapeutic Services (also see 095X, an extension of 094X), Pulmonary Rehabilitation

BILLING CODE 4120–01–C

In accordance with our longstanding policy, as we proposed, we are continuing to exclude: (1) Claims that had zero costs after summing all costs on the claim; and (2) claims containing packaging flag number 3. Effective for services furnished on or after July 1, 2004, the I/OCE assigned packaging flag number 3 to claims on which hospitals submitted token charges less than $1.01 for a service with status indicator ''S'' or ''T'' (a major separately payable service under the OPPS) for which the fiscal intermediary or MAC was required to allocate the sum of charges for services with a status indicator equaling ''S'' or ''T'' based on the relative weight of the APC to which each code was assigned. We do not believe that these charges, which were token charges as submitted by the hospital, are valid reflections of hospital resources. Therefore, we deleted these claims. We also deleted claims for which the charges equaled the revenue center payment (that is, the Medicare payment) on the assumption that, where the charge equaled the payment, to apply a CCR to the charge would not yield a valid estimate of relative provider cost. We are continuing these processes for the CY 2012 OPPS.

As we proposed, for this final rule with comment period, for the remaining claims, we then standardized 60 percent of the costs of the claim (which we have previously determined to be the labor-related portion) for geographic differences in labor input costs. We made this adjustment by determining the wage index that applied to the hospital that furnished the service and dividing the cost for the separately paid HCPCS code furnished by the hospital

by that wage index. The claims accounting that we provide for the proposed and final rule contains the formula we use to standardize the total cost for the effects of the wage index. As has been our policy since the inception of the OPPS, we proposed to use the pre-reclassified wage indices for standardization because we believe that they better reflect the true costs of items and services in the area in which the hospital is located than the post-reclassification wage indices and, therefore, would result in the most accurate unadjusted median costs.

In accordance with our longstanding practice, as proposed, for this final rule with comment period, we also excluded single and pseudo single procedure claims for which the total cost on the claim was outside 3 standard deviations from the geometric mean of units for each HCPCS code on the bypass list (because, as discussed above, we used claims that contain multiple units of the bypass codes).

After removing claims for hospitals with error CCRs, claims without HCPCS codes, claims for immunizations not covered under the OPPS, and claims for services not paid under the OPPS, approximately 109 million claims were left. Using these 109 million claims, we created approximately 110 million single and ''pseudo'' single procedure claims, of which we used slightly more than 108 million single bills (after trimming out approximately 888,000 claims as discussed in section II.A.1.a. of this final rule with comment period) in the CY 2012 median development and ratesetting.

We used these claims to calculate the final CY 2012 median costs for each separately payable HCPCS code and each APC. The comparison of HCPCS code-specific and APC medians determines the applicability of the 2 times rule. Section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median (or mean cost, if elected by the Secretary) for an item or service in the group is more than 2 times greater than the lowest median cost for an item or service within the same group (the 2 times rule). We note that, for purposes of identifying significant HCPCS for examination in the 2 times rule, we consider codes that have more than 1,000 single major claims or codes that have both greater than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC median cost to be significant (75 FR 71832). This longstanding definition of when a HCPCS code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 claims is negligible within the set of approximately 100 million single procedure or single session claims we use for establishing median costs. Similarly, a HCPCS code for which there are fewer than 99 single bills and which comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC median. Unlisted codes are not used in establishing the percent of claims contributing to the APC, nor are their costs used in the calculation of the APC median. Finally, we reviewed the median costs for the services for which we are proposing to pay separately under this final rule with comment period, and we reassigned HCPCS codes to different APCs where it was necessary to ensure clinical and resource homogeneity within the APCs. Section III. of this final rule with comment period includes a discussion of many of the HCPCS code assignment changes that resulted from examination of the median costs and for other reasons. The APC medians were recalculated after we reassigned the affected HCPCS codes. Both the HCPCS code-specific medians and the APC medians were weighted to account for the inclusion of multiple units of the bypass codes in the creation of ''pseudo'' single procedure claims.

As we discuss in sections II.A.2.d. and II.A.2.e. and in section VIII.B. of this final rule with comment period, in some cases, APC median costs are calculated using variations of the process outlined above. Specifically, section II.A.2.d. of this final rule with comment period addresses the calculation of single APC criteria-based median costs. Section II.A.2.e. of this final rule with comment period discusses the calculation of composite APC criteria-based median costs. Section VIII.B. of this final rule with comment period addresses the methodology for calculating the median costs for partial hospitalization services.

We did not receive any public comments on this aspect of the median calculation process that we proposed for CY 2012. Therefore, we are adopting it as final.

After consideration of the public comments we received, we are finalizing our proposed methodology for calculating median costs for purposes of creating payment weights and subsequent payment rates for the CY 2012 OPPS.

(2) APC Panel Recommendations Regarding Data Development

At the February 28–March 1, 2011 APC Panel Meeting, we provided the APC Panel Data Subcommittee with a list of all APCs fluctuating by greater than 10 percent when comparing the CY 2011 OPPS final rule median costs based on CY 2009 claims processed through June 30, 2010, to those based on CY 2010 OPPS/ASC final rule data (CY 2008 claims processed through June 30, 2009). We included explanatory data where possible to allow the Data Subcommittee to focus on APC median changes that required more investigation, based on its request (75 FR 71834). The APC Panel Data Subcommittee reviewed the fluctuations in the APC median costs but did not express particular concerns with the median cost changes.

We also provided the APC Panel Data Subcommittee with a summary of cost and CCR data related to the Myocardial Positron Emission Tomography (PET) imaging APC, APC 0307, as well as the associated diagnostic radiopharmaceutical, Rb82 rubidium, based on a request for data related to the decline in the APC median cost from the CY 2010 OPPS final rule to the CY 2011 OPPS proposed rule. The Data Subcommittee noted a decline in the CCRs associated with the HCPCS codes in APC 0307, as well as declines in the line-item costs of the associated diagnostic radiopharmaceutical.

At the February 28–March 1, 2011 APC Panel Meeting, the APC Panel made a number of recommendations related to the data process. The Panel's recommendations and our responses follow.

Recommendation 1: The Panel commends the CMS staff for responding to the data requests of the Data Subcommittee.

CMS Response to Recommendation 1: We appreciate this recommendation.

Recommendation 2: The Panel recommends that the work of the Data Subcommittee continue.

CMS Response to Recommendation 2: We are accepting this recommendation.

Recommendation 3: The Panel recommends that Agatha Nolen, D.Ph., M.S., F.A.S.H.P., serve as acting chairperson for the winter 2011 meeting of the Data Subcommittee.

CMS Response to Recommendation 3: We are accepting this recommendation.

At the August 10–12, 2011 APC Panel Meeting, CMS again provided the APC Panel Data Subcommittee with a list of all APCs fluctuating by greater than 10 percent when comparing the CY 2012 OPPS proposed rule median costs based

on CY 2010 claims processed through December 21, 2010, to those based on CY 2011 OPPS/ASC final rule data (CY 2009 claims processed through June 30, 2010). We also gave an overview of the ASP+X calculation and the CY 2012 proposal for separately paid drugs, and an overview of the proposed payment (with DRG Cap) for Cardiac Resynchronization Therapy-Defibrillator (CRT–D) composite. The APC Panel made a number of recommendations related to specific services. Recommendations (4–9) are discussed as part of the discussion of the specific service to which they pertain.

Recommendation 10: The Panel recommends that the work of the Data Subcommittee continue.

CMS Response to Recommendation 10: We are accepting this recommendation.

Recommendation 14: The Panel recommends that Daniel J. Pothen, M.S., R.H.I.A, C.H.P.S., C.P.H.I.M.S., C.C.S., C.C.S.-P., C.H.C., be named the chair of the Data Subcommittee

CMS Response to Recommendation 14: We are accepting this recommendation.

d. Calculation of Single Procedure APC Criteria-Based Median Costs

(1) Device-Dependent APCs

Device-dependent APCs are populated by HCPCS codes that usually, but not always, require that a device be implanted or used to perform the procedure. For a full history of how we have calculated payment rates for device-dependent APCs in previous years and a detailed discussion of how we developed the standard device-dependent APC ratesetting methodology, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66739 through 66742). Overviews of the procedure-to-device edits and device-to-procedure edits used in ratesetting for device-dependent APCs are available in the CY 2005 OPPS final rule with comment period (69 FR 65761 through 65763) and the CY 2007 OPPS/ASC final rule with comment period (71 FR 68070 through 68071).

In the CY 2012 OPPS/ASC proposed rule (76 FR 42190), for CY 2012, we proposed to use the standard methodology for calculating median costs for device-dependent APCs that was finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71834 through 71837). (We referred readers to section II.D.6. and II.A.e.6. of the proposed rule for detailed explanations of the proposed nonstandard methodology regarding cardiac resynchronization therapy). This methodology utilizes claims data that generally represent the full cost of the required device. Specifically, we proposed to calculate the median costs for device-dependent APCs for CY 2012 using only the subset of single procedure claims from CY 2010 claims data that pass the procedure-to-device and device-to-procedure edits; do not contain token charges (less than $1.01) for devices; do not contain the ''FB'' modifier signifying that the device was furnished without cost to the provider, supplier, or practitioner, or where a full credit was received; and do not contain the ''FC'' modifier signifying that the hospital received partial credit for the device. The procedure-to-device edits require that when a particular procedural HCPCS code is billed, the claim must also contain an appropriate device code, while the device-to-procedure edits require that a claim that contains one of a specified set of device codes also contain an appropriate procedure code. We stated in the proposed rule that we continue to believe the standard methodology for calculating median costs for device-dependent APCs gives us the most appropriate median costs for device-dependent APCs in which the hospital incurs the full cost of the device.

Table 3 of the proposed rule (76 FR 42191) listed the APCs for which we proposed to use our standard device-dependent APC ratesetting methodology (as explained in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71834 through 71837)) for CY 2012. In the proposed rule, we noted that there are five proposed device-dependent APC title changes and one proposed deletion for CY 2012. As discussed in detail in section II.A.2.d.(6) of the proposed rule, we proposed to change the title of APC 0083 from ''Coronary or Non-Coronary Angioplasty and Percutaneous Valvuloplasty'' to ''Level I Endovascular Revascularization of the Lower Extremity''; the title of APC 0229 from ''Transcatheter Placement of Intravascular Shunt and Stents'' to ''Level II Endovascular Revascularization of the Lower Extremity''; and the title of APC 0319 from ''Endovascular Revascularization of the Lower Extremity'' to ''Level III Endovascular Revascularization of the Lower Extremity.'' We also proposed to change the title of APC 0040 from ''Percutaneous Implantation of Neurostimulator Electrodes'' to ''Level I Implantation/Revision/Replacement of Neurostimulator Electrodes,'' and the title of APC 0061 from ''Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electrodes'' to ''Level II Implantation/Revision/Replacement of Neurostimulator Electrodes,'' as discussed in section III.D.1. of the proposed rule. In addition, as discussed in section II.A.2.e.(6) of the proposed rule, we proposed to delete APC 0418 (Insertion of Left Ventricular Pacing Electrode) for CY 2012. As we discussed in detail in section III.D.6. of the proposed rule, we proposed to limit the payment for services that are assigned to APC 0108 to the proposed IPPS standardized payment amount for MS–DRG 227 (Cardiac Defibrillator Implant without Cardiac Catheterization and without Medical Complications and Comorbidities), and we proposed to continue to apply the device edits and other standard features of the device-dependent APCs to APC 0108. Finally, we referred readers to Addendum A to the proposed rule for the proposed payment rates for device-dependent APCs for CY 2012.

Comment: Several commenters supported CMS' proposal to continue using the standard methodology for calculating median costs for device-dependent APCs as well as the continued use of device coding edits to ensure that hospitals are reporting charges for implanted devices. Some commenters recommended that CMS continue examining and refining the ratesetting methodology for procedures involving devices in order to encourage the continued development and proliferation of new technology, and that CMS further improve the accuracy of estimates for the costs of devices included in multiple procedure claims used for the purpose of setting relative weights. Some commenters asked for continued focus on coding education, particularly as it impacts the use of proper HCPCS supply codes, so that these codes are appropriately reported by hospital coders. Other commenters supported the mandatory reporting of all device HCPCS codes.

Response: We appreciate the commenters' support of the continued use of the standard device-dependent APC ratesetting methodology and the procedure-to-device and device-to-procedure edits. As we have stated in the past (75 FR 71835 and 74 FR 60367), we agree with the commenters that we should continue to encourage the development and proliferation of new technology under the OPPS. We have special mechanisms to provide payment for new technologies and services under the OPPS, including new technology APCs and transitional pass-through payments devices. We refer readers to sections III.C. and IV.A., respectively, of

this final rule with comment period for more information on these payment methodologies. For all OPPS services, we continue our efforts to use the data from as many claims as possible, through approaches such as use of the bypass list and date splitting of claims as described further in section II.A. of this final rule with comment period, and through methodologies such as increased packaging and composite APCs.

As we have stated in the past (73 FR 68535 through 68536 and 74 FR 60367), we agree that accurate reporting of device, supply, and technology charges will help to ensure that these items are appropriately accounted for in future years' OPPS payment rates. We encourage stakeholders to carefully review HCPCS code descriptors, as well as any guidance CMS may have provided for specific HCPCS codes. In addition, we have provided further instructions on the billing of medical and surgical supplies in the October 2008 OPPS update (Transmittal 1599, Change Request 6196, dated September 19, 2008) and the April 2009 OPPS update (Transmittal 1702, Change Request 6416, dated March 13, 2009). For HCPCS codes that are paid under the OPPS, providers may also submit inquiries to the AHA Central Office on HCPCS, which serves as a clearinghouse on the proper use of Level I HCPCS codes for hospitals and certain Level II HCPCS codes for hospitals, physicians, and other health professionals. Inquiries must be submitted using the approved form, which may be downloaded from the AHA Web site (*http://www.ahacentraloffice.org*) and either faxed to (312) 422–4583 or mailed directly to the AHA Central Office: Central Office on HCPCS, American Hospital Association, One North Franklin, Floor 29, Chicago, IL 60606.

Comment: Some commenters concurred with CMS' proposed determination that APC 0385 (Level I Prosthetic Urological Procedures) and APC 0386 (Level II Prosthetic Urological Procedures) should be categorized as device-dependent APCs. Other commenters expressed appreciation for the proposed increase in payment for APC 0425 (Level II Arthroplasty or Implantation with Prosthesis).

Response: We appreciate the commenters' support of the designation of APC 0385 and APC 0386 as device-dependent APCs and the proposed payment increase for APC 0425.

Comment: Several commenters expressed concern that the proposed CY 2012 payment rate for the implantation of cochlear implants, described by CPT code 69930 (cochlear device implantation, with or without mastoidectomy) which is assigned to APC 0259 (Level VII ENT Procedures), decreased by approximately 12 percent from that in the CY 2011 OPPS/ASC final rule with comment period. According to commenters, this payment rate is inconsistent with the average decrease in proposed payment of all OPPS APCs relative to CY 2011 of approximately 6 percent and is insufficient to cover hospitals' costs for providing this service and ensure that beneficiaries will continue to have access to cochlear implants. The commenters observed, based on their analysis of Medicare claims data, that while the overall median cost of APC 0259 decreased, the component parts of the APC (that is, the device, the procedure, and the other bundled supplies and services) either remained the same or increased. The commenters requested that CMS evaluate the data upon which the proposed CY 2012 payment rate for APC 0259 is based in order to ensure its validity.

Response: We appreciate the commenters' concerns regarding the proposed payment rate for procedures involving cochlear implants. Under the standard device-dependent APC ratesetting methodology, the median cost for APC 0259 is calculated using only those single bills that reflect the full cost of the cochlear implant device. While we will monitor the changes in APC 0259 over time, we believe that the payment rate for this service, calculated according to the standard device-dependent APC ratesetting methodology for the proposed rule and this final rule with comment period, appropriately reflects hospitals' relative costs for providing this procedure as reported to us in the claims and cost report data. We note that the median cost for CPT code 69930 calculated from the CY 2010 hospital claims and cost report data available for this final rule with comment is $28,892, approximately 6 percent less than the median cost of $30,730 calculated from the CY 2009 hospital claims and cost report data upon which the final CY 2011 payment rate was calculated.

After consideration of the public comments we received, we are finalizing our proposed CY 2012 payment policies for device-dependent APCs with modification. The CY 2012 OPPS payment rates for device-dependent APCs are based on their median costs calculated from CY 2010 claims and the most recent cost report data, using only single procedure claims that pass the procedure-to-device and device-to-procedure edits, do not contain token charges for devices (less than $1.01), do not have an ''FB'' modifier signifying that the device was furnished without cost or with full credit, and do not contain an ''FC'' modifier signifying that the hospital received partial credit for the device. We continue to believe that the median costs calculated from the single claims that meet these criteria represent the most valid estimated relative costs of these services to hospitals when they incur the full cost of the devices required to perform the procedures.

Table 3 below lists the APCs for which we used our standard device-dependent APC ratesetting methodology for CY 2012. We note that we are not finalizing our proposal to limit the payment for services that are assigned to APC 0108 to the IPPS standardized payment amount for MS–DRG 227, and that we are continuing to apply the device edits and other standard features of the device-dependent APCs to this APC for CY 2012. We also are deleting APC 0418 and changing the titles of APC 0108 and 0655 as we proposed. We refer readers to section II.A.2.e.(6) of this final rule with comment period for a detailed discussion of these final policies. We also note that we are revising the APC titles for APC 0083, 0229, and 0319 for CY 2012, as we discuss in section II.A.2.d.(6) of this final rule with comment period and that we are changing the APC titles for APC 0040 and APC 0061 as discussed in section III.D.4.a. of this final rule with comment period. We refer readers to Addendum A to this final rule with comment period (which is available via the Internet on the CMS Web site) for the final payment rates for these APCs for CY 2012.

BILLING CODE 4120–01–P

TABLE 3.--CY 2012 DEVICE-DEPENDENT APCs

CY 2012 APC	CY 2012 Status Indicator	CY 2012 APC Title
0039	S	Level I Implantation of Neurostimulator Generator
0040	S	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes
0061	S	Level II Implantation/Revision/Replacement of Neurostimulator Electrodes
0082	T	Coronary or Non-Coronary Atherectomy
0083	T	Coronary Angioplasty, Valvuloplasty, and Level I Endovascular Revascularization of the Lower Extremity
0084	S	Level I Electrophysiologic Procedures
0085	T	Level II Electrophysiologic Procedures
0086	T	Level III Electrophysiologic Procedures
0089	T	Insertion/Replacement of Permanent Pacemaker and Electrodes
0090	T	Insertion/Replacement of Pacemaker Pulse Generator
0104	T	Transcatheter Placement of Intracoronary Stents
0106	T	Insertion/Replacement of Pacemaker Leads and/or Electrodes
0107	T	Insertion of Cardioverter-Defibrillator
*0108	T	Insertion/Replacement/Repair of AICD Leads, Generator, and Pacing Electrodes
0115	T	Cannula/Access Device Procedures
0202	T	Level VII Female Reproductive Procedures
0227	T	Implantation of Drug Infusion Device
0229	T	Level II Endovascular Revascularization of the Lower Extremity
0259	T	Level VII ENT Procedures
0293	T	Level V Anterior Segment Eye Procedures
0315	S	Level II Implantation of Neurostimulator Generator
0318	S	Implantation of Cranial Neurostimulator Pulse Generator and Electrode
0319	T	Level III Endovascular Revascularization of the Lower Extremity
0384	T	GI Procedures with Stents

CY 2012 APC	CY 2012 Status Indicator	CY 2012 APC Title
0385	S	Level I Prosthetic Urological Procedures
0386	S	Level II Prosthetic Urological Procedures
0425	T	Level II Arthroplasty or Implantation with Prosthesis
0427	T	Level II Tube or Catheter Changes or Repositioning
0622	T	Level II Vascular Access Procedures
0623	T	Level III Vascular Access Procedures
0648	T	Level IV Breast Surgery
0652	T	Insertion of Intraperitoneal and Pleural Catheters
0653	T	Vascular Reconstruction/Fistula Repair with Device
0654	T	Insertion/Replacement of a Permanent Dual Chamber Pacemaker
*0655	T	Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing Electrode
0656	T	Transcatheter Placement of Intracoronary Drug-Eluting Stents
0674	T	Prostate Cryoablation
0680	S	Insertion of Patient Activated Event Recorders

*We refer readers to section II.A.2.e (6) of this final rule with comment period for detailed information on changes to APC 0108 and APC 0655.

BILLING CODE 4120–01–C

(2) Blood and Blood Products

Since the implementation of the OPPS in August 2000, we have made separate payments for blood and blood products through APCs rather than packaging payment for them into payments for the procedures with which they are administered. Hospital payments for the costs of blood and blood products, as well as for the costs of collecting, processing, and storing blood and blood products, are made through the OPPS payments for specific blood product APCs.

In the CY 2012 OPPS/ASC proposed rule (76 FR 42191 through 42192), we proposed to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology, which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. This methodology has been our standard ratesetting methodology for blood and blood products since CY 2005. It was developed in response to data analysis indicating that there was a significant difference in CCRs for those hospitals with and without blood-specific cost centers, and past public comments indicating that the former OPPS policy of defaulting to the overall hospital CCR for hospitals not reporting a blood-specific cost center often resulted in an underestimation of the true hospital costs for blood and blood products. Specifically, in order to address the differences in CCRs and to better reflect hospitals' costs, we proposed to continue to simulate blood CCRs for each hospital that does not report a blood cost center by calculating the ratio of the blood-specific CCRs to hospitals' overall CCRs for those hospitals that do report costs and charges for blood cost centers. We would then apply this mean ratio to the overall CCRs of hospitals not reporting costs and charges for blood cost centers on their cost reports in order to simulate blood-specific CCRs for those hospitals. We calculated the median costs upon which the proposed CY 2012 payment rates for blood and blood products are based using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific simulated blood-specific CCR for hospitals that did not report costs and charges for a blood cost center.

As we stated in the proposed rule (76 FR 42192), we continue to believe the hospital-specific, blood-specific CCR methodology best responds to the absence of a blood-specific CCR for a hospital than alternative methodologies, such as defaulting to the overall hospital CCR or applying an average blood-specific CCR across hospitals. Because this methodology takes into account the unique charging and cost accounting structure of each hospital, we believe that it yields more accurate estimated costs for these products. We believe that continuing with this methodology in CY 2012 would result in median costs for blood and blood products that appropriately reflect the relative estimated costs of these products for hospitals without blood cost centers and, therefore, for these blood products in general.

Comment: Some commenters asserted that there is a gap between CMS' proposed payments for blood and blood products and the costs incurred by

hospitals for the acquisition, management, and processing of blood and blood products, including high volume products such as leukocyte reduced red blood cells, described by HCPCS codes P9016 (Red blood cells, leukocytes reduced, each unit), P9021 (Red blood cells unit), and P9040 (Red blood cells, leukoreduced irradiated). These commenters stated that CMS should implement appropriate payment policies, such as paying no less than the payment rates in effect for CY 2011 for individual blood products in CY 2012, to close the gap between OPPS payment and the costs of blood and blood products and to ensure continued beneficiary access. They stated that this action is crucial, given that those costs continue to rise for a variety of reasons. For example, one commenter cited federally mandated requirements and recommendations by the U.S. Food and Drug Administration (FDA) as having a significant impact on the increasing costs of blood products, while another commenter noted that transfusion safety officers are being hired in most major hospitals to address improper transfusion and inappropriate use of blood. The commenters argued that, given the 2-year lag inherent in available claims data in the OPPS ratesetting process, the use of hospital claims data without adjustments likely will not reflect these rising costs in a timely manner.

Response: As we indicated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71838 through 71839), we continue to believe that using blood-specific CCRs applied to hospital claims data results in payments that appropriately reflect hospitals' relative costs of providing blood and blood products as reported to us by hospitals, which would reflect hospitals' changing costs due to factors cited by the commenters, such as FDA requirements, to the extent that these are affecting blood costs. We annually update payment groups and payment weights using the most recently available hospital claims and cost report data. This process allows us to recalibrate the payment groups and payment weights in response to changes in hospitals' costs from year to year in the most timely manner possible. A fundamental principle of the OPPS is that it is based on relative weights, and as we have stated in the past (73 FR 68541), it is the relativity of the costs to one another, rather than absolute cost, that is important in setting payment rates. To deviate from our standard OPPS ratesetting methodology by paying no less than the payment rates in effect for CY 2011 for individual blood products in CY 2012 would skew this relativity. We also note that the median costs per unit (calculated using the blood-specific CCR methodology) for this final rule with comment period increase for the majority of the most commonly provided blood and blood products (including the highest volume blood and blood product, described by HCPCS code P9016) compared to the CY 2011 median costs. For all APCs whose payment rates are based upon relative payment weights, we note that the quality and accuracy of reported units and charges significantly influence the median costs that are the basis for our payment rates, especially for low volume items and services.

After consideration of the public comments we received, we are finalizing, without modification, our CY 2012 proposal to calculate median costs upon which the CY 2012 payments rates for blood and blood products are based using our blood-specific CCR methodology, which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs (the methodology we have utilized since CY 2005). We believe that continuing this methodology in CY 2012 results in median costs for blood and blood products that appropriately reflect the relative estimated costs of these products for hospitals without blood cost centers and, therefore, for these products in general.

We refer readers to Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site) for the final CY 2012 payment rates for blood and blood products (which are identified with status indicator ''R''). For a more detailed discussion of the blood-specific CCR methodology, we refer readers to the CY 2005 OPPS proposed rule (69 FR 50524 through 50525). For a full history of OPPS payment for blood and blood products, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66807 through 66810).

(3) Allergy Tests (APCs 0370 and 0381)

In the CY 2006 OPPS final rule with comment period (70 FR 68610), we discussed the confusion raised by a number of providers related to the reporting of units for single and multiple allergy tests described by CPT codes 95004 through 95078. According to the providers, while some of these codes instruct providers to specify the number of tests or use the singular word ''tests'' or ''testing'' in their descriptors, others do not contain such instruction or do not contain ''tests'' or ''testing'' in their descriptors. In light of the variable hospital billing that may be inconsistent with the CPT code descriptors, as discussed in detail in the CY 2006 OPPS final rule with comment period (70 FR 68610), we examined CY 2004 claims and determined that the charges reported on many single procedure claims represent a ''per visit'' charge, rather than a ''per test'' charge, including claims for the allergy test codes that instruct providers to specify the number of tests. As a result of our analysis of our claims data, we differentiated single allergy tests (''per test'' from multiple allergy tests (''per visit'') by placing these services in two different APCs. We believed that making this distinction clarified billing for these services and more accurately placed them with like services sharing similar resource costs. We also provided billing guidance in CY 2006 in Transmittal 804 (issued on January 3, 2006) specifically clarifying that hospitals should report charges for the CPT codes that describe single allergy tests to reflect charges ''per test'' rather than ''per visit'' and should bill the appropriate number of units (as defined in the CPT code descriptor) of these CPT codes to describe all of the tests provided. Since 2006, we have analyzed our claims data to determine whether the reporting of these services has improved.

In the CY 2012 OPPS/ASC proposed rule (76 FR 42192), we proposed to continue to use our methodology of differentiating single allergy tests (''per test'') from multiple allergy tests (''per visit'') by assigning these services to two different APCs to provide accurate payments for these tests in CY 2012. Specifically, services proposed to be assigned to APC 0381 (Single Allergy Tests) reflect the CPT codes that describe single allergy tests in which CPT instructions direct providers to specify the number of tests performed. Alternatively, the procedures proposed for assignment to APC 0370 (Allergy Tests) describe multiple allergy tests per encounter; therefore, for these procedures, only one unit of the service is billed even if multiple tests are performed.

As discussed in the CY 2012 OPPS/ASC proposed rule (76 FR 42192), our analysis of the CY 2010 claims data available for the proposed rule for the single allergy tests, specifically those services assigned to APC 0381, did not reflect improved and more consistent hospital billing practices of ''per test'' for single allergy tests. The median cost of APC 0381 calculated for the proposed rule according to the standard single

claims OPPS methodology was approximately $51, significantly higher than the CY 2011 OPPS/ASC final rule median cost of approximately $33 that was calculated according to the ''per unit'' methodology, and greater than we would expect for these procedures that are to be reported ''per test'' with the appropriate number of units. Some claims for single allergy tests still appear to provide charges that represent a ''per visit'' charge, rather than a ''per test'' charge. Therefore, consistent with our payment policy for single allergy tests since CY 2006, we calculated a proposed ''per unit'' median cost for APC 0381, based upon 601 claims containing multiple units or multiple occurrences of a single CPT code. The proposed CY 2012 median cost for APC 0381 using the ''per unit'' methodology was approximately $34. For a full discussion of the ''per unit'' methodology for APC 0381, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66737).

In addition, we proposed that multiple allergy tests continue to be assigned to APC 0370 with a median cost calculation based on the standard OPPS methodology for CY 2012. This resulted in a proposed APC median cost of approximately $97 based on 283 claims.

We did not receive any public comments on our CY 2012 proposal for payment of single or multiple allergy tests. We are finalizing our CY 2012 proposal, without modification, to calculate a ''per unit'' median cost for APC 0381 as described above in this section. The final CY 2012 median cost of APC 0381 is approximately $31.

Furthermore, we also are finalizing our CY 2012 proposal, without modification, to use the standard OPPS methodology to set the APC payment rate for APC 0370. We are revising the title of APC 0370 from ''Allergy Tests'' to ''Multiple Allergy Tests'' so that the APC title more accurately describes all the services assigned to the APC. The final CY 2012 median cost of APC 0370 is approximately $80 based on 306 claims.

(4) Hyperbaric Oxygen Therapy (APC 0659)

Since the implementation of OPPS in August 2000, the OPPS has recognized HCPCS code C1300 (Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval) for hyperbaric oxygen (HBOT) provided in the hospital outpatient setting. In the CY 2005 final rule with comment period (69 FR 65758 through 65759), we finalized a ''per unit'' median cost calculation for APC 0659 (Hyperbaric Oxygen) using only claims with multiple units or multiple occurrences of HCPCS code C1300 because delivery of a typical HBOT service requires more than 30 minutes. We observed that claims with only a single occurrence of the code were anomalies, either because they reflected terminated sessions or because they were incorrectly coded with a single unit. In the same rule, we also established that HBOT would not generally be furnished with additional services that might be packaged under the standard OPPS APC median cost methodology. This enabled us to use claims with multiple units or multiple occurrences. Finally, we also used each hospital's overall CCR to estimate costs for HCPCS code C1300 from billed charges rather than the CCR for the respiratory therapy or other departmental cost centers. Our rationale for using the hospital's overall CCR can be found in the CY 2005 OPPS final rule with comment period (69 FR 65758 through 65759). The public comments on the CY 2005 OPPS proposed rule effectively demonstrated that hospitals report the costs and charges for HBOT in a wide variety of cost centers. Since CY 2005, we have used this methodology to estimate the median cost for HBOT. The median costs of HBOT using this methodology have been relatively stable for several years.

In the CY 2012 OPPS/ASC proposed rule (76 FR 42192), we proposed to continue using the same methodology to estimate a ''per unit'' median cost for HCPCS code C1300 for CY 2012. This methodology resulted in a proposed APC median cost of approximately $107 using 370,519 claims with multiple units or multiple occurrences for HCPCS code C1300 for CY 2012.

We did not receive any public comments on our proposal to continue to use our established ratesetting methodology for calculating the median cost of APC 0659 for payment of HBOT for CY 2012. We are finalizing our CY 2012 proposal, without modification, to continue to use our established ratesetting methodology for calculating the median cost of APC 0659 for payment of HBOT, with a final CY 2012 median cost of approximately $105.

(5) Payment for Ancillary Outpatient Services When Patient Expires (APC 0375)

In the November 1, 2002 final rule with comment period (67 FR 66798), we discussed the creation of the new HCPCS modifier ''–CA'' to address situations where a procedure on the OPPS inpatient list must be performed to resuscitate or stabilize a patient (whose status is that of an outpatient) with an emergent, life-threatening condition, and the patient dies before being admitted as an inpatient. HCPCS modifier ''CA'' is defined as a procedure payable only in the inpatient setting when performed emergently on an outpatient who expires prior to admission. In Transmittal A–02–129, issued on January 3, 2003, we instructed hospitals on the use of this modifier. For a complete description of the history of the policy and the development of the payment methodology for these services, we refer readers to the CY 2007 OPPS final rule with comment period (71 FR 68157 through 68158).

In the CY 2012 OPPS/ASC proposed rule (76 FR 42192 through 42193), we proposed to continue to use our established ratesetting methodology for calculating the median cost of APC 0375 (Ancillary Outpatient Services When Patient Expires) and to continue to make one payment under APC 0375 for the services that meet the specific conditions for using HCPCS modifier ''–CA.'' That is, we proposed to calculate the relative payment weight for APC 0375 by using all claims reporting a status indicator ''C'' (inpatient procedures) appended with HCPCS modifier ''–CA.'' For the history and detailed explanation of the methodology, we refer readers to the CY 2004 OPPS final rule (68 FR 63467 through 63468). We stated in the proposed rule that we continue to believe that this established ratesetting methodology results in the most appropriate aggregate median cost for the ancillary services provided in these unusual clinical situations.

We stated that we believe that hospitals are reporting the HCPCS modifier ''–CA'' according to the policy initially established in CY 2003. We noted that the claims frequency for APC 0375 has been relatively stable over the past few years. We noted that the median cost for APC 0375 has decreased based on the CY 2010 OPPS claims data used for the development of the proposed rates for CY 2012 compared to that for CY 2011. Variation in the median cost for APC 0375 is expected because of the small number of claims and because the specific cases are grouped by the presence of the HCPCS modifier ''–CA'' appended to an inpatient only procedure and not according to the standard APC criteria of clinical and resource homogeneity. Cost variation for APC 0375 from year to year is anticipated and acceptable as long as hospitals continue judicious reporting of the HCPCS modifier ''–CA.'' Table 4 of the proposed rule showed the number of claims and the median costs

for APC 0375 for CYs 2007, 2008, 2009, 2010, and 2011, and the proposed median cost for APC 0375 for CY 2012. For CY 2012, we proposed a median cost of approximately $5,711 for APC 0375 based on 155 claims.

We did not receive any public comments regarding this proposal. For the reasons explained in the CY 2012 OPPS/ASC proposed rule, we are finalizing our CY 2012 proposal, without modification, to continue to use our established ratesetting methodology for calculating the median cost of APC 0375, which has a final CY 2012 APC median cost of approximately $6,039. Table 4 below shows the number of claims and the final median costs for APC 0375 for CYs 2007, 2008, 2009, 2010, 2011, and 2012.

TABLE 4.--CLAIMS FOR ANCILLARY OUTPATIENT SERVICES WHEN PATIENT EXPIRES (–CA MODIFIER) FOR CYs 2007 THROUGH 2012

Prospective Payment Year	Number of Claims	APC Median Cost
CY 2007	260	$3,549
CY 2008	183	$4,945
CY 2009	168	$5,545
CY 2010	182	$5,911
CY 2011	168	$6,304
CY 2012	208	$6,039

(6) Endovascular Revascularization of the Lower Extremity (APCs 0083, 0229, and 0319)

For the CY 2011 update, the AMA's CPT Editorial Panel created 16 new CPT codes in the Endovascular Revascularization section of the 2011 CPT code book to describe endovascular revascularization procedures of the lower extremity performed for occlusive disease. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71841 through 71845), we discussed the process and methodology by which we assigned the new CY 2011 endovascular revascularization CPT codes to APCs that we believe are comparable with respect to clinical characteristics and resources required to furnish the services. Specifically, we were able to use the existing CY 2009 hospital outpatient claims data and most recent cost report data to create simulated medians for 12 of the 16 new separately payable codes for CY 2011. Because the endovascular revascularization CPT codes are new for CY 2011, we used our CY 2009 single and ''pseudo'' single claims data to simulate the new CY 2011 CPT code definitions. As shown in Table 7 of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71844), many of the new endovascular revascularization CPT codes were previously reported using a combination of CY 2009 CPT codes. In order to simulate median costs, we selected claims that we believe meet the definition for each of the new endovascular revascularization CPT codes. Table 7 showed the criteria we applied to select a claim to be used in the calculation of the median cost for the new codes (shown in Column A). As we stated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71842), we developed these criteria based on our clinicians' understanding of services that were reported by CY 2009 CPT codes that, in various combinations, reflect the services provided that are described by the new CPT codes for CY 2011.

After determining the simulated median costs for the procedures, we assigned each CPT code to appropriate APCs based on their clinical homogeneity and resource use. Of the 16 new codes, we assigned 9 CPT codes to APC 0083 (Coronary or Non-Coronary Angioplasty and Percutaneous Valvuloplasty) and 5 CPT codes to APC 0229 (Transcatheter Placement of Intravascular Shunts), and created new APC 0319 (Endovascular Revascularization of the Lower Extremity) for 2 CPT codes. Table 8 of the CY 2011 OPPS/ASC final rule with comment period displayed their final CY 2011 APC assignments and CPT median costs (75 FR 71845). We noted that because these CPT codes are new for CY 2011, they are identified with comment indicator ''NI'' in Addendum B to the CY 2011 OPPS/ASC final rule with comment period to identify them as a new interim APC assignment for the new year and subject to public comment. We specifically requested public comment on our methodology for simulating the median costs for these new CY 2011 CPT codes in addition to public comments on the payment rates themselves (75 FR 71845).

At its February 28–March 1, 2011 meeting, the APC Panel recommended that CMS provide data to allow the Panel to investigate and monitor the APC weights for the lower extremity revascularization procedures in light of CPT coding changes for CY 2011. In the CY 2012 OPPS/ASC proposed rule, we indicated that we were accepting the APC Panel's recommendation and will provide additional data to the Panel at an upcoming meeting.

In the CY 2012 OPPS/ASC proposed rule (76 FR 42190), we proposed to continue with the CY 2011 methodology that was described previously in this section in determining the APC assignments for the CPT codes that describe endovascular revascularization of the lower extremity. The predecessor endovascular revascularization CPT codes were in existence prior to CY 2011 and were assigned to APCs based on claims data and cost report data. Given that these data are available for the services described by the predecessor endovascular revascularization CPT codes, we proposed to continue for CY 2012 to use the existing hospital outpatient claims and cost report data from the previous endovascular revascularization CPT codes to simulate an estimated median cost for the new endovascular revascularization CPT codes in determining the appropriate APC

assignments. As has been our practice since the implementation of the OPPS in 2000, we review our latest claims data for ratesetting and, if necessary, revise the APC assignments for the upcoming year. In this case, review of the procedures with significant claims data in APC 0083 showed a 2 times rule violation. Specifically, APC 0083, as it was initially configured, showed that the range of the CPT median costs for the procedures with significant claims data was approximately between $3,252 (for CPT code 35476 (Transluminal balloon angioplasty, percutaneous; venous)) and $7,174 (for CPT code 37221 (Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed)), resulting in a 2 times rule violation. Because of its median cost, we stated that we believe that CPT code 37221 would be more appropriately placed in APC 0229, which had an initial estimated median cost of approximately $8,606, based on the clinical and resource characteristics of other procedures also assigned to APC 0229. Therefore, for CY 2012, we proposed to revise the APC assignment for CPT code 37221, from APC 0083 to APC 0229, to accurately reflect the cost and clinical features of the procedure. This proposed reassignment of CPT code 37221 from APC 0083 to APC 0029 would eliminate the 2 times rule violation for APC 0083 noted above. Based on this reconfiguration, the CY 2010 claims data available for the proposed rule were used to calculate a median cost of approximately $4,683 for APC 0083, approximately $8,218 for APC 0229, and approximately $14,556 for APC 0319. All three proposed median costs for CY 2012 were significantly greater than the CY 2011 OPPS/ASC final rule median costs of approximately $3,740 for APC 0083, approximately $7,940 for APC 0229, and approximately $13,751 for APC 0319.

In addition, we proposed to revise the APC titles for APCs 0083, 0229, and 0319 to better describe the procedures assigned to these APCs. Specifically, we proposed to revise the APC title for APC 0083 from ''Coronary or Non-Coronary Angioplasty and Percutaneous Valvuloplasty'' to ''Level I Endovascular Revascularization of the Lower Extremity''; for APC 0229, from ''Transcatheter Placement of Intravascular Shunt and Stents'' to ''Level II Endovascular Revascularization of the Lower Extremity''; and for APC 0319, from ''Endovascular Revascularization of the Lower Extremity'' to ''Level III Endovascular Revascularization of the Lower Extremity.''

We solicited public comments on the proposed status indicators and APC assignments for the endovascular revascularization of the lower extremity CPT codes for CY 2012. Table 5 of the proposed rule listed the endovascular revascularization of the lower extremity CPT codes along with their proposed status indicator and APC assignments for CY 2012. As noted previously, because these CPT codes are new for CY 2011, they are identified with comment indicator ''NI'' in Addendum B to the CY 2011 OPPS/ASC final rule with comment period to identify them as a new interim APC assignment for the new year and subject to public comment. We specifically requested public comment on our methodology for simulating the median costs for these new CY 2011 CPT codes in addition to public comments on the payment rates themselves (75 FR 71845). We respond to any public comments received on the CY 2011 OPPS/ASC final rule with comment period and the CY 2012 OPPS/ASC proposed rule below.

At its August 10–12, 2011 meeting, the APC Panel supported CMS' proposal to move HCPCS code 37221 (Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed) to APC 0229.

Comment: Several commenters supported the CY 2012 proposal to rename APCs 0083, 0229, and 0319 to better describe the procedures assigned to these APCs, and requested that CMS finalize these changes. The commenters also supported the proposed status indicator assignments of ''T'' for each of these APCs. One commenter agreed with the proposed renaming of APC 0229 and 0319 but asked that CMS change the APC title of APC 0038 to ''Coronary Angioplasty, Valvuloplasty, and Level I Endovascular Revascularization of the Lower Extremity'' in order to reflect the coronary as well as endovascular procedures assigned to that APC.

Response: We appreciate the commenters' support of our proposal to revise the titles for APCs 0083, 0229, and 0319. We agree with the commenter that a title of ''Coronary Angioplasty, Valvuloplasty, and Level I Endovascular Revascularization of the Lower Extremity'' would more accurately describe the procedures assigned to APC 0083. Therefore, we are finalizing our CY 2012 proposal, with modification, to revise the APC title for APC 0083 from ''Coronary or Non-Coronary Angioplasty and Percutaneous Valvuloplasty'' to ''Coronary Angioplasty, Valvuloplasty, and Level I Endovascular Revascularization of the Lower Extremity''; for APC 0229, from ''Transcatheter Placement of Intravascular Shunt and Stents'' to ''Level II Endovascular Revascularization of the Lower Extremity''; and for APC 0319, from ''Endovascular Revascularization of the Lower Extremity'' to ''Level III Endovascular Revascularization of the Lower Extremity.'' We also are finalizing our proposal, without modification, to continue to assign status indicator ''T'' to each of these APCs.

Comment: Many commenters supported our overall methodology for calculating simulated medians for the endovascular revascularization CPT codes established for 2011 and agreed with the APC reassignment for CPT code 37221 from APC 0083 to APC 0229. A few commenters cited that, during the August 2011 APC Panel meeting, the APC Panel recommended that CMS finalize this proposal.

Response: We appreciate the commenters' support of our overall methodology for calculating simulated medians for the endovascular revascularization CPT codes established for 2011. Based on our analysis of the hospital claims and cost report data available for this final rule with comment period, and in accordance with the feedback we received from many commenters, we continue to believe that CPT code 37221 is more appropriately placed in APC 0229 than in APC 0083. Our data shows 4,673 simulated single claims (out of 4,710 total claims) for CPT code 37221 with a CPT median cost of approximately $7,053, which is closer to the APC median cost of approximately $8,088 for APC 0229 than to the APC 0083 median cost of approximately $4,611.28. We also note that if CPT code 37221 were assigned to APC 0083, a 2 times violation would likely result. Therefore, after consideration of the public comments received and the APC Panel recommendation at its August 2011 meeting, we are finalizing our proposal, without modification, to assign CPT code 37221 to APC 0229, which has a final CY 2012 median cost of approximately $8,088.

Comment: Several commenters disagreed with the continued APC assignment for CPT code 37223 (Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal stent placement(s),

includes angioplasty within the same vessel, when performed) in APC 0083. They stated that the service described by CPT code 37223 is more similar clinically and in terms of resource utilization to the procedures assigned to APC 0229 because this service involves stent placement. The commenters also argued that CPT code 37223 is an add-on code to CPT code 37221, and should be assigned to APC 0229, which is the APC to which CPT code 37221 is assigned. They pointed out that CPT codes 37206 (Transcatheter placement of an intravascular stent(s) (except coronary, carotid, and vertebral vessel, and lower extremity arteries), percutaneous; each additional vessel) and 37208 (Transcatheter placement of an intravascular stent(s) (non-coronary vessel other than iliac and lower extremity arteries), open; each additional vessel) are also add-on CPT codes, and that they are assigned to the same APC as the primary codes with which they are billed (that is, APC 0229). The commenters further added that CPT code 37223, like CPT code 37221, requires the use of an implantable endovascular stent, and that the CY 2012 OPPS proposed payment rate of approximately $4,520 for CPT code 37223 does not take the cost of the device into consideration. They noted that any efficiencies to be gained by performing the procedure described by CPT code 37223 at the same time as the procedure described by CPT code 37223 would be captured appropriately in the multiple procedure discount that would apply as a result of both procedures being assigned status indicator ''T.''

Response: We are unable to simulate a median cost for CPT code 37223 using the CY 2010 claims data available for this final rule with comment period because we have no single service claims data that appropriately describe the procedure associated with CPT code 37223. Therefore, analysis of our hospital outpatient claims data does not support an APC reassignment for CPT code 37223 from APC 0083 to APC 0229 based on resource homogeneity, and we believe that the service described by CPT code 37223 is clinically similar to procedures in APC 0083. We note that we will have CY 2011 hospital claims available for CPT code 37223 and the other new endovascular revascularization CPT codes for the first time for CY 2013 OPPS ratesetting, and that we will closely monitor our data to ensure that the APC placements appropriately reflect hospitals' costs for these procedures.

We also note that when hospitals report CPT code 37223, we expect them to also report one of the following device HCPCS C-codes for the implantable stent used in those procedures:

- C1874 (Stent, coated/covered, with delivery system)
- C1875 (Stent, coated/covered, without delivery system)
- C1876 (Stent, non-coated/non-covered, with delivery system)
- C1877 (Stent, non-coated/non-covered, without delivery system)
- C2617 (Stent, non-coronary, temporary, without delivery system)
- C2625 (Stent, non-coronary, temporary, with delivery system)

These HCPCS C-codes were made effective April 1, 2001, and are a part of the procedure-to-device edits for CPT code 37223. Procedure-to-device edits, which have been in place for many procedures since 2005, require that when a particular service or procedural CPT or Level II HCPCS code is billed, the claim must also contain an appropriate device code.

After analysis of our claims data and consideration of the public comments received, we are finalizing our proposal, without modification, to continue to assign CPT code 37223 to APC 0083, which has a final CY 2012 median cost of approximately $4,611.

Comment: Some commenters disagreed with the APC assignment for CPT codes 37224 (Revascularization, endovascular, open or percutaneous, femoral/popliteal artery(s), unilateral; with transluminal angioplasty) and 37235 (Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed) to APC 0083, and stated that both procedures would be more appropriately placed in APC 0229 based on the economic and clinical coherence to other procedures already assigned to APC 0229.

Response: Analysis of our hospital outpatient claims shows 4,288 simulated single claims (out of 4,320 total claims) with a median cost of approximately $5,418 for CPT code 37224, while there were no claims submitted upon which we could simulate a median cost for CPT code 37235. The range of the median costs for APC 0083 with significant claims data is approximately between $3,230 to approximately $5,766, which is in line with the median cost of approximately $5,418 for CPT code 37224. Based on our claims data, we believe that CPT code 37224 is appropriately placed in APC 0083 which has a final median cost is approximately $4,611. As is the case with CPT code 37223, we do not have claims data to support the reassignment of CPT code 37235 to a different APC. We also believe that CPT codes 37224 and 37235 are sufficiently similar clinically to the other procedures in APC 0083 to warrant their continued placement in that APC. Therefore, we will continue to assign CPT codes 37224 and 37235 to APC 0083 for CY 2012.

We note that, similar to CPT code 37223, both CPT codes 37224 and 37235 are included as part of the procedure-to-device edits, and hospitals are reminded to refer to the latest edits on the CMS OPPS Web site. The updated lists of edits can be found under ''Device, Radiolabeled Product, and Procedure Edits'' at *http://www.cms.gov/HospitalOutpatientPPS/*.

After consideration of the public comments received on the CY 2011 OPPS/ASC final rule with comment period and the CY 2012 OPPS/ASC proposed rule and review of our claims data, we are finalizing our CY 2012 proposal, without modification, to continue with the CY 2011 methodology that we described in the CY 2012 OPPS/ASC proposed rule (76 FR 42193 through 42194) in determining the APC assignments for the CPT codes that describe endovascular revascularization of the lower extremity for the reasons set forth above. We also are finalizing our CY 2012 proposal, without modification, to revise the APC assignment for CPT code 37221, from APC 0083 to APC 0229. We are finalizing our CY 2012 proposal, with modification, to revise the APC titles for APCs 0083, 0229, and 0319 as described previously. Table 5 below lists the endovascular revascularization of the lower extremity CPT codes along with their final status indicator and APC assignments for CY 2012.

TABLE 5.—APCs TO WHICH ENDOVASCULAR REVASCULARIZATION OF THE LOWER EXTREMITY CPT CODES WILL BE ASSIGNED FOR CY 2012

CY 2012 CPT Code	CY 2012 Short Descriptor	CY 2011 SI	CY 2011 APC	Final CY 2012 SI	Final CY 2012 APC
37220	Iliac revasc	T	0083	T	0083
37221	Iliac revasc w/stent	T	0083	T	0229
37222	Iliac revasc add-on	T	0083	T	0083
37223	Iliac revasc w/stent add-on	T	0083	T	0083
37224	Fem/popl revas w/tla	T	0083	T	0083
37225	Fem/popl revas w/ather	T	0229	T	0229
37226	Fem/popl revasc w/stent	T	0229	T	0229
37227	Fem/popl revasc stnt & ather	T	0319	T	0319
37228	Tib/per revasc w/tla	T	0083	T	0083
37229	Tib/per revasc w/ather	T	0229	T	0229
37230	Tib/per revasc w/stent	T	0229	T	0229
37231	Tib/per revasc stent & ather	T	0319	T	0319
37232	Tib/per revasc add-on	T	0083	T	0083
37233	Tibper revasc w/ather add-on	T	0229	T	0229
37234	Revsc opn/prq tib/pero stent	T	0083	T	0083
37235	Tib/per revasc stnt & ather	T	0083	T	0083

(7) Non-Congenital Cardiac Catheterization (APC 0080)

For CY 2011, the AMA CPT Editorial Panel deleted 19 non-congenital cardiac catheterization-related CPT codes and replaced them with 20 new CPT codes in the Cardiac Catheterization and Injection-Related section of the 2011 CPT Code Book to describe more precisely the specific services provided during cardiac catheterization procedures. In particular, the CPT Editorial Panel deleted 19 non-congenital cardiac catheterization-related CPT codes from the 93500 series and created 14 new CPT codes in the 93400 series and 6 in the 93500 series. We discussed these coding changes in detail in the CY 2011 OPPS/ASC final rule with comment period, along with the process by which we assigned the new CPT codes to APCs that we believe are comparable with respect to clinical characteristics and resources required to furnish the cardiac catheterization services described by the new CPT codes (75 FR 71846 through 71849). As discussed in the final rule with comment period, we were able to use the existing CY 2009 hospital outpatient claims data and the most recent cost report data to create simulated medians for the new separately payable CPT codes for CY 2011. Specifically, to estimate the hospital costs associated with the 20 new non-congenital cardiac catheterization-related CPT codes based on their CY 2011 descriptors, we used claims and cost report data from CY 2009. Because of the substantive coding changes associated with the new non-congenital cardiac catheterization-related CPT codes for CY 2011, we used our CY 2009 single and ''pseudo'' single claims data to simulate the new CY 2011 CPT code definitions. We stated that many of the new CPT codes were previously reported using multiple CY 2009 CPT codes, and we provided a crosswalk of the new CY 2011 cardiac catheterization CPT codes mapped to the CY 2009 cardiac catheterization CPT codes in Table 11 of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71849). Table 11 showed the criteria we applied to select a claim to be used in the calculation of the median cost for the new codes (shown in column A). As we stated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71847 through 71848), we developed these criteria based on our clinicians' understanding of services that were reported by CY 2009 CPT codes that, in various combinations, reflect the services provided that are described in the new CPT codes. We used approximately 175,000 claims for the new non-congenital catheterization-related CPT codes, together with the single and ''pseudo'' single procedure claims for the remaining congenital catheterization-related CPT codes in APC 0080, to calculate CPT level median costs and the median cost for APC 0080 of approximately $2,698. We noted that, because the CPT codes listed in Table 11 are new for CY 2011, they were identified with comment indicator ''NI'' in Addendum B of that final rule with comment period to identify them

as subject to public comment. We specifically requested public comment on our methodology for simulating the median costs for these new CY 2011 CPT codes, in addition to public comments on the payment rates themselves (75 FR 71848).

In the CY 2012 OPPS/ASC proposed rule (76 FR 42195), for CY 2012, we proposed to continue to use the CY 2011 methodology in determining the APC assignments for the cardiac catheterization CPT codes. The predecessor cardiac catheterization CPT codes were in existence prior to CY 2011 and were assigned to APC 0080 based on claims data and cost report data. Given that these data are available for the services described by the predecessor cardiac catheterization CPT codes, we proposed for CY 2012 to continue to use the existing hospital outpatient claims and cost report data from the predecessor cardiac catheterization CPT codes to simulate an estimated median cost for the new cardiac catheterization CPT codes in determining the appropriate APC assignments. As has been our practice since the implementation of the OPPS in 2000, we review our latest claims data for ratesetting and, if necessary, revise the APC assignments for the upcoming year. Based on analysis of the CY 2010 claims data available for the proposed rule, the proposed median cost for APC 0080 was approximately $2,822 for CY 2012, which was slightly greater than the median cost of approximately $2,698 for the CY 2011 OPPS/ASC final rule with comment period. For CY 2012, we did not propose any changes to the CY 2011 APC assignments of any of the codes assigned to APC 0080 because the claims data available for the proposed rule support continuation of these APC assignments.

We solicited public comments on the proposed status indicators and the APC assignments for CY 2012 for the cardiac catheterization CPT codes. Table 6 of the proposed rule listed the new CY 2011 cardiac catheterization CPT codes along with their proposed status indicators and APC assignments for CY 2012.

Comment: Some commenters supported our CY 2012 proposal for payment of non-congenital cardiac catheterization.

Response: We appreciate the commenters' support of our payment methodology for the non-congenital cardiac catheterization procedures. Therefore, consistent with our rationale set forth above, we are finalizing our CY 2012 proposal, without modification, to continue with the CY 2011 methodology in determining the APC assignments for the non-congenital cardiac catheterization CPT codes. The final CY 2012 median cost for APC 0080 is approximately $2,721.

Table 6 below lists the CY 2012 cardiac catheterization CPT codes along with their final status indicators and APC assignments for CY 2012.

TABLE 6.—APCs TO WHICH NON-CONGENITAL CARDIAC CATHETERIZATION CPT CODES WILL BE ASSIGNED FOR CY 2012

CY 2012 HCPCS Code	CY 2012 Short Descriptor	CY 2011 SI	CY 2011 APC	Final CY 2012 SI	Final CY 2012 APC
93451	Right heart cath	T	0080	T	0080
93452	Left hrt cath w/ventrclgrphy	T	0080	T	0080
93453	R&l hrt cath w/ventriclgrphy	T	0080	T	0080
93454	Coronary artery angio s&i	T	0080	T	0080
93455	Coronary art/grft angio s&i	T	0080	T	0080
93456	R hrt coronary artery angio	T	0080	T	0080
93457	R hrt art/grft angio	T	0080	T	0080
93458	L hrt artery/ventricle angio	T	0080	T	0080
93459	L hrt art/grft angio	T	0080	T	0080
93460	R&l hrt art/ventricle angio	T	0080	T	0080
93461	R&l hrt art/ventricle angio	T	0080	T	0080
93462	L hrt cath trnsptl puncture	T	0080	T	0080
93463	Drug admin & hemodynmic meas	N	NA	N	NA
93464	Exercise w/hemodynamic meas	N	NA	N	NA
93563	Inject congenital card cath	N	NA	N	NA
93564	Inject hrt congntl art/grft	N	NA	N	NA
93565	Inject l ventr/atrial angio	N	NA	N	NA
93566	Inject r ventr/atrial angio	N	NA	N	NA
93567	Inject suprvlv aortography	N	NA	N	NA
93568	Inject pulm art hrt cath	N	NA	N	NA

(8) Cranial Neurostimulator and Electrodes (APC 0318)

For CY 2011, the AMA CPT Editorial Panel created a new CPT code 64568 (Incision for implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator) and indicated that it describes the services formerly included in the combinations of (1) CPT code 64573 (Incision for implantation of neurostimulator electrodes; cranial nerve) and CPT code 61885 (Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array); or (2) CPT code 64573 and CPT code 61886 (Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to two or more electrode arrays). As we discussed in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71850), our standard process for assigning new CPT codes to APCs is to assign the code to the APC that we believe contains services that are comparable with respect to clinical characteristics and resources required to furnish the service. A new CPT code is given a comment indicator of ''NI'' to identify it as a new interim APC assignment for the first year and the APC assignment for the new code is then open to public comment. In some, but not all, cases, we are able to use the existing data from established codes to simulate an estimated median cost for the new code to guide us in the assignment of the new code to an APC. For CY 2011, in the case of the new neurostimulator electrode and pulse generator implantation CPT code, we were able to use the existing CY 2009 claims and most current cost report data to create a simulated median cost.

Specifically, to estimate the hospital costs of CPT code 64568 based on its CY 2011 descriptor, we used CY 2009 claims and the most recent cost report data, using the single and ''pseudo'' single claims within this data set to simulate the definition of this service. We selected claims with CPT code 64573 on which CPT code 61885 or 61886 was also present and consistent with the description of the new CPT code 64568. We treated the summed costs on these claims as if they were a

single procedure claim for CPT code 64568. We created an estimated median cost of approximately $22,562 for CPT code 64568 from 298 single claims to set a final payment rate for CY 2011 for the new code. We created APC 0318 (Implantation of Cranial Neurostimulator Pulse Generator and Electrode) for CY 2011, to which CPT code 64568 is the only procedure assigned. APC 0225 (Implantation of Neurostimulator Electrodes, Cranial Nerve), which contained only the predecessor CPT code 64573, was deleted effective January 1, 2011. We noted that, because CPT code 64568 is new for CY 2011, it was identified with comment indicator ''NI'' in Addendum B of the CY 2011 OPPS/ASC final rule with comment period to identify it as subject to public comment. We specifically requested public comment on our methodology for simulating the median costs for this new CY 2011 CPT code, in addition to public comments on the payment rate itself (75 FR 71850).

In the CY 2012 OPPS/ASC proposed rule (76 FR 42195 through 42196), we proposed to use the same methodology we used in CY 2011 to estimate the hospital costs of CPT code 64568 and to continue to maintain CPT code 64568 as the only code assigned to APC 0318 for CY 2012.

Comment: One commenter on the CY 2011 OPPS final rule with comment period expressed appreciation for CMS' efforts to establish APC 0318.

Response: We appreciate the commenters' support for the creation of APC 0318.

We did not receive any public comments on our proposals for cost estimation or APC assignment of CPT code 64568 for CY 2012. We are finalizing our CY 2012 proposal, without modification, to use the same methodology we used in CY 2011 to estimate hospital costs of CPT code 64568. For this final rule with comment period, we created an estimated median cost of approximately $24,262 for CPT code 64568 from 455 single claims to set a payment rate for APC 0318 for CY 2012. We are maintaining CPT code 64568 as the only code assigned to APC 0318 for CY 2012.

(9) Brachytherapy Sources

(A) Background

Section 1833(t)(2)(H) of the Act, as added by section 621(b)(2)(C) of Pub. L. 108–173 (MMA), mandated the creation of additional groups of covered OPD services that classify devices of brachytherapy consisting of a seed or seeds (or radioactive source) (''brachytherapy sources'') separately from other services or groups of services. The additional groups must reflect the number, isotope, and radioactive intensity of the brachytherapy sources furnished and include separate groups for palladium-103 and iodine-125 sources.

Section 1833(t)(16)(C) of the Act, as added by section 621(b)(1) of Public Law 108–173, established payment for brachytherapy sources furnished from January 1, 2004 through December 31, 2006, based on a hospital's charges for each brachytherapy source furnished adjusted to cost. Under section 1833(t)(16)(C) of the Act, charges for the brachytherapy sources may not be used in determining any outlier payments under the OPPS for that period in which payment is based on charges adjusted to cost. Consistent with our practice under the OPPS to exclude items paid at cost from budget neutrality consideration, these items were excluded from budget neutrality for that time period as well.

Subsequent to the MMA, various amendments to the Act were made that resulted in the extension of the payment period for brachytherapy sources based on a hospital's charges adjusted to cost through December 31, 2009. The CY 2011 OPPS/ASC final rule with comment period summarizes these amendments to the Act and our proposals to pay for brachytherapy sources at prospective payment rates based on their source specific median costs from CY 2007 through CY 2009 (75 FR 71977 through 71981).

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60533 through 60537), we adopted for CY 2010 the general OPPS prospective payment methodology for brachytherapy sources, consistent with section 1833(t)(2)(C) of the Act, with payment rates based on source-specific median costs. For CY 2011, we continued to use the general OPPS prospective payment methodology for brachytherapy sources, consistent with section 1833(t)(2)(C) of the Act (75 FR 71980). We also finalized our proposals to continue the policy we first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537 and 75 FR 71980) regarding payment for new brachytherapy sources for which we have no claims data, based on the same reasons we discussed in the 2008 OPPS/ASC final rule with comment period (72 FR 66786; which was superseded by section 142 of Pub. L. 110–275). That policy is intended to enable us to assign future new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates based on our consideration of external data and other relevant information regarding the expected costs of the sources to hospitals.

Consistent with our policy regarding APC payments made on a prospective basis, for CYs 2010 and 2011, we finalized proposals to subject brachytherapy sources to outlier payments under section 1833(t)(5) of the Act, and also to subject brachytherapy source payment weights to scaling for purposes of budget neutrality (75 FR 71980 through 71981 and 75 FR 60537). Hospitals could receive outlier payments for brachytherapy sources if the costs of furnishing brachytherapy sources meet the criteria for outlier payment. In addition, as noted in the CY 2010 and CY 2011 OPPS/ASC final rules with comment period (74 FR 60534 and 75 FR 71978 and 71979, respectively), implementation of prospective payments for brachytherapy sources provided opportunities for eligible hospitals to receive additional payments in CY 2010 and CY 2011 under certain circumstances through the 7.1 percent rural adjustment, as described in section II.E. of this final rule with comment period.

(B) OPPS Payment Policy

As we have stated previously (72 FR 66780, 73 FR 41502, 74 FR 60533 through 60534, and 75 FR 71978), we believe that adopting the general OPPS prospective payment methodology for brachytherapy sources is appropriate for a number of reasons. The general OPPS payment methodology uses median costs based on claims data to set the relative payment weights for hospital outpatient services. This payment methodology results in more consistent, predictable, and equitable payment amounts per source across hospitals by eliminating some of the extremely high and low payment amounts resulting from payment based on hospitals' charges adjusted to cost. We believe that the OPPS prospective payment methodology, as opposed to payment based on hospitals' charges adjusted to cost, would also provide hospitals with incentives for efficiency in the provision of brachytherapy services to Medicare beneficiaries. Moreover, this approach is consistent with our payment methodology for the vast majority of items and services paid under the OPPS.

In the CY 2012 OPPS/ASC proposed rule (76 FR 42196 through 42197), we proposed to use the median costs from CY 2010 claims data for setting the proposed CY 2012 payment rates for brachytherapy sources, as we proposed for most other items and services that will be paid under the CY 2012 OPPS. We proposed to continue the other payment policies for brachytherapy

sources we finalized and first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537). We proposed to pay for the stranded and non-stranded NOS codes, HCPCS codes C2698 and C2699, at a rate equal to the lowest stranded or non-stranded prospective payment rate for such sources, respectively, on a per source basis (as opposed, for example, to a per mCi), which is based on the policy we established in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66785). The proposed payment methodology for NOS sources would provide payment to a hospital for new sources and, at the same time, encourage interested parties to quickly bring new sources to our attention so that specific coding and payment could be established.

We also proposed to continue the policy we first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537) regarding payment for new brachytherapy sources for which we have no claims data, based on the same reasons we discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66786; which was superseded for a period of time by section 142 of Pub. L. 110–275). That policy is intended to enable us to assign new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates set based on our consideration of external data and other relevant information regarding the expected costs of the sources to hospitals.

Consistent with our policy regarding APC payments made on a prospective basis, as we did for CY 2011, we proposed to subject brachytherapy sources to outlier payments under section 1833(t)(5) of the Act, and also to subject brachytherapy source payment weights to scaling for purposes of budget neutrality. Hospitals can receive outlier payments for brachytherapy sources if the costs of furnishing brachytherapy sources meet the criteria for outlier payment. In addition, as noted in the CY 2010 and CY 2011 OPPS/ASC final rules with comment period (74 FR 60534 and 75 FR 71978 through 71979, respectively), implementation of prospective payments for brachytherapy sources would provide opportunities for eligible hospitals to receive additional payments in CY 2012 under certain circumstances through the 7.1 percent rural adjustment, as described in section II.E. of the proposed rule.

Therefore, we proposed to pay for brachytherapy sources at prospective payment rates based on their source-specific median costs for CY 2012. We referred readers to Addendum B to the proposed rule (which is available via the Internet on the CMS Web site) for the proposed CY 2012 payment rates for brachytherapy sources, identified with status indicator ''U.'' For more detailed discussion of the legislative history surrounding brachytherapy sources and our proposed and final policies for CY 2004 through CY 2011, we refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 71977 through 71981).

Comment: Some commenters requested that CMS discard its prospective payment methodology for brachytherapy sources based on source-specific median costs, and revert to payments based on brachytherapy charges adjusted to costs, for a variety of reasons. The commenters claimed that the claims data show a huge variation in costs per unit; that there continues to be, in the CY 2012 proposed rule data, longstanding instability and fluctuation of costs; that more than one half of the current brachytherapy sources have proposed payment rates based on 50 or fewer hospitals (a number that a commenter reported has declined from 2010 to 2012); and that proposed payment rates are unstable and fluctuate significantly. The commenters were also concerned that rank order anomalies continue to exist in proposed source payment rates, such as between C2635, high activity palladium, and C2640 and C2641, which represent forms of low activity palladium. The commenters also claimed that the charges adjusted to cost method would cost the Medicare program approximately $10.8 million less than the prospective payment methodology based on median cost per source. The commenters claimed that the number of hospitals providing brachytherapy treatment and the number of beneficiaries treated with brachytherapy have declined from 2010 to 2011 because some hospitals cannot recover their costs under the prospective payment rates adopted in CY 2010. The commenters also pointed out that High Dose Rate (HDR) Iridium-192 may treat multiple patients over a 90-day source life, making its true cost dependent on the number of patients treated, and thus making fair prospective payment difficult to achieve.

Response: As we stated previously (72 FR 66782; 74 FR 60534; 75 FR 71979), we believe that median costs based on hospital claims data for brachytherapy sources have produced reasonably consistent per-source cost estimates over the past several years, comparable to the patterns we have observed for many other OPPS services whose payments are set based upon relative payment weights from claims data. We believe that our per-source payment methodology specific to each source's radioisotope, radioactive intensity, and stranded or non-stranded configuration, supplemented by payment based on the number of sources used in a specific clinical case, adequately accounts for the major expected sources of variability across treatments. As we also explained previously (72 FR 66782; 74 FR 60535; 75 FR 71979), a prospective payment system such as the OPPS relies on the concept of averaging, where the payment may be more or less than the estimated cost of providing a service for a particular patient, but with the exception of outlier cases, it is adequate to ensure access to appropriate care. In the case of brachytherapy sources for which the law requires separate payment groups, without packaging, the costs of these individual items could be expected to show greater variation than some other APCs under the OPPS because higher variability in costs for some component items and services is not balanced with lower variability for others and because relative weights are typically estimated using a smaller set of claims. Nevertheless, we believe that prospective payment for brachytherapy sources based on median costs from claims calculated according to the standard OPPS methodology is appropriate and provides hospitals with the greatest incentives for efficiency in furnishing brachytherapy treatment.

As we have stated previously (75 FR 71979), under the budget neutral provision for the OPPS, it is the relativity of costs of services, not their absolute costs, that is important, and we believe that brachytherapy sources are appropriately paid according to the standard OPPS payment approach. Furthermore, we are not concerned that some sources may have median costs and payment rates based on 50 or fewer providers, because it is not uncommon for OPPS prospective payment rates to be based on claims from a relatively small number of hospitals that furnished the service in the year of claims data available for the OPPS update year. Fifty hospitals may report hundreds of brachytherapy source claims for many cases and comprise the universe of providers using particular low volume sources, for which we are required to pay separately by statute. Further, our methodology for estimating median costs for brachytherapy sources utilizes all line-item charges for those sources, which allows us to use all

hospital reported charge and estimated cost information to set payment rates for these items. Therefore, no brachytherapy source claims are lost. We have no reason to believe that prospective payment rates based on claims from those providers furnishing a particular source do not appropriately reflect the cost of that source to hospitals.

In the case of high and low activity iodine-125 sources, our claims data show that the cost of the high activity source is greater than the low activity sources, as we have noticed in the past. However, this relationship is reversed for palladium-103 sources, as one commenter pointed out. As we have stated in the past (75 FR 71979), we have no information about the expected cost differential between high and low activity sources of various isotopes other than what is available in our claims and hospital cost report data. For high activity palladium-103, only 12 hospitals reported this service in CY 2010, compared to 150 and 211 providers for low activity palladium sources described by HCPCS codes C2640 and C2641, respectively. As we stated regarding this issue in the CY 2010 and CY 2011 OPPS/ASC final rule with comment period (74 FR 60535 and 75 FR 71979), it is clear that fewer providers furnished high activity palladium-103 sources than low activity palladium sources, and we expect that the hospital cost distribution for those hospitals could be different than the cost distribution of the large number of providers reporting the low activity sources. These varied cost distributions clearly contribute to the observed relationship in median costs between the different types of sources. However, we see no reason why our standard ratesetting methodology for brachytherapy sources that relies on all claims from all hospitals furnishing brachytherapy sources would not yield valid median costs for those hospitals furnishing the different brachytherapy sources upon which CY 2012 prospective payments rates are based.

Prospective payment for brachytherapy sources based on their median costs makes the source payment an integral part of the OPPS, rather than a separate cost-based payment methodology within the OPPS, as indicated previously (75 FR 71980). We believe that consistent and predictable prospectively established payment rates under the OPPS for brachytherapy sources are appropriate because we do not believe that the hospital resource costs associated with specific brachytherapy sources would vary greatly across hospitals or clinical conditions under treatment, other than through differences in the numbers of sources utilized that would be accounted for in the standard OPPS payment methodology we are finalizing for CY 2012.

As we indicated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71980), we agree that high dose rate (HDR) brachytherapy sources such as HDR irirdium-192 have a fixed active life and must be replaced every 90 days; as a result, hospitals' per-treatment cost for the source would be dependent on the number of treatments furnished per source. The source cost must be amortized over the life of the source. Therefore, in establishing their charges for HDR iridium, we expect hospitals to project the number of treatments that would be provided over the life of the source and establish their charges for the source accordingly, as we have stated previously (72 FR 66783; 74 FR 60535; 75 FR 71980). For most of these OPPS services, our practice is to establish prospective payment rates based on the median costs from hospitals' claims data to provide incentives for efficient and cost-effective delivery of these services.

We do not agree with the commenters that prospective brachytherapy source payment based on median costs would increase aggregate Medicare expenditures using the charges-adjusted-to-cost methodology compared to the proposed prospective payment methodology. Our past studies, such as that discussed in the CY 2010 final rule with comment period (74 FR 60535), have shown that payment at charges adjusted to cost results in higher aggregate payment for brachytherapy sources than does prospective payment. As we indicated in the CY 2010 final rule with comment period and the CY 2011 final rule with comment period (74 FR 60535 and 75 FR 71980), we have traditionally found that charge inflation for brachytherapy sources appears to be higher than the market basket inflation update applicable to prospective payments under the OPPS. Therefore, we found that the estimated payments we calculated for brachytherapy charges adjusted to cost were greater than the estimated prospective payment rates because the hospital market basket grows more slowly than the charges for brachytherapy sources. The commenter did not provide its aggregate payments study in its comment to the CY 2012 OPPS/ASC proposed rule, and we do not know whether the commenter's study took into account factors such as charge inflation. Moreover, the OPPS is a prospective payment system that ensures equitable prospective payment of services across providers, and efficient use of resources, including brachytherapy sources, which since CY 2010 are part of OPPS prospective payment.

Concerning the comment that some providers may have decided to discontinue offering brachytherapy services because the OPPS payment rates for sources were too low, as we have noted in the past (75 FR 71980), there are many reasons why some providers may discontinue services, such as brachytherapy. For example, changes in medical technology or emphasis on different treatment forms for a medical condition can influence whether a set of services are continued. In addition, providers accept payment from a number of payers in addition to Medicare, and we believe a global shift by a provider to discontinue any services would be influenced by factors other than our payment rates alone.

Comment: One commenter supported the proposed payment policy for new brachytherapy sources for which we have no claims data, namely, to assign new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates based on CMS' consideration of external data and other relevant information regarding the expected costs of the sources to hospitals.

Response: We appreciate the commenter's support for this payment policy.

After consideration of the public comments we received, we are finalizing our proposal to pay for brachytherapy sources at prospective payment rates based on their source-specific median costs for CY 2012. We refer readers to Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site) for the final CY 2012 payment rates for brachytherapy sources, identified with status indicator ''U.'' We also are finalizing our proposals to continue our policies regarding payment for NOS codes for stranded and non-stranded sources and new brachytherapy sources for which we have no claims data. Specifically, we are finalizing our proposals to continue payment for stranded and non-stranded NOS codes, HCPCS codes C2698 and C2699, at a rate equal to the lowest stranded or non-stranded prospective payment for such sources, respectively as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66786); and our proposal to assign HCPCS codes for new brachytherapy sources to their own APCs, with proposed payment rates based on consideration of external data and other

relevant information, in the absence of claims data. Once claims data are available, our standard ratemaking process will be applied to the calculation of the median cost for the new brachytherapy source.

Consistent with our policy regarding APC payments made on a prospective basis, we are finalizing our proposal to subject the cost of brachytherapy sources to the outlier provision of section 1833(t)(5) of the Act, and also to subject brachytherapy source payment weights to scaling for purposes of budget neutrality.

As stated in the proposed rule (76 FR 42197), we continue to invite hospitals and other parties to submit recommendations to us for new HCPCS codes to describe new brachytherapy sources consisting of a radioactive isotope, including a detailed rationale to support recommended new sources. Such recommendations should be directed to the Division of Outpatient Care, Mail Stop C4–05–17, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244. We will continue to add new brachytherapy source codes and descriptors to our systems for payment on a quarterly basis.

e. Calculation of Composite APC Criteria-Based Median Costs

As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66613), we believe it is important that the OPPS enhance incentives for hospitals to provide only necessary, high quality care and to provide that care as efficiently as possible. For CY 2008, we developed composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. Combining payment for multiple independent services into a single OPPS payment in this way enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves. An additional advantage to the composite APC model is that we can use data from correctly coded multiple procedure claims to calculate payment rates for the specified combinations of services, rather than relying upon single procedure claims which may be low in volume and/or incorrectly coded. Under the OPPS, we currently have composite APC policies for extended assessment and management services, low dose rate (LDR) prostate brachytherapy, cardiac electrophysiologic evaluation and ablation services, mental health services, and multiple imaging services. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for a full discussion of the development of the composite APC methodology (72 FR 66611 through 66614 and 66650 through 66652).

In the CY 2012 OPPS/ASC proposed rule (76 FR 42197), for CY 2012, we proposed to continue, with some modifications, our established composite APC policies for extended assessment and management, LDR prostate brachytherapy, cardiac electrophysiologic evaluation and ablation, mental health services, and multiple imaging services, as discussed in sections II.A.2.e.(1), II.A.2.e.(2), II.A.2.e.(3), II.A.2.e.(4), and II.A.2.e.(5), respectively, of the proposed rule. We also proposed to create a new composite APC for cardiac resynchronization therapy services, as discussed in section II.A.2.e.(6) of the proposed rule.

After consideration of the public comments we received as discussed below, for CY 2012, we are finalizing, without modification, our proposal to modify some aspects of our established composite APC policies for extended assessment and management, LDR prostate brachytherapy, cardiac electrophysiologic evaluation and ablation, mental health services, and multiple imaging services, as discussed in sections II.A.2.e.(1), II.A.2.e.(2), II.A.2.e.(3), II.A.2.e.(4), and II.A.2.e.(5), respectively, of this final rule with comment period. We also are finalizing, with modification, our proposal to create a new composite APC for cardiac resynchronization therapy services, as discussed in section II.A.2.e.(6) of this final rule with comment period.

(1) Extended Assessment and Management Composite APCs (APCs 8002 and 8003)

In the CY 2012 OPPS/ASC proposed rule (76 FR 42197 through 42198), for CY 2012, we proposed to continue to include composite APC 8002 (Level I Extended Assessment and Management Composite) and composite APC 8003 (Level II Extended Assessment and Management Composite) in the OPPS for CY 2012. For CY 2008, we created these two composite APCs to provide payment to hospitals in certain circumstances when extended assessment and management of a patient occur (an extended visit). In most circumstances, observation services are supportive and ancillary to the other services provided to a patient. In the circumstances when observation care is provided in conjunction with a high level visit or direct referral and is an integral part of a patient's extended encounter of care, payment is made for the entire care encounter through one of two composite APCs as appropriate.

As defined for the CY 2008 OPPS, composite APC 8002 describes an encounter for care provided to a patient that includes a high level (Level 5) clinic visit or direct referral for observation services in conjunction with observation services of substantial duration (72 FR 66648 through 66649). Composite APC 8003 describes an encounter for care provided to a patient that includes a high level (Level 4 or 5) Type A emergency department visit, a high level (Level 5) Type B emergency department visit, or critical care services in conjunction with observation services of substantial duration. HCPCS code G0378 (Observation services, per hour) is assigned status indicator ''N,'' signifying that its payment is always packaged. As noted in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66648 through 66649), the Integrated Outpatient Code Editor (I/OCE) evaluates every claim received to determine if payment through a composite APC is appropriate. If payment through a composite APC is inappropriate, the I/OCE, in conjunction with the OPPS Pricer, determines the appropriate status indicator, APC, and payment for every code on a claim. The specific criteria that must be met for the two extended assessment and management composite APCs to be paid are provided below in the description of the claims that were selected for the calculation of the proposed CY 2012 median costs for these composite APCs. We did not propose to change these criteria for the CY 2012 OPPS.

When we created composite APCs 8002 and 8003 for CY 2008, we retained as general reporting requirements for all observation services those criteria related to physician order and evaluation, documentation, and observation beginning and ending time as listed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66812). These are more general requirements that encourage hospitals to provide medically reasonable and necessary care and help to ensure the proper reporting of observation services on correctly coded hospital claims that reflect the full charges associated with all hospital resources utilized to provide the reported services. We also issued guidance clarifying the correct method for reporting the starting time for observation services (sections 290.2.2 through 290.5 in the Medicare Claims Processing Manual (Pub. 100–4), Chapter 4, through Transmittal 1745, Change Request 6492, issued May 22, 2009 and implemented July 6, 2009).

We did not propose to change these reporting requirements for the CY 2012 OPPS.

For CY 2012, we proposed to continue the extended assessment and management composite APC payment methodology for APCs 8002 and 8003 (76 FR 42198). We stated that we continue to believe that the composite APCs 8002 and 8003 and related policies provide the most appropriate means of paying for these services. We proposed to calculate the median costs for APCs 8002 and 8003 using all single and ''pseudo'' single procedure claims for CY 2010 that meet the criteria for payment of each composite APC.

Specifically, to calculate the proposed median costs for composite APCs 8002 and 8003, we selected single and ''pseudo'' single procedure claims that met each of the following criteria:

1. Did not contain a HCPCS code to which we have assigned status indicator ''T'' that is reported with a date of service 1 day earlier than the date of service associated with HCPCS code G0378. (By selecting these claims from single and ''pseudo'' single claims, we already assure that they would not contain a code for a service with status indicator ''T'' on the same date of service.);

2. Contained eight or more units of HCPCS code G0378; and

3. Contained one of the following codes:

• In the case of composite APC 8002, HCPCS code G0379 (Direct referral of patient for hospital observation care) on the same date of service as HCPCS code G0378; or CPT code 99205 (Office or other outpatient visit for the evaluation and management of a new patient (Level 5)); or CPT code 99215 (Office or other outpatient visit for the evaluation and management of an established patient (Level 5)) provided on the same date of service or one day before the date of service for HCPCS code G0378.

• In the case of composite APC 8003, CPT code 99284 (Emergency department visit for the evaluation and management of a patient (Level 4)); CPT code 99285 (Emergency department visit for the evaluation and management of a patient (Level 5)); CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes); or HCPCS code G0384 (Level 5 hospital emergency department visit provided in a Type B emergency department) provided on the same date of service or one day before the date of service for HCPCS code G0378. (As discussed in detail in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68684), we added HCPCS code G0384 to the eligibility criteria for composite APC 8003 for CY 2009.)

As discussed further in section VII. of the proposed rule and this final rule with comment period, and consistent with our CY 2008, CY 2009, CY 2010, and CY 2011 final policies (as discussed in section IX. of the final rules with comment period for these calendar years), when calculating the median costs for the clinic, Type A emergency department visit, Type B emergency department visit, and critical care APCs (0604 through 0617 and 0626 through 0630), we utilize our methodology that excludes those claims for visits that are eligible for payment through the two extended assessment and management composite APCs, that is APC 8002 or APC 8003. We believe that this approach results in the most accurate cost estimates for APCs 0604 through 0617 and 0626 through 0630 for CY 2012.

At its February 28–March 1, 2011 meeting, the APC Panel recommended that CMS consider expanding the extended assessment and management composite APCs for CY 2012. In the proposed rule, we indicated that we are accepting this recommendation.

As discussed in the CY 2012 OPPS/ASC proposed rule (76 FR 42198), consistent with our decision to accept the APC Panel's recommendation, we have examined various ways of potentially expanding the current extended assessment and management composite APCs to further limit the possibility that total beneficiary copayments would exceed the inpatient deductible during extended observation encounters. We did not propose for CY 2012 the expanded extended assessment and management composite APCs that we analyzed because, while the composites that we modeled would serve to further limit the number of beneficiaries with copayments that exceeded the inpatient deductible, the modeled composites also had the effect of possibly increasing copayments by a small amount for the majority of beneficiaries undergoing extended observation. In addition, expanded assessment and management composite APCs do not address certain concerns about extended observation services raised by stakeholders at CMS' observation listening session last year (that is, observation time not counting towards the 3-day prior hospitalization requirement for the skilled nursing facility benefit). As we stated in the proposed rule, we will continue our efforts to model other composite structures for a possible new extended assessment and management composite structure for CY 2013.

In summary, for CY 2012, we proposed to continue to include composite APCs 8002 and 8003 in the OPPS. We proposed to continue the extended assessment and management composite APC payment methodology and criteria that we finalized for CYs 2009, 2010, and 2011. We also proposed to calculate the median costs for APCs 8002 and 8003 using the same methodology that we used to calculate the medians for composite APCs 8002 and 8003 for the CY 2008 OPPS (72 FR 66649). That is, we used all single and ''pseudo'' single procedure claims from CY 2010 that met the criteria for payment of each composite APC and applied the standard packaging and trimming rules to the claims before calculating the proposed CY 2012 median costs. The proposed CY 2012 median cost resulting from this methodology for composite APC 8002 was approximately $395, which was calculated from 16,770 single and ''pseudo'' single bills that met the required criteria. The proposed CY 2012 median cost for composite APC 8003 was approximately $735, which was calculated from 225,874 single and ''pseudo'' single bills that met the required criteria.

Comment: Commenters supported CMS' policy to package payment for observation care and to not provide additional payment through an extended assessment and management composite APC payment when observation services are billed with significant surgical procedures. One commenter stated that the observation services in such cases are most likely related to post-procedural recovery, and thus no additional payment is warranted. The commenter argued, however, that when observation services are billed along with minor surgical procedures, the observation services should be paid separately. The commenter suggested that CMS utilize the MPFS definition of minor surgical procedures and reassign the codes currently assigned status indicator ''T'' to two newly created status indicators ''T1''(for general surgical procedures) and ''T2'' (for minor surgical procedure as defined in MPFS) in order to allow observation services to be paid separately when provided with a minor surgical procedure with the suggested status indicator ''T2.''

Response: We appreciate the commenters' support of our policy not to allow payment of APC 8002 or 8003 for claims that include a HCPCS code to which we have assigned status indicator ''T'' that is reported with a date of service on the same day as or one day prior to the date of the service

associated with HCPCS code G0378. We agree with the commenters that payment for such services is included in the payment for the surgical procedure. We appreciate the commenter's suggestions to define minor surgical procedures and to develop new status indicators to allow for separate payment for observation services when billed with a minor surgical procedure and will take these suggestions into consideration for possible future rulemaking. At this time, we have not proposed to make any policy changes to allow for separate payment for observation services when billed with a minor surgical procedure, nor have we proposed to create new status indicators for CY 2012. Therefore, we are not making any such changes in this final rule with comment period.

After consideration of the public comments we received, we are adopting as final, without modification, our CY 2012 proposal to continue to include composite APCs 8002 and 8003 in the OPPS and to continue the extended assessment and management composite APC payment methodology and criteria that we finalized for CYs 2009 through 2011. We applied the standard packaging and trimming rules to the claims and calculated the median costs for APCs 8002 and 8003 using all single and ''psuedo'' single procedure claims from CY 2010 that meet the criteria for payment of each composite APC. The final CY 2012 median cost resulting from this methodology for APC 8002 is approximately $393, which was calculated from 18,447 single and ''psuedo'' single bills that met the required criteria. The final CY 2012 median cost for composite APC 8003 is approximately $721, which was calculated from 247,334 single and ''psuedo'' single bills that met the required criteria.

(2) Low Dose Rate (LDR) Prostate Brachytherapy Composite APC (APC 8001)

LDR prostate brachytherapy is a treatment for prostate cancer in which hollow needles or catheters are inserted into the prostate, followed by permanent implantation of radioactive sources into the prostate through the needles/catheters. At least two CPT codes are used to report the composite treatment service because there are separate codes that describe placement of the needles/catheters and the application of the brachytherapy sources: CPT code 55875 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) and CPT code 77778 (Interstitial radiation source application; complex). Generally, the component services represented by both codes are provided in the same operative session in the same hospital on the same date of service to the Medicare beneficiary being treated with LDR brachytherapy for prostate cancer. As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66653), OPPS payment rates for CPT code 77778, in particular, had fluctuated over the years. We were frequently informed by the public that reliance on single procedure claims to set the median costs for these services resulted in use of mainly incorrectly coded claims for LDR prostate brachytherapy because a correctly coded claim should include, for the same date of service, CPT codes for both needle/catheter placement and application of radiation sources, as well as separately coded imaging and radiation therapy planning services (that is, a multiple procedure claim).

In order to base payment on claims for the most common clinical scenario, and to further our goal of providing payment under the OPPS for a larger bundle of component services provided in a single hospital encounter, beginning in CY 2008, we began providing a single payment for LDR prostate brachytherapy when the composite service, reported as CPT codes 55875 and 77778, is furnished in a single hospital encounter. We based the payment for composite APC 8001 (LDR Prostate Brachytherapy Composite) on the median cost derived from claims for the same date of service that contain both CPT codes 55875 and 77778 and that do not contain other separately paid codes that are not on the bypass list. In uncommon occurrences in which the services are billed individually, hospitals have continued to receive separate payments for the individual services. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66652 through 66655) for a full history of OPPS payment for LDR prostate brachytherapy and a detailed description of how we developed the LDR prostate brachytherapy composite APC.

In the CY 2012 OPPS/ASC proposed rule (76 FR 42199), we proposed to continue paying for LDR prostate brachytherapy services using the composite APC methodology proposed and implemented for CY 2008 through CY 2011. That is, we proposed to use CY 2010 claims on which both CPT codes 55875 and 77778 were billed on the same date of service with no other separately paid procedure codes (other than those on the bypass list) to calculate the payment rate for composite APC 8001. Consistent with our CY 2008 through CY 2011 practice, we proposed not to use the claims that meet these criteria in the calculation of the median costs for APCs 0163 (Level IV Cystourethroscopy and Other Genitourinary Procedures) and 0651 (Complex Interstitial Radiation Source Application), the APCs to which CPT codes 55875 and 77778 are assigned, respectively. We proposed that the median costs for APCs 0163 and 0651 would continue to be calculated using single and ''pseudo'' single procedure claims. We stated that we believe that this composite APC contributes to our goal of creating hospital incentives for efficiency and cost containment, while providing hospitals with the most flexibility to manage their resources. We also continue to believe that data from claims reporting both services required for LDR prostate brachytherapy provide the most accurate median cost upon which to base the composite APC payment rate.

Using a partial year of CY 2010 claims data available for the CY 2012 proposed rule, we were able to use 556 claims that contained both CPT codes 55875 and 77778 to calculate the median cost upon which the proposed CY 2012 payment for composite APC 8001 is based. The proposed median cost for composite APC 8001 for CY 2012 was approximately $3,364. This was an increase compared to the CY 2011 final median cost for this composite APC of approximately $3,195 based on 849 single bill claims from a full year of CY 2009 claims data. The proposed CY 2012 median cost for this composite APC was slightly less than $3,555, the sum of the proposed median costs for APCs 0163 and 0651 ($2,658 + $897), the APCs to which CPT codes 55875 and 77778 map if one service is billed on a claim without the other. We stated that we believe the proposed CY 2012 median cost for composite APC 8001 of approximately $3,364, calculated from claims we believe to be correctly coded, would result in a reasonable and appropriate payment rate for this service in CY 2012.

Comment: One commenter expressed concern with CMS' methodology to use claims for median cost calculation for APC 8001 with both CPT codes 55875 and 77778 on the same date of service and no other separately paid services that are not on the bypass list, which resulted in 556 CY 2012 proposed rule claims. The commenter noted that this is only 12 percent of all CY 2012 proposed rule claims containing CPT codes 55875 and 77778. The commenter stated that its analysis of commonly included procedure codes with LDR procedures would include CPT code

77332 (Treatment devices, design and construction; simple (simple block, simple bolus)), which the commenter recommended be added to the bypass list. This would add 406 claims to the median cost calculation based on the commenter's analysis of CY 2012 proposed rule claims.

Response: We disagree with the commenter that 556 claims is not a robust number of single claims for ratesetting purposes. There are many services for which we have median costs based on hundreds of single and ''pseudo'' single claims. Moreover, the CY 2012 proposed rule median cost of approximately $3,364, the CY 2012 final median cost of approximately $3,340, and the CY 2011 final median cost of approximately $3,195 all compare favorably and show stability in the median cost calculation for APC 8001. We do not believe the median cost would remain stable to such a degree if the claims used in ratesetting for composite APC 8001 were inadequate or inaccurately reflected hospitals' costs for providing the service described by CPT codes 55875 and 77778. We also do not believe it is appropriate to include CPT code 77332 on the bypass list for the reasons discussed in section II.A.1.b. of this final rule with comment period.

Comment: One commenter requested that CMS implement the proposed CY 2012 payment rate for composite APC 8001, due to the increased median cost for APC 8001.

Response: We appreciate the commenter's support for our proposed payment rate for composite APC 8001. We note that we base final OPPS rates on median costs calculated using a full year of hospital claims and cost report data rather than a partial year's data, which were the data available for the proposed rule.

After consideration of the public comments we received, we are finalizing, without modification, our proposal to continue paying for LDR prostate brachytherapy services using the composite APC methodology implemented for CYs 2008, 2009, 2010, and 2011 described above in this section. The final CY 2012 median cost for composite APC 8001 is approximately $3,340, calculated from 595 single bills.

(3) Cardiac Electrophysiologic Evaluation and Ablation Composite APC (APC 8000)

Cardiac electrophysiologic evaluation and ablation services frequently are performed in varying combinations with one another during a single episode of care in the hospital outpatient setting. Therefore, correctly coded claims for these services often include multiple codes for component services that are reported with different CPT codes and that, prior to CY 2008, were always paid separately through different APCs (specifically, APC 0085 (Level II Electrophysiologic Evaluation), APC 0086 (Ablate Heart Dysrhythm Focus), and APC 0087 (Cardiac Electrophysiologic Recording/Mapping)). As a result, there would never be many single bills for cardiac electrophysiologic evaluation and ablation services, and those that are reported as single bills would often represent atypical cases or incorrectly coded claims. As described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66655 through 66659), the APC Panel and the public expressed persistent concerns regarding the limited and reportedly unrepresentative single bills available for use in calculating the median costs for these services according to our standard OPPS methodology.

Effective January 1, 2008, we established APC 8000 (Cardiac Electrophysiologic Evaluation and Ablation Composite) to pay for a composite service made up of at least one specified electrophysiologic evaluation service and one specified electrophysiologic ablation service. Calculating a composite APC for these services allowed us to utilize many more claims than were available to establish the individual APC median costs for these services, and we also saw this composite APC as an opportunity to advance our stated goal of promoting hospital efficiency through larger payment bundles. In order to calculate the median cost upon which the payment rate for composite APC 8000 is based, we used multiple procedure claims that contained at least one CPT code from group A for evaluation services and at least one CPT code from group B for ablation services reported on the same date of service on an individual claim. Table 9 in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66656) identified the CPT codes that are assigned to groups A and B. For a full discussion of how we identified the group A and group B procedures and established the payment rate for the cardiac electrophysiologic evaluation and ablation composite APC, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66655 through 66659). Where a service in group A is furnished on a date of service that is different from the date of service for a code in group B for the same beneficiary, payments are made under the appropriate single procedure APCs and the composite APC does not apply.

In the CY 2012 OPPS/ASC proposed rule (76 FR 42200), we proposed to continue to pay for cardiac electrophysiologic evaluation and ablation services using the composite APC methodology proposed and implemented for CY 2008 through CY 2011. Consistent with our CY 2008 through CY 2011 practice, we proposed not to use the claims that meet the composite payment criteria in the calculation of the median costs for APC 0085 and APC 0086, to which the CPT codes in both groups A and B for composite APC 8000 are otherwise assigned. Median costs for APCs 0085 and 0086 would continue to be calculated using single procedure claims. We stated that we continue to believe that the composite APC methodology for cardiac electrophysiologic evaluation and ablation services is the most efficient and effective way to use the claims data for the majority of these services and best represents the hospital resources associated with performing the common combinations of these services that are clinically typical. Furthermore, this approach creates incentives for efficiency by providing a single payment for a larger bundle of major procedures when they are performed together, in contrast to continued separate payment for each of the individual procedures.

For CY 2012, using a partial year of CY 2010 claims data available for the proposed rule, we were able to use 11,156 claims containing a combination of group A and group B codes and calculated a proposed median cost of approximately $11,598 for composite APC 8000. This was an increase compared to the CY 2011 final median cost for this composite APC of approximately $10,673 based on a full year of CY 2009 claims data. We stated in the CY 2012 OPPS/ASC proposed rule (76 FR 42200) that we believe the proposed median cost of $11,598 calculated from a high volume of correctly coded multiple procedure claims would result in an accurate and appropriate proposed payment for cardiac electrophysiologic evaluation and ablation services when at least one evaluation service is furnished during the same clinical encounter as at least one ablation service.

Comment: One commenter supported CMS' proposal to continue its current composite methodology for cardiac electrophysiologic evaluation and ablation services, stating that it is the most efficient and effective method to use claims data for most of the cardiac

electrophysiologic services, and best represents the resources associated with the combined services.

Response: We appreciate the commenter's support.

We are finalizing our proposal for CY 2012, without modification, to continue to pay for cardiac electrophysiologic evaluation and ablation services using the composite APC methodology implemented for CY 2008 through CY 2011. For this final rule with comment period, we were able to use 11,706 claims from CY 2010 containing a combination of group A and group B codes and calculated a final CY 2012 median cost of approximately $11,313 for composite APC 8000. Table 7 below list the groups of procedures upon which we based composite APC 8000 for CY 2012.

TABLE 7.—GROUPS OF CARDIAC ELECTROPHYSIOLOGIC EVALUATION AND ABLATION PROCEDURES UPON WHICH COMPOSITE APC 8000 IS BASED

Codes Used in Combinations: At Least One in Group A and One in Group B	CY 2012 CPT Code	Single Code CY 2012 APC	CY 2012 SI (Composite)
Group A			
Comprehensive electrophysiologic evaluation with right atrial pacing and recording, right ventricular pacing and recording, His bundle recording, including insertion and repositioning of multiple electrode catheters, without induction or attempted induction of arrhythmia	93619	0085	Q3
Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia; with right atrial pacing and recording, right ventricular pacing and recording, His bundle recording	93620	0085	Q3
Group B			
Intracardiac catheter ablation of atrioventricular node function, atrioventricular conduction for creation of complete heart block, with or without temporary pacemaker placement	93650	0085	Q3
Intracardiac catheter ablation of arrhythmogenic focus; for treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathways, accessory atrioventricular connections or other atrial foci, singly or in combination	93651	0086	Q3
Intracardiac catheter ablation of arrhythmogenic focus; for treatment of ventricular tachycardia	93652	0086	Q3

(4) Mental Health Services Composite APC (APC 0034)

In the CY 2012 OPPS/ASC proposed rule (76 FR 42200 through 42201), for CY 2012, we proposed to continue our longstanding policy of limiting the aggregate payment for specified less resource-intensive mental health services furnished on the same date to the payment for a day of partial hospitalization, which we consider to be the most resource-intensive of all outpatient mental health treatment for CY 2012. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18452 through 18455) for the initial discussion of this longstanding policy. We stated that we continue to believe that the costs associated with administering a partial hospitalization program represent the most resource-intensive of all outpatient mental health treatment. Therefore, we did not believe that we should pay more for a day of individual mental health services under the OPPS than the partial hospitalization per diem payment.

As discussed in detail in section VIII. of the proposed rule, for CY 2012, we proposed to continue using a provider-specific two tiered payment approach for partial hospitalization services that distinguishes payment made for services furnished in a CMHC from payment made for services furnished in a hospital. Specifically, we proposed one APC for partial hospitalization program days with three services furnished in a CMHC (APC 0172 (Level I Partial Hospitalization (3 services) for CMHCs)) and one APC for days with four or more services furnished in a CMHC (APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs)). We proposed that the payment rates for these two APCs be based upon the median per diem costs calculated using data only from CMHCs. Similarly, we proposed one APC for partial hospitalization program days with three services furnished in a hospital (APC 0175, Level I Partial Hospitalization (3 services) for Hospital-Based PHPs), and one APC for days with four or more services furnished in a hospital (APC 0176, Level II Partial Hospitalization (4 or more services) for Hospital-Based PHPs). We proposed that the payment rates for these two APCs be based on the median per diem costs calculated using data only from hospitals.

Because our longstanding policy of limiting the aggregate payment for specified less resource-intensive mental health services furnished on the same date to the payment rate for the most resource-intensive of all outpatient mental health treatment, for CY 2012, we proposed to continue to set the payment rate for APC 0034 (Mental Health Services Composite) at the same rate as we proposed for APC 0176, which is the maximum partial hospitalization per diem payment. As we stated in the CY 2012 OPPS/ASC proposed rule (76 FR 42201), we believe this APC payment rate would provide the most appropriate payment for composite APC 0034, taking into consideration the intensity of the mental health services and the differences in the HCPCS codes for mental health services that could be paid through this composite APC compared with the HCPCS codes that could be paid through partial hospitalization APC 0176. When the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on one date of service based on the payment rates associated with the APCs for the individual services exceeds the maximum per diem partial hospitalization payment, we proposed that those specified mental health services would be assigned to APC 0034. We proposed that APC 0034 would have the same payment rate as APC 0176 and that the hospital would continue to be paid one unit of APC 0034. The I/OCE currently determines whether to pay these specified mental health services individually or to make a single payment at the same rate as the APC 0176 per diem rate for partial hospitalization for all of the specified mental health services furnished by the hospital on that single date of service, and we proposed for CY 2012 that it would continue to determine this.

We did not receive any comments on this proposal. We continue to believe that the costs associated with administering a partial hospitalization program represent the most resource intensive of all outpatient mental health treatment, and we do not believe that CMS should pay more for a day of individual mental health services under the OPPS than the partial hospitalization per diem payment. Therefore, we are finalizing our CY 2012 proposal, without modification, to limit the aggregate payment for specified less intensive outpatient mental health services furnished on the same date by a hospital to the payment for a day of partial hospitalization, specifically APC 0176.

(5) Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)

Prior to CY 2009, hospitals received a full APC payment for each imaging service on a claim, regardless of how many procedures were performed during a single session using the same imaging modality. Based on extensive data analysis, we determined that this practice neither reflected nor promoted the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session (73 FR 41448 through 41450). As a result of our data analysis, and in response to ongoing recommendations from MedPAC to improve payment accuracy for imaging services under the OPPS, we expanded the composite APC model developed in CY 2008 to multiple imaging services. Effective January 1, 2009, we provide a single payment each time a hospital bills more than one imaging procedure within an imaging family on the same date of service. We utilize three imaging families based on imaging modality for purposes of this methodology: (1) Ultrasound; (2) computed tomography (CT) and computed tomographic angiography (CTA); and (3) magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA). The HCPCS codes subject to the multiple imaging composite policy and their respective families are listed in Table 13 of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71859 through 71860).

While there are three imaging families, there are five multiple imaging composite APCs due to the statutory requirement at section 1833(t)(2)(G) of the Act that we differentiate payment for OPPS imaging services provided with and without contrast. While the ultrasound procedures included in the policy do not involve contrast, both CT/CTA and MRI/MRA scans can be provided either with or without contrast. The five multiple imaging composite APCs established in CY 2009 are:

- APC 8004 (Ultrasound Composite);
- APC 8005 (CT and CTA without Contrast Composite);
- APC 8006 (CT and CTA with Contrast Composite);
- APC 8007 (MRI and MRA without Contrast Composite); and
- APC 8008 (MRI and MRA with Contrast Composite).

We define the single imaging session for the ''with contrast'' composite APCs as having at least one or more imaging procedures from the same family performed with contrast on the same date of service. For example, if the hospital performs an MRI without contrast during the same session as at least one other MRI with contrast, the hospital will receive payment for APC 8008, the ''with contrast'' composite APC.

Hospitals continue to use the same HCPCS codes to report imaging procedures, and the I/OCE determines when combinations of imaging procedures qualify for composite APC payment or map to standard (sole service) APCs for payment. We make a single payment for those imaging procedures that qualify for composite APC payment, as well as any packaged services furnished on the same date of service. The standard (noncomposite) APC assignments continue to apply for single imaging procedures and multiple imaging procedures performed across families. For a full discussion of the development of the multiple imaging composite APC methodology, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68559 through 68569).

At its February 2010 meeting, the APC Panel recommended that CMS continue providing analysis on an ongoing basis of the impact on beneficiaries of the multiple imaging composite APCs as data become available. In the CY 2011 OPPS/ASC proposed rule, we indicated that we were accepting this recommendation and would provide the requested analysis to the APC Panel at a future meeting (75 FR 46212). As we discuss in the CY 2012 OPPS/ASC proposed rule, at the February 28–March 1, 2011 APC Panel meeting, CMS staff provided an updated analysis of the multiple imaging composite APCs to the Panel, comparing partial year CY 2010 imaging composite cost and utilization data to comparable CY 2009 data in order to meet the APC Panel request that we provide analysis of the impact on beneficiaries of the multiple imaging composite APCs (76 FR 42201).

In the CY 2012 OPPS/ASC proposed rule (76 FR 42201), for CY 2012, we proposed to continue paying for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite payment methodology. The proposed CY 2012 payment rates for the five multiple imaging composite APCs (APC 8004, APC 8005, APC 8006, APC 8007, and APC 8008) were based on median costs calculated from a partial year of CY 2010 claims available for the CY 2012 OPPS/ASC proposed rule that qualified for composite payment under the current policy (that is, those claims with more than one procedure within the same family on a single date of service). To calculate the proposed median costs, we used the same methodology that we used to calculate the final CY 2011 median costs for these composite APCs. That is, we removed any HCPCS codes in the OPPS imaging families that overlapped with codes on our bypass list (''overlap bypass codes'') to avoid splitting claims with multiple units or multiple occurrences of codes in an OPPS imaging family into new ''pseudo'' single claims. The imaging HCPCS codes that we removed from the bypass list for purposes of calculating the proposed multiple imaging composite APC median costs appear in Table 9 of the CY 2012 OPPS/ASC proposed rule. (We noted that, consistent with our proposal in section II.A.1.b. of the CY 2012 proposed rule to add CPT code 71550 (Magnetic resonance (eg, proton) imaging, chest (eg, for evaluation of hilar and mediastinal lymphadenopathy); without contrast material(s)) to the list of bypass codes for CY 2012, we also proposed to add CPT code 71550 to the list of proposed OPPS imaging family services overlapping with HCPCS codes on the proposed CY 2012 bypass list (76 FR 42201 through 42202). We integrated the identification of imaging composite ''single session'' claims, that is, claims with multiple imaging procedures within the same family on the same date of service, into the creation of ''pseudo'' single procedure claims to ensure that claims were split in the ''pseudo'' single process into accurate reflections of either a composite ''single session'' imaging service or a standard sole imaging service resource cost. Like all single bills, the new composite ''single session'' claims were for the same date of service and contained no other separately paid services in order to isolate the session imaging costs. Our last step after processing all claims through the ''pseudo'' single process was to reassess the remaining multiple procedure claims using the full bypass list and bypass process in order to determine if we could make other ''pseudo'' single bills. That is, we assessed whether a single separately paid service remained on the claim after removing line-items for the ''overlap bypass codes.''

As discussed in detail in section III.D.2. of the CY 2012 OPPS/ASC proposed rule, we proposed to establish two APCs to which we would propose to assign the codes created for CY 2011 by the AMA's CPT Editorial Board for combined abdominal and pelvis CT services (76 FR 42235). Specifically, we proposed to create new APC 0331 (Combined Abdominal and Pelvis CT Without Contrast), to which we proposed to assign CPT code 74176 (Computed tomography, abdomen and pelvis; without contrast material); and we proposed to create new APC 0334 (Combined Abdominal and Pelvis CT With Contrast), to which we proposed to assign CPT codes 74177 (Computed tomography, abdomen and pelvis; with contrast material(s)) and 74178 (Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by contrast material(s) and further sections in one or both body regions) for the CY 2012 OPPS. As noted and listed in section III.D.2. of the proposed rule, we selected claims of predecessor codes of new CPT codes 74176, 74177, and 74178 to calculate the costs of proposed new APCs 0331 and 0334, respectively (76 FR 42235). Therefore, we proposed not to use those claims listed in Table 21 in section III.D.2. of the proposed rule in calculating the costs of APCs 8005 and 8006.

We were able to identify 1 million ''single session'' claims out of an estimated 2 million potential composite cases from our ratesetting claims data, or approximately half of all eligible claims, to calculate the proposed CY 2012 median costs for the multiple imaging composite APCs. We listed in Table 8 of the proposed rule the HCPCS codes that would be subject to the proposed multiple imaging composite policy, the approximate proposed median costs for the imaging composite APCs, and their respective families for CY 2012. The HCPCS codes listed in Table 8 were assigned status indicator ''Q3''' in Addendum B to the proposed rule (which is available via the Internet on the CMS Web site) to identify their status as potentially payable through a composite APC. Their proposed composite APC assignment was identified in Addendum M to the proposed rule (which is available via the Internet on the CMS Web site). Table 9 of the proposed rule listed the OPPS imaging family services that overlap with HCPCS codes on the proposed CY 2012 bypass list.

Comment: Some commenters requested that CMS provide separate APC payment when multiple imaging services are provided on the same date of service but at different times, because, according to the commenters, services at different times require additional resources than services performed together. The commenters indicated that hospitals providing emergent services are more likely than other hospitals to provide multiple imaging services, some of which are provided in the same day but at different times. The commenters stated that when imaging services are not provided at the same encounter, the same economies of scale are not realized as when imaging services are provided together. For example, cases in which it

is necessary to perform CT scans of the chest, abdomen, and pelvis, and also a CT scan of the brain and/or soft tissues of the neck, must be split into two separate encounters separated by a period of time, due to required repositioning of the patient, and safety requirements. One commenter requested that hospitals report a modifier or condition code to report situations in which multiple imaging services are provided on the same date but at different times, in order to afford additional payment in those circumstances. The commenter further opined that the fact that CMS allows separate payment for multiple E/M services on the same date of service shows that CMS recognizes that resources are expended for each clinic visit, and that this is an identical concept to multiple imaging services on the same date but at differing sessions.

Response: As we stated in the CY 2010 and CY 2011 final rules with comment period (74 FR 60399 and 75 FR 71858 through 71859), we do not agree with the commenters that multiple imaging procedures of the same modality provided on the same date of service but at different times should be exempt from the multiple imaging composite payment methodology. As we indicated in the CY 2009 through CY 2011 OPPS/ASC final rules with comment period (73 FR 68565; 74 FR 60399; 75 FR 71859), we believe that composite payment is appropriate even when procedures are provided on the same date of service but at different times because hospitals do not expend the same facility resources each and every time a patient is seen for a distinct imaging service in a separate imaging session. In most cases, we expect that patients in these circumstances would receive imaging procedures at different times during a single prolonged hospital outpatient encounter. The efficiencies that may be gained from providing multiple imaging procedures during a single session are achieved in ways other than merely not having to reposition the patient. Even if the same level of efficiencies could not be gained for multiple imaging procedures performed on the same date of service but at different times, we expect that any higher costs associated with these cases would be reflected in the claims data and cost reports we use to calculate the median costs for the multiple imaging composite APCs and, therefore, in the payment rates for the multiple imaging composite APCs. Therefore, we do not believe it is necessary or appropriate for hospitals to report imaging procedures provided on the same date of service but during different sittings any differently than they would report imaging procedures performed consecutively in one sitting with no time in between the imaging services. In addition, for the above reasons, we do not believe it is necessary to implement a modifier or condition code to distinguish between such cases. We believe that the comparison to our E/M visit policy of providing separate payments to separate clinic visits on the same day is not relevant because, unlike radiology departments, clinics often operate independently from each other in different parts of the hospital with separate staffs providing different services.

Comment: A few commenters, who expressed concern that providers may receive inadequate compensation and a resulting decrease in beneficiary access, stated that CMS should continue to provide analyses to the APC Panel of the impact of its imaging composite APC policy on payment and usage of imaging services. One commenter noted the updated analysis that CMS staff provided at the February 28–March 1, 2011 APC Panel meeting. The commenter appreciated the shared information, and recommended that CMS continue to monitor costs, provide information on the impact of multiple imaging composite APCs, and use the information learned to ensure beneficiary access, as well as to evaluate whether the existing multiple imaging composite APC methodology accurately reflects all costs of proving the services. Other commenters agreed with CMS' decision not to propose any expansion of imaging composite APCs, opining that no expansion of the imaging composite APCs should be considered until robust data on the current policy is available for public review and comment. One commenter expressed concern with CMS' proposal to create two additional multiple imaging composite APCs.

Response: We will continue to monitor the multiple imaging composite APC rate methodology and the cost of providing imaging services. We will report any information to the APC Panel and the public, as appropriate. Any expansion to the multiple imaging composite APCs would be subject to notice and comment rulemaking. We note that we did not propose to create two additional multiple imaging composite APCs for CY 2012 as one commenter indicated.

Comment: Some commenters stated that, while they understood the multiple imaging composite APCs are intended to encourage efficiencies, they were concerned that the methodology employs arbitrary reductions absent data and may adversely affect beneficiary access to those imaging services subject to the policy. Other commenters stated that the efficiencies to be gained from multiple imaging procedures cannot be extrapolated across modalities.

Response: The median costs upon which the payment rates for the multiple imaging composite APCs are based are calculated using CY 2010 claims that qualified for composite payment, including those with only two imaging procedures and those with substantially higher numbers of imaging procedures. Therefore, because the payment rates reflect actual hospitals' actual costs for providing multiple imaging services during a single session, we do not agree with the commenter that the policy employs arbitrary reductions. As we have stated in the past (75 FR 71858 and 74 FR 60400), we do not agree that the composite APC payment rates are insufficient to reflect the current costs of diagnostic imaging procedures when more than two imaging procedures are performed, and we do not believe that, in aggregate, OPPS payment for multiple imaging services will be inadequate so as to limit beneficiary access. We note that the multiple imaging composite APC methodology is applied only when multiple imaging procedures of the same imaging modality are performed during the same session, and is not applied across imaging modalities.

After consideration of the public comments we received, we are adopting our CY 2012 proposal, without modification, to continue paying for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite payment methodology. The CY 2012 payment rates for the five multiple imaging composite APCs (APC 8004, APC 8005, APC 8006, APC 8007, and APC 8008) are based on median costs calculated from the CY 2010 claims that would have qualified for composite payment under the current policy (that is, those claims with more than one procedure within the same family on a single date of service). Using the same ratesetting methodology described in the CY 2012 OPPS/ASC proposed rule (76 FR 42202), we were able to identify approximately 1.1 million ''single session'' claims out of an estimated 2.2 million potential composite cases from our ratesetting claims data, or approximately half of all eligible claims, to calculate the final CY 2012 median costs for the multiple imaging composite APCs.

Table 8 below lists the HCPCS codes that will be subject to the multiple imaging composite policy and their respective families and approximate composite APC median costs for CY 2012. Table 9 below lists the OPPS imaging family services that overlap with HCPCS codes on the CY 2012 bypass list.

BILLING CODE 4120–01–P

TABLE 8.—OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCs

Family 1 – Ultrasound	
CY 2012 APC 8004 (Ultrasound Composite)	**CY 2012 Approximate APC Median Cost = $192**
76604	Us exam, chest
76700	Us exam, abdom, complete
76705	Echo exam of abdomen
76770	Us exam abdo back wall, comp
76775	Us exam abdo back wall, lim
76776	Us exam k transpl w/Doppler
76831	Echo exam, uterus
76856	Us exam, pelvic, complete
76870	Us exam, scrotum
76857	Us exam, pelvic, limited
Family 2 - CT and CTA with and without Contrast	
CY 2012 APC 8005 (CT and CTA without Contrast Composite)*	**CY 2012 Approximate APC Median Cost = $432**
70450	Ct head/brain w/o dye
70480	Ct orbit/ear/fossa w/o dye
70486	Ct maxillofacial w/o dye
70490	Ct soft tissue neck w/o dye
71250	Ct thorax w/o dye
72125	Ct neck spine w/o dye
72128	Ct chest spine w/o dye
72131	Ct lumbar spine w/o dye
72192	Ct pelvis w/o dye
73200	Ct upper extremity w/o dye
73700	Ct lower extremity w/o dye
74150	Ct abdomen w/o dye
74261	Ct colonography, w/o dye
74176	Ct angio abd & pelvis
CY 2012 APC 8006 (CT and CTA with Contrast Composite)	**CY 2012 Approximate APC Median Cost = $722**
70487	Ct maxillofacial w/dye

70460	Ct head/brain w/dye
70470	Ct head/brain w/o & w/dye
70481	Ct orbit/ear/fossa w/dye
70482	Ct orbit/ear/fossa w/o&w/dye
70488	Ct maxillofacial w/o & w/dye
70491	Ct soft tissue neck w/dye
70492	Ct sft tsue nck w/o & w/dye
70496	Ct angiography, head
70498	Ct angiography, neck
71260	Ct thorax w/dye
71270	Ct thorax w/o & w/dye
71275	Ct angiography, chest
72126	Ct neck spine w/dye
72127	Ct neck spine w/o & w/dye
72129	Ct chest spine w/dye
72130	Ct chest spine w/o & w/dye
72132	Ct lumbar spine w/dye
72133	Ct lumbar spine w/o & w/dye
72191	Ct angiograph pelv w/o&w/dye
72193	Ct pelvis w/dye
72194	Ct pelvis w/o & w/dye
73201	Ct upper extremity w/dye
73202	Ct uppr extremity w/o&w/dye
73206	Ct angio upr extrm w/o&w/dye
73701	Ct lower extremity w/dye
73702	Ct lwr extremity w/o&w/dye
73706	Ct angio lwr extr w/o&w/dye
74160	Ct abdomen w/dye
74170	Ct abdomen w/o & w/dye
74175	Ct angio abdom w/o & w/dye
74262	Ct colonography, w/dye
75635	Ct angio abdominal arteries
74177	Ct angio abd&pelv w/contrast
74178	Ct angio abd & pelv 1+ regns
* If a “without contrast” CT or CTA procedure is performed during the same session as a “with contrast” CT or CTA procedure, the I/OCE will assign APC 8006 rather than APC 8005.	

Family 3 - MRI and MRA with and without Contrast	
CY 2012 APC 8007 (MRI and MRA without Contrast Composite)*	**CY 2012 Approximate APC Median Cost = $700**
70336	Magnetic image, jaw joint
70540	Mri orbit/face/neck w/o dye
70544	Mr angiography head w/o dye
70547	Mr angiography neck w/o dye
70551	Mri brain w/o dye
70554	Fmri brain by tech
71550	Mri chest w/o dye
72141	Mri neck spine w/o dye
72146	Mri chest spine w/o dye
72148	Mri lumbar spine w/o dye
72195	Mri pelvis w/o dye
73218	Mri upper extremity w/o dye
73221	Mri joint upr extrem w/o dye
73718	Mri lower extremity w/o dye
73721	Mri jnt of lwr extre w/o dye
74181	Mri abdomen w/o dye
75557	Cardiac mri for morph
75559	Cardiac mri w/stress img
C8901	MRA w/o cont, abd
C8904	MRI w/o cont, breast, uni
C8907	MRI w/o cont, breast, bi
C8910	MRA w/o cont, chest
C8913	MRA w/o cont, lwr ext
C8919	MRA w/o cont, pelvis
C8932	MRA, w/o dye, spinal canal
C8935	MRA, w/o dye, upper extr
CY 2012 APC 8008 (MRI and MRA with Contrast Composite)	**CY 2012 Approximate APC Median Cost = $1,001**
70549	Mr angiograph neck w/o&w/dye
70542	Mri orbit/face/neck w/dye
70543	Mri orbt/fac/nck w/o & w/dye
70545	Mr angiography head w/dye
70546	Mr angiograph head w/o&w/dye

70548	Mr angiography neck w/dye
70552	Mri brain w/dye
70553	Mri brain w/o & w/dye
71551	Mri chest w/dye
71552	Mri chest w/o & w/dye
72142	Mri neck spine w/dye
72147	Mri chest spine w/dye
72149	Mri lumbar spine w/dye
72156	Mri neck spine w/o & w/dye
72157	Mri chest spine w/o & w/dye
72158	Mri lumbar spine w/o & w/dye
72196	Mri pelvis w/dye
72197	Mri pelvis w/o & w/dye
73219	Mri upper extremity w/dye
73220	Mri uppr extremity w/o&w/dye
73222	Mri joint upr extrem w/dye
73223	Mri joint upr extr w/o&w/dye
73719	Mri lower extremity w/dye
73720	Mri lwr extremity w/o&w/dye
73722	Mri joint of lwr extr w/dye
73723	Mri joint lwr extr w/o&w/dye
74182	Mri abdomen w/dye
74183	Mri abdomen w/o & w/dye
75561	Cardiac mri for morph w/dye
75563	Card mri w/stress img & dye
C8900	MRA w/cont, abd
C8902	MRA w/o fol w/cont, abd
C8903	MRI w/cont, breast, uni
C8905	MRI w/o fol w/cont, brst, un
C8906	MRI w/cont, breast, bi
C8908	MRI w/o fol w/cont, breast,
C8909	MRA w/cont, chest
C8911	MRA w/o fol w/cont, chest
C8912	MRA w/cont, lwr ext
C8914	MRA w/o fol w/cont, lwr ext
C8918	MRA w/cont, pelvis
C8920	MRA w/o fol w/cont, pelvis

C8931	MRA, w/dye, spinal canal
C8933	MRA, w/o&w/dye, spinal canal
C8934	MRA, w/dye, upper extremity
C8936	MRA, w/o&w/dye, upper extr
* If a "without contrast" MRI or MRA procedure is performed during the same session as a "with contrast" MRI or MRA procedure, the I/OCE will assign APC 8008 rather than APC 8007.	

TABLE 9.--OPPS IMAGING FAMILY SERVICES OVERLAPPING WITH HCPCS CODES ON THE CY 2012 BYPASS LIST

Family 1 – Ultrasound	
76700	Us exam, abdom, complete
76705	Echo exam of abdomen
76770	Us exam abdo back wall, comp
76775	Us exam abdo back wall, lim
76776	Us exam k transpl w/Doppler
76856	Us exam, pelvic, complete
76870	Us exam, scrotum
76857	Us exam, pelvic, limited
Family 2 - CT and CTA with and without Contrast	
70450	Ct head/brain w/o dye
70480	Ct orbit/ear/fossa w/o dye
70486	Ct maxillofacial w/o dye
70490	Ct soft tissue neck w/o dye
71250	Ct thorax w/o dye
72125	Ct neck spine w/o dye
72128	Ct chest spine w/o dye
72131	Ct lumbar spine w/o dye
72192	Ct pelvis w/o dye
73200	Ct upper extremity w/o dye
73700	Ct lower extremity w/o dye
74150	Ct abdomen w/o dye
Family 3 - MRI and MRA with and without Contrast	
70336	Magnetic image, jaw joint
70544	Mr angiography head w/o dye
70551	Mri brain w/o dye

BILLING CODE 4120–01–C

(6) Cardiac Resynchronization Therapy Composite APC (APCs 0108, 0418, 0655, and 8009)

Cardiac resynchronization therapy (CRT) uses electronic devices to sequentially pace both sides of the heart to improve its output. CRT utilizes a pacing electrode implanted in combination with either a pacemaker or an implantable cardioverter defibrillator (ICD). CRT performed by the implantation of an ICD along with a pacing electrode is referred to as ''CRT–D.'' CRT performed by the implantation of a pacemaker along with a pacing electrode is referred to as ''CRT–P.''

CRT–D services are described by combinations of CPT codes for the insertion of pulse generators and the insertion of the leads associated with ICDs, along with the insertion of the pacing electrode. For the implantation of a pulse generator, hospitals may use CPT code 33240 (Insertion of single or dual chamber pacing cardioverter-defibrillator pulse generator), which is the only CPT code assigned to APC 0107 (Insertion of Cardioverter-Defibrillator) for CY 2011, in combination with CPT code 33225 (Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of pacing cardioverter-defibrillator or pacemaker pulse generator (including upgrade to dual chamber system)), which is assigned to APC 0418 (Insertion of Left Ventricular Pacing Electrode) for CY 2011. For the implantation of a pulse generator and leads, hospitals may use CPT code 33249 (Insertion or repositioning of electrode lead(s) for single or dual chamber pacing cardioverter-defibrillator and insertion of pulse generator), which is the only CPT code assigned to APC 0108 (Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads) for CY 2011, in combination with CPT code 33225.

For CRT–P services, hospitals may use CPT codes 33206 (Insertion or replacement of permanent pacemaker with transvenous electrode(s); atrial) and 33207 (Insertion or replacement of permanent pacemaker with transvenous electrode(s); ventricular), which are assigned to APC 0089 (Insertion/Replacement of Permanent Pacemaker and Electrodes) for CY 2011, in combination with CPT code 33225. Hospitals also may use CPT code 33208 (Insertion or replacement of permanent pacemaker with transvenous electrode(s); atrial and ventricular), for the implantation of a pacemaker with leads, which is assigned to APC 0655 (Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker), in combination with CPT code 33225.

A number of commenters who responded to prior OPPS proposed rules, as well as public presenters to the APC Panel, have recommended that CMS establish new composite APCs for CRT–D services, citing significant fluctuations in the median cost for CPT code 33225 and the payment rate for APC 0418. The commenters and presenters have pointed out that, because the definition of CPT code 33225 specifies that the pacing electrode is inserted at the same time as an ICD or pacemaker, CMS would not have many valid single or pseudo single claims upon which to calculate an accurate median cost. These commenters and presenters also asserted that claims data for these services demonstrate that the percentage of single claims available for use in CRT ratesetting is very low compared to the total number of claims submitted for CRT–D or CRT–P services. The APC Panel at its February and August 2009 meetings recommended that CMS evaluate the implications of the creation of a new composite APC for CRT–D services and recommended that CMS reconsider creating a composite APC or a group of composite APCs for CRT–D and CRT–P services. While we did not propose to create any new composite APCs for CY 2010 or CY 2011, we accepted both of these APC Panel recommendations (75 FR 71852).

As described in the CY 2012 OPPS/ASC proposed rule (76 FR 42203 through 42206), in response to the APC Panel recommendations and the comments we received, we evaluated the implications of creating four composite APCs for CRT services, which would include the ICD and pacemaker insertion procedures listed previously in this section (described by CPT codes 33240, 33249, 33206, 33207, and 33208) performed in combination with the insertion of a pacing electrode (described by CPT code 33225). Table 10 of the proposed rule and Table 10 below outline the four potential composite APCs that we modeled. Specifically, we provide a description of each potential composite APC, the combination of CPT codes that we used to define the potential composite APC, the frequency of claims that met the definition of the potential composite APC that could be used to calculate a median cost for the potential composite APC, and the median cost calculated for the potential composite APC using CY 2010 claims data available for the proposed rule, that is, those claims processed between January 1 and December 31, 2010.

TABLE 10.—POTENTIAL COMPOSITE APCs

Potential Composite APC	Description	Component APCs	CPT Codes	CY 2010 Frequency	CY 2012 Payment Estimate Based on Proposed Rule Claims Data
A	Cardiac Resynchronization Therapy - ICD Pulse Generator and Leads	0418 0107	33225 33240	21	$35,623
B	Cardiac Resynchronization Therapy - ICD Pulse Generator	0418 0108	33225 33249	2,358	$38,854
C	Cardiac Resynchronization Therapy - Pacemaker Pulse Generator, and Leads (Atrial or Ventricular)	0418 0089	33225 33206 33207	84	$17,306
D	Cardiac Resynchronization Therapy - Pacemaker Pulse Generator, and Leads (Atrial and Ventricular)	0418 0655	33225 33208	314	$18,705

For CY 2012, under the authority of section 1833(t)(1)(B) of the Act, we proposed to create a new composite APC 8009 (Cardiac Resynchronization Therapy with Defibrillator Composite), listed as potential composite APC ''B'' in Table 10 above, for CRT–D services. This proposed composite APC was the only modeled composite in the study with significant claims volume, as shown above in Table 10, and would provide a single payment for a procedure currently assigned to APC 0418 together with a procedure currently assigned to APC 0108 (Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads) when performed on the same date of service. Specifically, we proposed to create composite APC 8009, which would be used when the procedures described by CPT code 33225 and CPT code 33249 are performed on the same day, in order to recognize the inherent challenges in calculating accurate median costs for CPT code 33225 based on single procedure claims utilized in the standard OPPS ratesetting methodology, and to address the public commenters' concerns regarding the fluctuations in median costs for APC 0418. We stated that we believe a composite payment methodology is appropriate for these services and would result in more accurate payment for these services because such a methodology is specifically designed to provide payment for two or more procedures when they are provided in the same encounter, thus enabling us to use more claims data to calculate median costs, and to use claims data that more accurately represents the full cost of the services when they are furnished in the same encounter. We also stated that we believe that there is sufficient claims volume for CPT code 33225 and CPT code 33249 provided in the same encounter to warrant creation of the composite APC. In addition, we indicated that we believe the claims volume for CPT 33225 and CPT 33249 is sufficient to demonstrate that these services are commonly performed

together. While the other combinations of CRT procedures listed in Table 10 may also be performed together, we did not propose to implement composite APCs for these services because of the low frequency with which CPT code 33225 was reported in the claims data in combination with other CPT codes that describe the insertion of an ICD and a pacemaker. As we have stated previously (74 FR 60392), because of the complex claims processing and ratesetting logic involved, in the past, we have explored composite APCs only for combinations of services that are commonly performed together. Because of the low frequency of the other combinations of CRT procedures listed in Table 10 above, we did not consider them to be commonly performed together.

Under the authority of section 1833(t)(2)(E) of the Act, we also proposed to cap the payment rate for composite APC 8009 at the most comparable Medicare-severity diagnosis-related group (MS–DRG) payment rate established under the IPPS that would be provided to acute care hospitals for providing CRT–D services to hospital inpatients. Specifically, we proposed a payment rate for APC 8009 as the lesser of the APC 8009 median cost or the IPPS payment rate for MS–DRG 227 (Cardiac Defibrillator Implant without Cardiac Catheterization without Major Complication or Comorbidity), as adopted in the FY 2012 IPPS/LTCH PPS final rule. We stated that we would establish the OPPS payment amount as the FY 2012 IPPS standardized payment amount for MS–DRG 227 under this proposal. In the FY 2012 IPPS/LTCH proposed rule, this amount was $26,364.93. We calculated the standardized payment rate for MS–DRG 227 ($26,364.93) by multiplying the normalized weight from Table 5 of the FY 2012 IPPS/LTCH proposed rule (5.1370) by the sum of the non-labor and labor-related shares of the proposed FY 2012 IPPS operating standardized amount (nonwage-adjusted) ($5,132.36), which were obtained from Table 1B of the FY 2012 IPPS/LTCH proposed rule. For further detail on the calculation of the IPPS proposed FY 2012 payments rates, we refer readers to the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 26028 through 26029).

We stated that we consider the standardized payment rate for MS–DRG 227 to represent appropriate payment for a comparable package of services furnished to outpatients. We also stated that we believe that, because this MS–DRG includes defibrillator implantation for those inpatients without major complications or comorbidities, it represents the payment made for hospital inpatients who are most similar to patients who would receive CRT–D services on an outpatient basis because hospital outpatients are generally less sick than hospital inpatients and because patients who have complications or comorbitities would be most likely to be admitted to inpatient status to receive CRT–D services. Similar to the proposed payment rate for composite APC 8009, the proposed payment rate for MS–DRG 227 included the device costs associated with CRT–D services, along with the service costs associated with CPT codes 33225 and 33249, which are the procedures that are reported for implanting those devices. We stated that we believe that we should not pay more for these services under the proposed OPPS composite APC payment than under the IPPS because the OPPS payment would, by definition, include fewer items and services than the corresponding IPPS MS–DRG payment. For example, the IPPS MS–DRG payment includes payment for drugs and diagnostic tests that would be separately payable under the OPPS. We explained that a payment cap is necessary, therefore, to ensure that we do not create an inappropriate payment incentive to provide CRT–D services in one setting of care as opposed to another by paying more for CRT–D services in the outpatient setting compared to the inpatient setting. We also explained that we believe that limiting payment for CRT–D services under the OPPS to the IPPS MS–DRG payment will ensure appropriate and equitable payment to hospitals because patients who receive these services in the hospital outpatient setting are not as sick as patients who have been admitted to receive this same service in the hospital inpatient setting. Therefore, we expect it would be less costly to provide care for these patients, who would also spend less time in the facility.

In the CY 2012 OPPS/ASC proposed rule (76 FR 42241 through 42242), we also addressed cases when CPT codes 33225 and 33249 are performed on different dates of service. We proposed to retain CPT code 33249 in APC 0108, but to reassign CPT code 33225 to APC 0108 on the basis that these codes are similar in clinical characteristics and median cost. We proposed to revise the title of APC 0108 to read ''Insertion/Replacement/Repair of AICD Leads, Generator, and Pacing Electrodes'' for CY 2012. We also proposed to reassign CPT code 33224 (Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or pacing cardioverter-defibrillator pulse generator (including revision of pocket, removal, insertion, and/or replacement of generator)) from APC 0418 to APC 0655, and to change the title of APC 0655 from ''Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker'' to ''Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing Electrode.'' In the CY 2012 OPPS/ASC proposed rule (76 FR 42205), we stated that we believe that reassigning CPT code 33224 to APC 0655 will promote stability in payment for CPT code 33224 because CPT code 33224 would then be assigned to an APC with similar median costs, but with a higher volume of services and, therefore, will benefit from the stability in APC median costs and payment rates that generally result as the volume of services within an APC increases. Because these proposed actions would result in APC 0418 containing no CPT codes, we proposed to delete APC 0418.

In addition, as with composite APC 8009 and under the authority of section 1833(t)(2)(E) of the Act, we proposed to limit the payment for services assigned to APC 0108 to the IPPS standardized payment amount for MS–DRG 227. In other words, we proposed a payment rate for APC 0108 as the lesser of the APC 0108 median cost or the IPPS standardized payment rate for MS–DRG 227. We stated that we believe that MS–DRG 227 is the most comparable DRG to APC 0108 because, like APC 0108, MS–DRG 227 includes implantation of a defibrillator in patients who do not have medical complications or comorbidities. If we were to base payment for APC 0108 on our calculated median cost of approximately $27,361, it would result in a payment under the CY 2012 OPPS that would exceed our proposed standardized payment under the IPPS for MS–DRG 227 of $26,364.93. We stated that we do not believe that it would be equitable to pay more for the implantation of a cardioverter defibrillator or implantation of a left ventricular pacing electrode for an outpatient encounter, which, by definition, includes fewer items and services than an inpatient stay during which the patient has the same procedure.

In order to ensure that hospitals correctly code for CRT services in the future, we proposed to create claim processing edits that would return claims to providers unless CPT code 33225 is billed in conjunction with one of the following CPT codes, as specified by the AMA in the CPT code book:

• 33206 (Insertion or replacement of permanent pacemaker with transvenous electrode(s); atrial);
• 33207 (Insertion or replacement of permanent pacemaker with transvenous electrode(s); ventricular);
• 33208 (Insertion or replacement of permanent pacemaker with transvenous electrode(s); atrial and ventricular);
• 33212 (Insertion or replacement of pacemaker pulse generator only; single chamber, atrial or ventricular);
• 33213 (Insertion or replacement of pacemaker pulse generator only; dual chamber, atrial or ventricular);
• 33214 (Upgrade of implanted pacemaker system, conversion of single chamber system to dual chamber system (includes removal of previously placed pulse generator, testing of existing lead, insertion of new lead, insertion of new pulse generator));
• 33216 (Insertion of a single transvenous electrode, permanent pacemaker or cardioverter-defibrillator);
• 33217 (Insertion of 2 transvenous electrodes, permanent pacemaker or cardioverter-defibrillator);
• 33222 (Revision or relocation of skin pocket for pacemaker);
• 33233 (Removal of permanent pacemaker pulse generator);
• 33234 (Removal of transvenous pacemaker electrode(s); single lead system, atrial or ventricular);
• 33235 (Removal of transvenous pacemaker electrode(s); dual lead system, atrial or ventricular);
• 33240 (Insertion of single or dual chamber pacing cardioverter-defibrillator pulse generator); or
• 33249 (Insertion or repositioning of electrode lead(s) for single or dual chamber pacing cardioverter-defibrillator and insertion of pulse generator).

In summary, for CY 2012, we proposed to create a composite APC for CRT–D services billed with CPT code 33225 and CPT code 33249 on the same date of service (Composite APC 8009 (Cardiac Resynchronization Therapy—ICD Pulse Generator and Leads)), for which we proposed that payment would be capped at the IPPS payment rate for MS–DRG 227. In other words, we would calculate payment for APC 8009 based on the lesser of the APC 8009 median cost or the IPPS standardized payment for MS–DRG 227. We also proposed to reassign CPT code 33225 to APC 0108 and to continue to assign CPT code 33249 to APC 0108 when they are furnished on different dates of service; to calculate payment for APC 0108 based on the lesser of the APC 0108 median cost or the IPPS standardized payment for MS–DRG 227; and to delete APC 0418. Finally, we proposed to implement claims processing edits that would return to providers incorrectly coded claims on which a pacing electrode insertion (CPT code 33225) is billed without an ICD or pacemaker insertion. The proposed changes would all be made in a budget neutral manner, in the same way that payment for other composite APCs and the reassignment of codes to APCs are budget neutral within the OPPS.

At its August 10–11 meeting, the APC Panel recommended that CMS establish the payment rates for APC 8009 (Cardiac Resynchronization Therapy with Defibrillator, Composite) and APC 0108 (Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads) using only outpatient claims data. We are accepting this recommendation and will use only outpatient claims data to establish the payment rates for ICD and CRT–D implantation procedures, as discussed in greater detail in response to comments below.

Comment: Many commenters supported the creation of a composite APC for CRT–D services, and the restructuring of APC 0108 in order to address the median cost fluctuations in APC 0418. Many commenters objected to the proposal to cap payments for the composite APC 8009 and for APC 0108 at the IPPS payment rate for MS–DRG 227. While some commenters acknowledged that limiting the payment for CRT–D services provided to hospital outpatients makes intuitive sense and applauded CMS for exploring Medicare payment across payment systems rather than limiting policy proposals to within a single payment system, they expressed concern that CMS had not demonstrated that the services included in composite APC 8009 and APC 0108 are the same services included in MS–DRG 227. Many commenters noted that there could be legitimate explanations for the higher hospital outpatient cost estimates for CRT that would support higher hospital outpatient payments, such as the inclusion of less expensive ICD-only cases in the MS–DRG 227 payment bundle and geographic variations in cost for CRT–D devices provided to hospital inpatients and hospital outpatients. They asserted that MS–DRG 227 is an inappropriate comparator because it includes CRT–D implantation procedures, along with less expensive ICD-only cases. Other commenters argued that a payment cap is inappropriate because the proposed payment rate of approximately $26,365 for composite APC 8009 would fail to cover the cost of CRT–D devices used in the procedures described by CPT codes 33225 and 33249 based on CMS' calculation of APC costs associated with devices presented in Table 24 of the CY 2012 OPPS/ASC proposed rule.

The leading manufacturers of CRT devices argued that the payment cap is unnecessary, projecting that average actual payment differences (after accounting for wage index adjustments, indirect medical education (IME) payments, and disproportionate share hospital (DSH) payments) under the CRT–D composite APC (with no payment cap applied) and MS–DRG 227 would be unsubstantial and unlikely to create inappropriate payment incentives, indicating that a significant shift in site of care (from hospital inpatient to hospital outpatient) for implantable defibrillator implants has already been taking place over the past several years despite lower OPPS payment rates. Other commenters urged CMS to postpone the proposal to link IPPS and OPPS payments for CRT services until data from the new cost centers for implantable devices provides more accurate information for median cost development.

Many commenters also stated that the cap as described in the proposed rule is not an accurate reflection of the equivalent IPPS payment for CRT–D services because the operating and capital standardized amounts paid to inpatient hospitals were not included, indicating that, according to the IPPS final rule, the total payment cap should be approximately $29,000. Other commenters added that IME and DSH payments also should be included in the cap calculation. The commenters urged CMS to take these MS–DRG payment adjustments into consideration if an IPPS payment cap were applied to composite APC 8009 and APC 0108.

Response: We appreciate the commenters' suggestions presented in response to our proposal to cap the OPPS payment for CRT–D services at the IPPS payment for MS–DRG 227, and the commenters' support for the creation of a composite APC for CRT–D services. After revisiting this issue, we agree that while MS–DRG 227 includes less expensive ICD-only cases, along with CRT–D system implants, proposed APC 8009 would include only CRT–D cases (and not ICD-only cases), and therefore does not represent a comparable package of services. Therefore, because there are significant differences in these payment bundles, and because we believe a payment cap would only be appropriate for comparable packages of services, we agree with the commenters that a better approach at this time would be to refrain from implementing our CY 2012 proposal to cap the hospital outpatient payment rate for CRT–D services or ICD

implantation procedures based on the IPPS payment rate for MS–DRG 227.

As described in the proposed rule, we continue to believe that we should recognize the inherent challenges in calculating accurate median costs for CPT code 33225 based on single procedure claims utilized in the standard OPPS ratesetting methodology, and that we should address the commenters' past concerns regarding the fluctuations in median costs for the APC to which this service has been assigned. We also continue to believe that it is important to ensure that we do not create an inappropriate payment incentive to provide services in one setting of care as opposed to another, also as stated in the proposal. In light of these goals, and taking into consideration the commenters' observations that the hospital inpatient and outpatient payment bundles for CRT–D services are different, we are modifying our proposal to create composite APC 8009 for CRT–D services. Under this final rule with comment period, we will treat CPT codes 33225 and 33249 as a single, composite service when they are performed on the same day as proposed, but rather than assigning them to composite APC 8009, we are assigning them to existing APC 0108 for CY 2012. We believe that this APC assignment is appropriate because the CRT–D procedure described by the combination of CPT codes 33225 and 33249 is clinically similar to the basic (nonresynchronization) ICD insertion procedure described by CPT code 33249 when it is performed by itself and assigned to APC 0108. Both procedures involve the insertion of one or more electrodes into the heart with subsequent connection to a cardiac pacing and defibrillation device. The difference between CRT–D and ICD insertion is the use of an additional pacing wire, but we note that APC 0108, in general, and CPT code 33249, specifically, already reflect a range of numbers of electrodes. We also note that the CRT–D procedure and the ICD-only procedure have similar final CY 2012 median costs of approximately $38,468 (based on 3,145 single claims) and $26,988 (based on 7,910 single claims), respectively, and that the placement of these procedures in the same APC does not violate the 2 times rule. We also are finalizing our proposal to change the title of APC 0108 to ''Insertion/Replacement/Repair of AICD Leads, Generator, and Pacing Electrodes'' because this APC will provide payment for ICD procedures, including CRT–D services.

In calculating the median costs upon which the payment rate for APC 0108 is based for CY 2012, for this final rule with comment period, we included single procedure claims for the individual services assigned to APC 0108, as well as single procedure claims that contain the composite CRT–D service, defined as the combination of CPT codes 33225 and 33249 with the same date of service. We were able to use 11,055 single bills from the CY 2012 final rule claims data (3,145 composite CRT–D service claims and 7,910 claims for other services assigned to APC 0108) to calculate a median cost of approximately $29,839. We note that under this policy, hospitals will continue to use the same CPT codes to report CRT–D procedures, and the I/OCE will determine when combinations of procedures qualify for composite service payment or map to standard (sole service) APCs for payment. We will make a single payment for those procedures that qualify for composite service payment, as well as any packaged services furnished on the same date of service. Because CPT codes 33225 and 33249 may be treated as a composite service for payment purposes, we are assigning them status indicator ''Q3'' (Codes that may be paid through a composite APC) in Addendum B to this final rule with comment period. The assignment of CPT codes 33225 and 33249 to APC 0108 when treated as a composite service also will be reflected in Addendum M to this final rule with comment period (which is available via the Internet on the CMS Web site).

By continuing to recognize these procedures as a single, composite service, we are able to use a higher volume of correctly coded claims for CPT code 33225 and, therefore, to address the inherent ratesetting challenges associated with CPT code 33225 and stabilize payment for this service. We also note that this policy is consistent with the principles of a prospective payment system, specifically to place similar services that utilize technologies with varying costs in the same APC in order to promote efficiency and decisionmaking based on individual patient's clinical needs rather than financial considerations. By calculating the median cost for APC 0108 using claims from both ICD-only cases and CRT–D cases, we allow the costs of each to influence the overall median cost for the APC, which will rise or fall in the future depending on hospitals' utilization patterns. As indicated earlier, this methodology allows us to accept the APC Panel's recommendation to calculate payment for these services using only hospital outpatient claims data.

Comment: A few commenters questioned CMS' authority under section 1833(t)(2)(E) of the Act to cap the payment rate for an OPPS composite APC at a comparable MS–DRG payment rate established under the IPPS, arguing that they believe this provision of the Act applies only to adjustments made within the OPPS, and does not give CMS authority to make equitable adjustments across payment systems.

Many commenters pointed out that CMS has held strongly to the principle of setting OPPS payment rates based only on hospital outpatient claims and cost report data since the beginning of the OPPS, often refusing stakeholders' requests to use external data or make cross-system payment comparisons as the basis for setting payment rates. The commenters stated that for CMS to cross payment systems and deviate from this longstanding policy would introduce a significant level of uncertainty and unpredictability. Other commenters stated that crossing payment systems for the first time under the OPPS represents a significant departure from the standard OPPS ratesetting methodology, undermines the integrity of the OPPS, discourages hospitals from providing care in the most appropriate setting, and adversely affects investment in new technologies.

Some commenters also argued that CMS should not assume the hospital inpatient cost data for CRT–D services is more valid than hospital outpatient cost data. To the contrary, commenters noted that there are various mechanisms in place for hospital outpatient claims, such as the procedure-to-device edits, to ensure that hospitals report the full costs of devices provided in hospital outpatient departments, while there are no similar mechanisms in place for devices provided in hospital inpatient settings of care. The commenters pointed out that the OPPS and the IPPS have been designed to be internally consistent but not comparable to each other, noting that the methods used to establish relative weights in each system are independent and unrelated.

Commenters also stated that if CMS were to set a precedent for looking across payment systems in this circumstance, then CMS should be consistent and make cross-system payment comparisons for all items and services, such as separately payable drugs and biologicals, which are paid at a lower per drug payment rate when they are provided in hospital outpatient settings compared to physician office settings.

Response: Although we are not finalizing our proposal to institute a payment cap for composite APC 8009 and APC 0108, we believe we have broad authority under the statute to implement a cap on the payment rate for an OPPS APC at a comparable MS–DRG payment rate established under the IPPS. We also disagree that we cannot explore this policy option because it would be unprecedented and involve data other than data obtained from hospital outpatient claims. It is not unprecedented for CMS to use data from one payment system in the calculations for another in specific circumstances. For example, as described in detail in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72033) and in section XIII.C.1.b. of this CY 2012 OPPS/ASC final rule with comment period, we use physician claims data in determining which procedures will be designated as ''office-based'' for the ASC list of covered surgical procedures, and in setting the ASC payment rate, we use the lower of the MPFS nonfacility PE RVU -based amount or the amount calculated using the ASC standard ratesetting methodology for the procedure. Even if the use of such data were unprecedented, we do not believe that we should neglect to pursue innovations and refinements to Medicare payment policy because any such innovations and refinements would be new. We also disagree that a payment policy to create payment parity between the IPPS and OPPS in one clinical area would necessitate the creation of parity across payment systems for all items and services. We note that there could be many different payment approaches that could be chosen for comparison purposes for any given item or service, giving rise to implementation issues. That is, comparisons could be made between the OPPS and the payment methodologies for services furnished in the physician's office setting such as the MPFS for physicians' services or ASP for certain covered Part B drugs, as the commenter suggested, or comparisons could be made between the OPPS and the IPPS or other payment systems, and the ''payment parity'' resulting from those comparisons would be vastly different. For example, while the commenters' suggested approach to achieve payment parity between the hospital outpatient setting and the physician office setting for drugs and biologicals would usually result in higher hospital outpatient payment rates of ASP+ 6 percent, an approach that would achieve payment parity between the hospital outpatient setting and the hospital inpatient setting would result in payment for most drugs and biologicals being packaged into the associated APC procedure payment, because payment for most drugs and biologicals under the IPPS is included in the MS–DRG payment. In addition, immediately applying such a policy across all items and services (rather than incrementally for items and services in one clinical area or a handful of clinical areas through notice-and-comment rulemaking) may result in payment instability as payments would potentially increase and decrease for thousands of services.

We note that we may consider examining the issue of payment parity with respect to other payment systems, even when the data upon which the cost of a service is calculated are from a different source, because such an approach may deter inappropriate migration of services to a setting of care based on financial consideration rather than clinical needs.

Although we are not implementing our proposal to cap payment for CRT–D services in CY 2012, we will continue to explore methods to ensure our payment systems do not provide inappropriate payment incentives to provide services in one setting of care as opposed to another setting of care.

Comment: Some commenters contested the statement in the CY 2012 OPPS/ASC proposed rule that hospital outpatients are generally less sick than hospital inpatients, arguing that not all patients with comorbidities are admitted as inpatients. Several commenters stated that CMS has not provided evidence to support the claim that CRT–D services on an outpatient basis would include fewer items and services than on an inpatient basis.

Response: As indicated previously, we are not implementing our proposal to cap payment for CRT–D services at the IPPS payment rate for MS–DRG 227. We continue to believe, however, that the Medicare beneficiaries who receive a service on an outpatient basis would generally not be expected to be as sick as those who are admitted to the hospital to receive the same service. The Medicare Benefit Policy Manual (100–02), Chapter 1, Section 10 (available on the CMS Web site at: *http://www.cms.gov/manuals/Downloads/bp102c01.pdf*) defines an inpatient as a person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services. As stated in the manual, factors to be considered when making the decision to admit include such things as the severity of the signs and symptoms exhibited by the patient and the medical predictability of something adverse happening to the patient. We believe this supports our statement that, generally, patients who can receive a service on an outpatient basis rather than be admitted as inpatients are not as sick as patients who would need to be admitted as inpatients to receive those same services.

We also continue to believe that the costs of providing a service to a hospital inpatient, in general, may exceed the costs for providing the same service on an outpatient basis. In general, payment for outpatient care through an APC consists only of the cost of the procedure, certain packaged ancillary services, and the cost of nursing and other staff care during the immediate recovery period. Patients are able to go home quickly (and if they are not able to go home quickly, they would typically be admitted). In general, the payment for operating costs of inpatient hospital services under the IPPS includes similar services that would be paid under the OPPS through an APC, plus associated diagnostic testing, drugs, laboratory tests, and the cost of an extended recovery over several days. Inpatient care is typically associated with longer periods of recovery, which may be triggered by increased complications, increased comorbidity, or increased risk. Although an individual outpatient case may be more expensive than an individual inpatient case, inpatients, on the average, will be sicker and more costly than outpatients receiving similar services.

Comment: A few commenters disagreed with the proposed reassignment of CPT code 33224 to APC 0655, and the proposed reassignment of CPT code 33225 to APC 0108. According to the commenters, the claims data upon which CMS calculated the proposed median cost of CPT code 33225 was flawed because it included many claims that should have been rejected if CMS applied its device-to-procedure edits. The commenters provided data analysis indicating that there were only 13 single bills that met the criteria of the device-dependent APC ratesetting methodology, and that the median cost calculated from those 13 single bills is approximately $8,149 rather than the median cost of approximately $34,018 calculated by CMS using 458 single bills from the data available for the CY 2012 proposed rule. The commenters requested that CMS maintain APC 0418, and continue to assign to it CPT codes 33224 and 33225, based on their estimated median cost of approximately $8,149 for CPT code 33225 and CMS' estimated median cost of approximately $12,418 for CPT code 33224. The commenters expressed

general concern that the device-to-procedure edits were not being applied correctly to hospital outpatient claims.

Response: We appreciate the commenters bringing to our attention potential problems with the claims used to calculate the proposed CY 2012 median cost for CPT code 33225. We are investigating the possibility that erroneous claims may have made it pass the claims processing logic in place to enforce the device-to-procedure and procedure-to-device edits, and how they may have been present in the set of claims we used in ratesetting for the proposed rule. We note that we used a total of 28 single bills for CPT code 33225 to calculate a median cost of approximately $18,855 for this final rule with comment period, which is consistent with the much lower number of single bills identified by the commenters in the proposed rule data set and consistent with the number of single bills for this service in prior years' hospital outpatient claims data. We will continue to examine this issue in order to ensure that the claims we use to calculate median costs for these CPT codes, as well as all CPT codes assigned to device-dependent APCs, conform with the device-dependent APC ratesetting methodology outlined in section II.A.2.d.(1) of this final rule with comment period.

We do not agree with the commenters that we should maintain APC 0418 for CPT codes 33224 and 33225. Based on the hospital outpatient claims and cost report data available for this final rule with comment period, we calculated a final median cost of approximately $12,418 using 198 single bills (out of 831 total bills) for CPT code 33224, and a final median cost of approximately $18,855 using 28 single bills (out of 10,424 total bills) for CPT code 33225. We continue to believe that CPT code 33224 appropriately aligns, both in terms of clinical characteristics and resource utilization, with other procedures assigned to APC 0655, which has a final CY 2012 median cost of approximately $9,638, because the median cost of CPT code 33224 is relatively close to the overall APC median cost and APC 0655 includes pacemaker insertion procedures. Therefore, we are finalizing our proposal, without modification, to assign CPT code 33224 to APC 0655.

In addition, we agree with commenters that CPT code 33225 should not be assigned to APC 0108. We believe that CPT code 33225 should be assigned to APC 0655, rather than APC 0108 or APC 0418, when it is not performed on the same day as the service described by CPT code 33249, based upon the median cost calculated for CPT code 33225 using data available for this final rule with comment period and based upon the commenters' estimates presented in their analysis of this CPT code's cost. While we acknowledge that the final rule median cost of approximately $18,855 is higher than the median costs of the other procedures assigned to APC 0655, we believe this is an appropriate assignment for this CPT code from a clinical perspective because the procedure described by CPT code 33225 differs from the procedure described by CPT code 33224 (which is in APC 0655) only in the position of the end of the electrode within the heart. In addition, CPT code 33225 is also similar to other procedures assigned to APC 0655, such as CPT code 33214 (Upgrade of implanted pacemaker system, conversion of single chamber system to dual chamber system (includes removal of previously placed pulse generator, testing of existing lead, insertion of new lead, insertion of new pulse generator), which describes the upgrade of a pacemaker which generally includes new hardware and placement of a new electrodes. We also note that this assignment does not violate the 2 times rule. Therefore, for CY 2012, we are modifying our proposal to reassign CPT code 33225 to APC 0108 when it is performed without CPT code 33249. Instead, CPT code 33225 is reassigned to APC 0655 when it is performed without CPT code 33249. We also are finalizing our proposals to change the title of APC 0655 to ''Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing Electrode'' and to delete APC 0418.

Comment: Many commenters supported the proposal to implement claims processing edits that would return claims to providers unless CPT code 33225 is billed in conjunction with one of the clinically appropriate CPT codes specified by the AMA in the CPT code book.

Response: We appreciate the commenters' support. We are implementing our CY 2012 proposal, without modification, to create claims processing edits for CPT code 33225 that would return claims to providers if CPT code 33225 is not correctly billed on the claim in conjunction with one of the clinically appropriate CPT codes specified by the AMA in the CPT code book, as described previously in this section.

In summary, after consideration of the public comments we received and the APC Panel recommendation, we are not finalizing our proposal to implement a payment cap for CRT–D services and ICD implantation procedures based upon the payment rate for IPPS MS–DRG 227 as proposed. Instead, we will recognize CPT codes 33225 and 33249 as a single, composite service when they are performed on the same day as proposed. However, for CY 2012, rather than assigning the procedures described by CPT codes 33225 and 33249 when they are performed on the same day to composite APC 8009, we are assigning them to existing APC 0108. We are implementing our proposal to change the title of APC 0108 to ''Insertion/Replacement/Repair of AICD Leads, Generator, and Pacing Electrodes'' because this APC will provide payment for ICD procedures including CRT–D services. Hospitals will continue to use the same CPT codes to report CRT–D procedures and ICD-only procedures, and the I/OCE will identify when the combination of CPT codes 33225 and 33249 on the same day qualify for composite service payment. We will make a single composite payment for such cases. When not performed on the same day as the service described by CPT code 33225, the service described by CPT code 33249 will continue to be assigned to APC 0108. When not performed on the same day as the service described by CPT code 33249, the service described by CPT code 33225 will be assigned to APC 0655 (we note that this is a modification from our proposal to assign CPT code 33225 when it does not appear with CPT code 33249 to APC 0108). We also are finalizing our proposals to reassign CPT code 33224 to APC 0655 for CY 2012, to change the title of APC 0655 from ''Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker'' to ''Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing Electrode,'' and to delete APC 0418.

In addition, we are finalizing our proposed policy to implement claims processing edits that will return to providers incorrectly coded claims on which a pacing electrode insertion (the procedure described by CPT code 33225) is billed without a procedure to insert an ICD or pacemaker.

3. Changes to Packaged Services

a. Background

The OPPS, like other prospective payment systems, relies on the concept of averaging, where the payment may be more or less than the estimated cost of providing a service or bundle of services for a particular patient, but with the exception of outlier cases, the payment is adequate to ensure access to appropriate care. Packaging payment for

multiple interrelated services into a single payment creates incentives for providers to furnish services in the most efficient way by enabling hospitals to manage their resources with maximum flexibility, thereby encouraging long-term cost containment. For example, where there are a variety of supplies that could be used to furnish a service, some of which are more expensive than others, packaging encourages hospitals to use the least expensive item that meets the patient's needs, rather than to routinely use a more expensive item. Packaging also encourages hospitals to negotiate carefully with manufacturers and suppliers to reduce the purchase price of items and services or to explore alternative group purchasing arrangements, thereby encouraging the most economical health care. Similarly, packaging encourages hospitals to establish protocols that ensure that necessary services are furnished, while carefully scrutinizing the services ordered by practitioners to maximize the efficient use of hospital resources. Packaging payments into larger payment bundles promotes the stability of payment for services over time. Finally, packaging also may reduce the importance of refining service specific payment because there is more opportunity for hospitals to average payment across higher cost cases requiring many ancillary services and lower cost cases requiring fewer ancillary services. For these reasons, packaging payment for services that are typically ancillary and supportive to a primary service has been a fundamental part of the OPPS since its implementation in August 2000.

We assign status indicator ''N'' to those HCPCS codes that we believe are always integral to the performance of the primary modality; therefore, we always package their costs into the costs of the separately paid primary services with which they are billed. Services assigned status indicator ''N'' are unconditionally packaged.

We assign status indicator ''Q1'' (''STVX–Packaged Codes''), ''Q2'' (''T–Packaged Codes''), or ''Q3'' (Codes that may be paid through a composite APC) to each conditionally packaged HCPCS code. An ''STVX-packaged code'' describes a HCPCS code whose payment is packaged when one or more separately paid primary services with the status indicator of ''S,'' ''T,'' ''V,'' or ''X'' are furnished in the hospital outpatient encounter. A ''T-packaged code'' describes a code whose payment is packaged when one or more separately paid surgical procedures with the status indicator of ''T'' are provided during the hospital outpatient encounter. ''STVX-packaged codes'' and ''T-packaged codes'' are paid separately in those uncommon cases when they do not meet their respective criteria for packaged payment. ''STVX-packaged codes'' and ''T-packaged codes'' are conditionally packaged. We refer readers to section XI.A.1. of this final rule with comment period and Addenda D1 (which is referenced in section XVII. of this final rule with comment period and available via the Internet on the CMS Web site) with other Addenda, for a complete listing of status indicators and the meaning of each.

We use the term ''dependent service'' to refer to the HCPCS codes that represent services that are typically ancillary and supportive to a primary diagnostic or therapeutic modality. We use the term ''independent service'' to refer to the HCPCS codes that represent the primary therapeutic or diagnostic modality into which we package payment for the dependent service. In future years, as we consider the development of larger payment groups that more broadly reflect services provided in an encounter or episode of-care, it is possible that we might propose to bundle payment for a service that we now refer to as ''independent.''

Hospitals include HCPCS codes and charges for packaged services on their claims, and the estimated costs associated with those packaged services are then added to the costs of separately payable procedures on the same claims in establishing payment rates for the separately payable services. We encourage hospitals to report all HCPCS codes that describe packaged services that were provided, unless the CPT Editorial Panel or CMS provide other guidance. The appropriateness of the OPPS payment rates depends on the quality and completeness of the claims data that hospitals submit for the services they furnish to our Medicare beneficiaries.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66610 through 66659), we adopted the packaging of payment for items and services in seven categories into the payment for the primary diagnostic or therapeutic modality to which we believe these items and services are typically ancillary and supportive. The seven categories are: (1) Guidance services; (2) image processing services; (3) intraoperative services; (4) imaging supervision and interpretation services; (5) diagnostic radiopharmaceuticals; (6) contrast media; and (7) observation services. We specifically chose these categories of HCPCS codes for packaging because we believe that the items and services described by the codes in these categories are typically ancillary and supportive to a primary diagnostic or therapeutic modality and, in those cases, are an integral part of the primary service they support.

In addition, in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66650 through 66659), we finalized additional packaging for the CY 2008 OPPS, which included the establishment of new composite APCs for CY 2008, specifically APC 8000 (Cardiac Electrophysiologic Evaluation and Ablation Composite), APC 8001 (LDR Prostate Brachytherapy Composite), APC 8002 (Level I Extended Assessment & Management Composite), and APC 8003 (Level II Extended Assessment & Management Composite). In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68559 through 68569), we expanded the composite APC model to one new clinical area—multiple imaging services. We created five multiple imaging composite APCs for payment in CY 2009 that incorporate statutory requirements to differentiate between imaging services provided with contrast and without contrast as required by section 1833(t)(2)(G) of the Act. The multiple imaging composite APCs are: (1) APC 8004 (Ultrasound Composite); (2) APC 8005 (CT and CTA without Contrast Composite); (3) APC 8006 (CT and CTA with Contrast Composite); (4) APC 8007 (MRI and MRA without Contrast Composite); and (5) APC 8008 (MRI and MRA with Contrast Composite). We discuss composite APCs in more detail in section II.A.2.e. of this final rule with comment period.

We recognize that decisions about packaging and bundling payment involve a balance between ensuring that payment is adequate to enable the hospital to provide quality care and establishing incentives for efficiency through larger units of payment. Therefore, in the CY 2012 OPPS/ASC proposed rule (76 FR 42206), we invited public comments regarding our packaging proposals for the CY 2012 OPPS.

b. Packaging Issues

(1) CMS Presentation of Findings Regarding Expanded Packaging at the February 28–March 1, 2011 and August 10–11, 2011 APC Panel Meetings

In deciding whether to package a service or pay for a code separately, we have historically considered a variety of factors, including whether the service is normally provided separately or in conjunction with other services; how likely it is for the costs of the packaged code to be appropriately mapped to the

separately payable codes with which it was performed; and whether the expected cost of the service is relatively low.

As discussed in section I.D. of the proposed rule and this final rule with comment period, the APC Panel advises CMS on the clinical integrity of payment groups and their weights, and the APC Panel has had a Packaging Subcommittee that is now renamed the Subcommittee for APC Groups and Status Indicator (SI) Assignments to reflect that its function has expanded to include assisting CMS with assignment of HCPCS codes to APCs. As part of its function, the APC Panel studies and makes recommendations on issues pertaining to services that are not separately payable under the OPPS, but whose payments are bundled or packaged into APC payments. The APC Panel has considered packaging issues at several earlier meetings. For discussions of earlier APC Panel meetings and recommendations, we refer readers to previously published hospital OPPS/ASC proposed and final rules on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS/HORD/list.asp.*

(2) Packaging Recommendations of the APC Panel at its February 28–March 1, 2011 Meeting

During the February 28–March 1, 2011 APC Panel meeting, the APC Panel accepted the report of the Subcommittee for APC Groups and Status Indicator (SI) Assignment, heard several public presentations related to packaged services, discussed the deliberations of the subcommittee, and made five recommendations related to packaging and to the function of the subcommittee. The Report of the February 28–March 1, 2011 meeting of the APC Panel may be found at the CMS Web site at: *http://www.cms.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp.*

To summarize, the APC Panel made five recommendations regarding the packaging of payment under the CY 2012 OPPS. Below we present each of these five packaging recommendations and our responses to those recommendations. The first APC Panel recommendation that relates to packaging and that we discuss in this section is APC Panel Recommendation 4. Two other recommendations, Recommendations 12 and 13, which evolved from the discussions of the APC Groups and Status Indicator Subcommittee, are related specifically to HCPCS codes, were discussed in section III.D. of the proposed rule, and are addressed in section III.D. of this final rule with comment period. Recommendation 12 was that CMS reassign HCPCS code 65778 (Placement of amniotic membrane on the ocular surface for wound healing; self-retaining) and HCPCS code 65779 (Placement of amniotic membrane on the ocular surface for wound healing; single layer, sutured) to APC 0233 (Level III Anterior Segment Eye Procedures) and that CMS furnish data when data become available for these two codes. Recommendation 13 was that CMS create an intermediate-level upper gastrointestinal procedures APC.

APC Panel Recommendation 4: That HCPCS code 31627 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with computer-assisted, image-guided navigation (List separately in addition to code for primary procedure[s])) should continue to be assigned a status indicator of ''N.'' The Panel further recommended that CMS continue to collect claims data for HCPCS code 31627.

CMS Response to Recommendation 4: HCPCS code 31627 was new for CY 2010, and we assigned a new interim status indicator of ''N'' in our CY 2010 OPPS/ASC final rule with comment period based on our policy of packaging guidance and intraoperative services that are ancillary and dependent upon an independent separately paid procedure. At the APC Panel's February 2010 meeting, the manufacturer of the electromagnetic navigation bronchoscopy (ENB) technology, one of several technologies that can be used to perform the service described by HCPCS code 31627, asserted that use of the ENB technology during a bronchoscopy procedure enables access to distal lesions that are otherwise not accessible without use of the ENB technology. The manufacturer also stated that without separate payment for the ENB technology, hospitals would likely not adopt the technology and the population that would likely benefit from the ENB technology would not have access to this technology. In response to the manufacturer's presentation at the February 2010 Panel meeting, the APC Panel asked CMS to consider whether HCPCS code 31627 should be packaged or paid separately; and if it should be paid separately, the APC Panel asked CMS to investigate the appropriate APC assignment. The report of the February 2010 APC Panel meeting is available at: *http://www.cms.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp.*

We stated in the CY 2011 OPPS/ASC proposed rule (75 FR 46223) that we considered and analyzed the information available to us for HCPCS code 31627 and believed that the code described a procedure that is supportive of and ancillary to the primary diagnostic or therapeutic modality. Therefore, we proposed to package payment for HCPCS code 31627. We stated that, by proposing to package payment for this procedure, we would be treating it in the same manner as similar computer assisted, navigational diagnostic procedures that are supportive of and ancillary to a primary diagnostic or therapeutic modality.

At its August 23–24, 2010 meeting, the APC Panel listened to discussions regarding whether HCPCS code 31627 should remain packaged for CY 2011. After hearing presentations from the public, the APC Panel recommended that CMS continue to package payment for HCPCS code 31627 into payment for the major separately paid procedure with which it is performed and asked that CMS bring claims data on the cost of HCPCS code 31627 to the APC Panel's winter 2011 meeting for review. After consideration of all of the information provided by commenters on this issue, and hearing the discussion of the issue by the APC Panel at its August 23–24, 2010 meeting, we accepted the APC Panel's recommendation to continue to package payment for HCPCS code 31627 into the payment for the major separately paid procedure with which it is reported for CY 2011. In addition, we also accepted the APC Panel's recommendation that CMS bring claims data for HCPCS code 31627 to the winter 2011 APC Panel meeting. The report of the August 2010 APC Panel meeting is available at: *http://www.cms.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp.*

At its meeting on February 28–March 1, 2011, the APC Panel listened to a public presentation in which the manufacturer of the ENB technology requested that HCPCS code 31627 be paid separately on the basis that the cost of the technology is substantially higher than the OPPS payment for APC 0076 (Level I Endoscopy Lower Airway), the APC to which most bronchoscopy codes are assigned and into which payment for HCPCS code 31627 is packaged. The manufacturer stated that if CMS does not pay HCPCS code 31627 separately, hospitals will not furnish the procedure to hospital outpatients.

In response to the request of the APC Panel at its August 2010 meeting, we presented the available data on HCPCS code 31627 that could be derived from the hospital outpatient claims that were paid under the OPPS for services on and after January 1, 2010 through and

including September 30, 2010, as processed through the CMS common working file by December 31, 2010. Specifically, using the limited set of APC Panel data, CMS found that 119 hospitals billed for 573 units of HCPCS code 31627, and that HCPCS code 31627 had a median cost of approximately $329 per unit. We also found that HCPCS code 31627 is reported on 0 to 4 percent of the claims for bronchoscopy codes with which CPT guidance states that it is permissible to report HCPCS code 31627, with the exception of HCPCS code 31626 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of fiducial markers, single or multiple). HCPCS code 31627 was reported on approximately 52 percent of claims for HCPCS code 31626 in the APC Panel data. The APC Panel considered this information in its formulation of Recommendation 4 that CMS continue to package payment for HCPCS code 31627 into the payment for the bronchoscopy code with which HCPCS code 31627 is reported. Subsequent to the APC Panel meeting, examination and analysis of the CY 2012 proposed rule data found that 149 hospitals reported 867 units of HCPCS code 31627, and that HCPCS code 31627 had a proposed rule median cost of approximately $344 per unit.

After considering the public presentation and the information presented by CMS staff, the APC Panel recommended that HCPCS code 31627 continue to be assigned a status indicator of ''N.'' The Panel further recommended that CMS continue to collect claims data for HCPCS code 31627. In the CY 2012 OPPS/ASC proposed rule (76 FR 42208), we proposed to accept both of the APC Panel's recommendations for the CY 2012 OPPS. Specifically, we proposed to assign HCPCS code 31627 to status indicator ''N'' for the CY 2012 OPPS and, therefore, proposed to package payment for the procedure into payment for the bronchoscopy to which we believe that it is ancillary and supportive. As with all packaged items and services, we propose that the cost we calculate for CPT code 31627 would be added to the costs on the single bill for the bronchoscopy code with which the service reported by CPT code 31627 is furnished, and therefore, the cost of CPT code 31627 would be incorporated into the payment for the APC to which that bronchoscopy code is assigned. We stated in the proposed rule that we continue to believe that HCPCS code 31627, for which there are several different technologies, describes a service that is supportive and ancillary to the primary bronchoscopy procedure with which it must be reported, as defined by CPT. HCPCS code 31627 describes a computer assisted image guided navigation service that is not furnished without a bronchoscopy. As defined by CPT, HCPCS code 31627 may only be furnished in addition to a bronchoscopy service and, therefore, we believe that it is ancillary and supportive to the bronchoscopy service with which it must be reported. We agreed to provide further claims information on HCPCS code 31627 to the APC Panel when it becomes available.

Comment: One commenter supported the APC Panel recommendation at its February 2011 meeting that CMS provide further claims information on HCPCS code 31627 to the APC Panel when it becomes available.

Response: We appreciate the commenter's support and will furnish further information on HCPCS code 31627 to the APC Panel at a future meeting.

For CY 2012, we are continuing to package payment for HCPCS code 31627 into payment for the separately paid procedure with which it is furnished because we continue to believe that it is ancillary and supportive to the bronchoscopy with which it is performed, as set forth in the CY 2012 proposed rule (76 FR 42207 through 42208). Therefore, we have assigned HCPCS code 31627 a status indicator of ''N'' for CY 2012.

APC Panel Recommendation 5: That CMS consider a more appropriate APC assignment for HCPCS code 31626 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of fiducial markers), the most common code with which HCPCS code 31627 was billed in 2010.

CMS Response to Recommendation 5: In the CY 2012 OPPS/ASC proposed rule, we accepted this recommendation and, therefore, proposed to reassign HCPCS code 31626 (which had a proposed CY 2012 APC median cost of approximately $2,708) from APC 0076 (which had a proposed CY 2012 APC median cost of approximately $751) to APC 0415 (Level II Endoscopy Lower Airway), which had a proposed CY 2012 APC median cost of approximately $2,007. We agreed with the APC Panel that it appears that the proposed APC median cost of HCPCS code 31626 of $2,708 justified placement in an APC that has a median cost that is more similar to the APC median cost for this code. We stated that we believe that APC 0415 is the most appropriate clinically similar APC because the proposed CY 2012 median cost for APC 0415 of $2,007 is more similar in clinical resource for HCPCS code 31626 than the proposed CY 2012 median cost for APC 0076 of $715.

Comment: Commenters supported our proposal to move HCPCS code 31626 to APC 0415 for CY 2012.

Response: We appreciate the commenters' support and are finalizing our proposal for the reasons set forth above.

For CY 2012, we are moving HCPCS code 31626 from APC 0076 to APC 0415, which has a final median cost of approximately $2,024.

APC Panel Recommendation 6: That Judith Kelly, R.H.I.T., R.H.I.A., C.C.S., continue to chair the APC Groups and Status Indicator (SI) Assignments Subcommittee for 2011.

CMS Response to Recommendation 6: In the CY 2012 OPPS/ASC proposed rule, we indicated that we accepted the APC Panel's recommendation that Judith Kelly, R.H.I.T., R.H.I.A., C.C.S. continue to chair the APC Groups and Status Indicator Assignments Subcommittee for 2011.

We did not receive any public comments on this recommendation. We appreciate the services of Ms. Kelly as chair of the Subcommittee for CY 2011.

APC Panel Recommendation 7: That CMS furnish the results of its investigation of claims that contain the following unconditionally packaged codes without separately paid procedures:

- HCPCS code G0177 (Training and educational services related to the care and treatment of patient's disabling mental health problems per session (45 minutes or more));
- HCPCS code G0378 (Hospital observation service, per hour);
- HCPCS code 75940 (Percutaneous placement of IVC filter, radiological supervision and interpretation); and
- HCPCS code 76937 (Ultrasound guidance for vascular access requiring ultrasound evaluation of potential access sites, documentation of selected vessel patency, concurrent realtime ultrasound visualization of vascular needle entry, with permanent recording and reporting (List separately in addition to code for primary procedure)).

CMS Response to Recommendation 7: In the CY 2012 OPPS/ASC proposed rule, we indicated that we accepted the APC Panel's recommendation that CMS furnish the results of its investigation of claims that contain the unconditionally packaged codes, HCPCS code G0177, HCPCS code G0378, HCPCS code 75940,

and HCPCS code 76937, at a future APC Panel meeting.

Comment: One commenter supported the APC Panel recommendation that CMS furnish the results of its investigation of claims that contain the following unconditionally packaged codes without separately paid procedures: HCPCS code 75940 and HCPCS code 76937.

Response: As we indicated in the proposed rule (76 FR 42208), we will furnish this information to the APC Panel at a future meeting.

APC Panel Recommendation 8: That the work of the APC Groups and Status Indicator (SI) Assignments Subcommittee continue.

CMS Response to Recommendation 8: In the CY 2012 OPPS/ASC proposed rule, we indicated that we accepted the APC Panel's recommendation that the work of the APC Groups and Status Indicator Assignments Subcommittee continue.

We did not receive any public comments on this recommendation.

(3) Packaging Recommendations of the APC Panel at Its August 2011 Meeting

During the August 10–11, 2011 APC Panel meeting, the APC Panel accepted the report of the Subcommittee for APC Groups and Status Indicator (SI) Assignments, heard several public presentations related to packaged services, discussed the deliberations of the subcommittee, and made three recommendations related to packaging and to the function of the subcommittee. The subcommittee also made recommendations with regard to APC placement of specific services that are discussed in section III.D of this final rule with comment period. The Report of the August 10–11, 2011 meeting of the APC Panel may be found at the CMS Web site at: *http://www.cms.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp.*

Below we present each of the three recommendations related to packaging and our responses to those recommendations. Recommendations that evolved from the discussions of the Subcommittee on APC Groups and Status Indicator Assignments that are specific to the APC assignment of HCPCS codes and removal of HCPCS codes from the inpatient only list are discussed in sections III and IX, respectively, of this final rule with comment period.

APC Panel Recommendation 9: That CMS give HCPCS code 65778 (Placement of amniotic membrane on the ocular surface for wound healing; self-retaining) a status indicator of ''T'' and provide the Panel with correlating claims data when available.

CMS Response to Recommendation 9: We refer readers section III.D.5.a of this final rule with comment period for discussion of this recommendation.

APC Panel Recommendation 11: The Panel recommends that Judith Kelly, R.H.I.T., R.H.I.A., C.C.S., remain the chair of the APC Groups and SI Assignments Subcommittee.

CMS Response to Recommendation 11: We accept the recommendation that Judith Kelly, R.H.I.T., R.H.I.A., C.C.S., remain the chair of the APC Groups and SI Assignments Subcommittee. We appreciate Ms. Kelly's continuing service in this position.

APC Panel Recommendation 12: The Panel recommends that the work of the APC Groups and SI Assignments Subcommittee continue.

CMS Response to Recommendation 12: We are accepting the APC Panel's recommendation that the work of the APC Groups and SI Assignments Subcommittee continue.

(4) Other Packaging Proposals and Policies for CY 2012

The HCPCS codes that we proposed be packaged either unconditionally (for which we continue to assign status indicator ''N''), or conditionally (for which we continue to assign status indicators ''Q1,'' ''Q2,'' or ''Q3''), were displayed in Addendum B of the CY 2012 OPPS/ASC proposed rule (76 FR 42208). The supporting documents for the CY 2012 OPPS/ASC proposed rule, including but not limited to Addendum B, are available at the CMS Web site at: *www.cms.hhs.gov/HospitalOutpatientPPS/HORD*. To view the proposed status indicators by HCPCS code in Addendum B, select ''CMS 1525–P'' and then select the folder labeled ''2012 OPPS Proposed Rule Addenda'' or ''2012 OPPS Final Rule with Comment Period Addenda'' from the list of supporting files. Open the zipped file and select Addendum B, which is available as both an Excel file and a text file.

Comment: Commenters stated that CMS' packaging policies would likely lead to less efficient use of resources, limited access to innovative treatment options, and greater instability in payments because the policies are based on several flawed assumptions. Commenters believed that, to the extent that hospitals control the array of services they provide, CMS' packaging policies assume that the same incentives apply to services furnished in hospital outpatient departments as to inpatient services. One commenter stated that under the hospital inpatient prospective payment system (IPPS), hospitals have an incentive to provide care, including advanced technologies, in an efficient manner to ensure the lowest cost for the patient's diagnosis. In contrast, in hospital outpatient departments, because Medicare payment is based on procedures rather than diagnoses, the commenter believed that hospitals have an incentive to provide the lowest cost item or service included in an APC. The commenter further believed that if that service does not fully address the patient's needs, the hospital would receive better payment by bringing the patient back for a second visit or admitting the patient for inpatient care than by providing a more costly option within the same APC.

Moreover, the commenters believed that when an APC's payment rate is significantly less than the cost of a technology, hospitals have a strong disincentive to use that technology, even if it could reduce the costs of care at a later date. The commenters believed that CMS' use of expanded packaging has the risk of encouraging hospitals to forego performing needed services and using new technologies that may be more resource intensive during one visit, but could save the patient future outpatient department visits or inpatient care.

Response: Packaging payment for items and services that are ancillary to and dependent on the major procedure for which a payment rate is established is a fundamental concept of the OPPS, based in regulation in the definition of costs that are included in the national payment rate for a service (42 CFR 419.2(b)) and in place since the inception of the OPPS (65 FR 18447). We continue to believe that packaging creates incentives for hospitals and their physician partners to work together to establish appropriate protocols that eliminate unnecessary services where they exist and institutionalize approaches to providing necessary services more efficiently. With respect to new services or new applications of existing technology, we believe that packaging payment for ancillary and dependent services creates appropriate incentives for hospitals to seriously consider whether a new service or a new technology offers a benefit that is sufficient to justify the cost of the new service or new technology. Where this review results in reductions in services that are only marginally beneficial or influences hospitals' choices to not utilize certain technologies, we believe that these changes could improve, rather than harm, the quality of care for Medicare beneficiaries because every service furnished in a hospital carries

some level of risk to the patient and the beneficiary would be spared the risk associated with the additional service or different technology. Moreover, we believe that hospitals strive to provide the best care they can to the patients they serve so that when new technologies are proven to improve the quality of care, their utilization will increase appropriately, whether the payment for them is packaged or not. While we believe hospitals are committed to provide optimal care to their patients, we are aware that there are financial pressures on hospitals that might motivate some providers to split services among different hospital encounters in such a way as to maximize payments. While we do not expect that hospitals would routinely change the way they furnish services or the way they bill for services in order to maximize payment, we recognize that it would be possible and we consider that possibility as we annually review hospital claims data. We will continue to examine claims data for patterns of fragmented care, and if we find a pattern in which a hospital appears to be dividing care across multiple days, we will refer it for investigation to the QIO or to the Program Safeguard Contractor, as appropriate to the circumstances we find.

Comment: Commenters asked that CMS make underlying payment rates for packaged services, including utilization rates, estimated median costs, and numbers of hospitals furnishing various services, available to the public. In addition, commenters asked that CMS study and report annually to the APC Panel and to the public on the impact of packaged payment on beneficiary access to care. One commenter believed that the APC Panel recommended that CMS report annually on the impact of packaging on net payments for patient care.

Response: Each year, CMS makes available an extensive amount of OPPS data that can be used for any data analysis an interested party would care to perform. Specifically, we make available a considerable amount of data for public analysis each year through the supporting data files that are posted on the CMS Web site in association with the display of the proposed and final rules. In addition, as we discuss in detail in section II.A.2. of this final rule with comment period, we make available the public use files of claims, including, for CY 2008 and later, supplemental line item cost data for every HCPCS code under the OPPS, and a detailed narrative description of our data process for the annual OPPS/ASC proposed and final rules that the public can use to perform any desired analyses. Therefore, commenters are able to examine and analyze these data to develop specific information to assess the impact and effect of packaging for the services of interest to them. This information is available to support public requests for changes to payments under the OPPS, whether with regard to separate payment for a packaged service or other issues. We understand that the OPPS is a complex payment system and that it may be difficult to determine the quantitative amount of packaged cost included in the median cost for every independent service. However, commenters routinely provide us with meaningful analyses at a very detailed and service-specific level based on the claims data we make available. We routinely receive complex and detailed public comments, including extensive code-specific data analysis on packaged and separately paid codes, using the data from current and prior proposed and final rules. The APC Panel did not recommend at either the February 2011 or August 2011 meetings that CMS should report annually on the impact of packaging on net payments for patient care.

Comment: Commenters stated that CMS assumes that its packaging policies will allow it to continue to collect the data it needs to set appropriate, stable payment rates in the future, but that this assumption is flawed. Commenters stated that CMS' past experience with packaging payment for ancillary items indicates that hospitals do not submit codes for services that do not directly affect their payment and see no reason to believe that this will change. The commenters asked that CMS require complete and correct coding for packaged services so that all items and services that are not individually paid must be included on the claim to provide CMS with essential data for future OPPS updates. Commenters expressed concern about what they believed to be decreases in the number of hospitals reporting services as a result of packaging and bundling. They believed that the decline could be due to one or both of two reasons: Hospitals may no longer be providing these services; or hospitals could be providing these services but not reporting codes and charges for them, denying CMS accurate data for use in rate setting. The commenters were concerned that decreased reporting of services will result in the costs of packaged services not being included in the payment for the independent service with which they are furnished.

Response: We do not believe that there has been or will be a significant change in what hospitals report and charge for the outpatient services they furnish to Medicare beneficiaries and other patients as a result of our current packaging methodology. Medicare cost reporting standards specify that hospitals must impose the same charges for Medicare patients as for other patients. We are often told by hospitals that many private payers pay based on a percentage of charges and that, in accordance with Medicare cost reporting rules and generally accepted accounting principles, hospital chargemasters do not differentiate between the charges to Medicare patients and other patients. Therefore, we have no reason to believe that hospitals will stop reporting HCPCS codes and charges for packaged services they provide to Medicare beneficiaries. As we stated in the CY 2009 OPPS/ASC final rule with comment period (74 FR 68575), we strongly encourage hospitals to report a charge for each packaged service they furnish, either by billing the packaged HCPCS code and a charge for that service if separate reporting is consistent with CPT and CMS instructions, by increasing the charge for the separately paid associated service to include the charge for the packaged service, or by reporting the charge for the packaged service with an appropriate revenue code but without a HCPCS code. Any of these means of charging for the packaged service will result in the cost of the packaged service being incorporated into the cost we estimate for the separately paid service. If a HCPCS code is not reported when a packaged service is provided, we acknowledge that it can be challenging to specifically track the utilization patterns and resource cost of the packaged service itself. However, we have no reason to believe that hospitals have not considered the cost of the packaged service in reporting charges for the independent, separately paid service. We expect that hospitals, as other prudent businesses, have a quality review process that ensures that they accurately and completely report the services they furnish, with appropriate charges for those services to Medicare and all other payers. We encourage hospitals to report on their claim for payment all HCPCS codes that describe packaged services that were furnished, unless the CPT Editorial Panel or CMS provides other guidance. To the extent that hospitals include separate charges for packaged services on their claims, the estimated costs of those packaged services are then added to the costs of separately paid procedures on the same claims and used in establishing

payment rates for the separately paid services. It is impossible to know with any certainty whether hospitals are failing to report HCPCS codes and charges for services for which the payment is packaged into payment for the independent service with which the packaged service is furnished. Moreover, if a hospital fails to report the HCPCS codes and charges for packaged services, the reason may be that the hospital has chosen to package the charge for the ancillary and dependent service into the charge for the service with which it is furnished. Although we prefer that hospitals report HCPCS codes and charges for all services they furnish, if the hospital's charge for the independent service also reflects the charge for all ancillary and supportive services it typically provides, the absence of HCPCS codes and separate charges would not result in inappropriately low median cost for the independent service, although CMS would not know which specific ancillary and supportive services were being furnished. If a hospital is no longer providing a service, there may be many reasons that a hospital chooses not to provide a particular service or chooses to cease providing a particular service, including, but not limited to, because the hospital has determined that it is no longer cost effective for the hospital to furnish the service and that there may be other hospitals in the community that can furnish the service more efficiently.

Comment: One commenter asked that CMS reinstate separate payment for radiation oncology guidance procedures because these services are vital to the safe provision of radiation therapy and unconditionally packaging payment for them may discourage hospitals from providing them.

Response: We recognize that radiation oncology guidance services, like most packaged services, are important to providing safe and high quality care to patients. However, we continue to believe that hospitals will invest in services that represent genuinely increased value to patient care, and if hospitals can furnish them efficiently. We will continue to pay separately for innovative technologies if a device meets the conditions for separate payment as a pass-through device or if a new procedure meets the criteria for payment as a new technology APC.

After considering the public comments we received, for CY 2012, we are continuing to package payment for the services for which we proposed unconditional or conditional packaged payment in the proposed rule for the reasons set forth above. The HCPCS codes for which payment will be packaged into payment for the independent separately paid procedures with which the codes are reported either unconditionally (for which we continue to assign status indicator ''N''), or conditionally (for which we continue to assign status indicators ''Q1'', ''Q2'', or ''Q3'') are displayed in Addendum B of this final rule with comment period (which is referenced in section XVIII. of this final rule with comment period and available via the Internet on the CMS Web site). The supporting documents for this CY 2012 OPPS/ASC final rule with comment period, including but not limited to Addendum B, are available at *www.cms.gov/HospitalOutpatientPPS/HORD*. To view the status indicators by HCPCS code in Addendum B, select ''CMS 1525–FC'' and then select the folder labeled ''2012 OPPS Proposed Rule Addenda'' or ''2012 OPPS Final Rule With Comment Period Addenda'' from the list of supporting files. Open the zipped file and select Addendum B, which is available as both an Excel file and a text file.

The continuation of our standard policy regarding packaging of drugs and biologicals, implantable biologicals, contrast agents and diagnostic radiopharmaceuticals is discussed in section V.B. of this final rule with comment period. We note that an implantable biological that is surgically inserted or implanted through a surgical incision or a natural orifice is commonly referred to throughout this final rule with comment period as an ''implantable biological.''

The creation of a new composite APC for CY 2012 for payment of the insertion of cardiac resynchronization devices is discussed in section II.A.2.e.(6) of this final rule with comment period.

4. Calculation of OPPS Scaled Payment Weights

As we proposed in the CY 2012 OPPS/ASC proposed rule (76 FR 42209), using the APC median costs discussed in sections II.A.1. and II.A.2. of this final rule with comment period, we calculated the final relative payment weights for each APC for CY 2012 shown in Addenda A and B to this final rule with comment period (which are referenced in section XVII. of this final rule with comment period and available via the Internet on the CMS Web site). In years prior to CY 2007, we standardized all the relative payment weights to APC 0601 (Mid Level Clinic Visit) because mid-level clinic visits were among the most frequently performed services in the hospital outpatient setting. We assigned APC 0601 a relative payment weight of 1.00 and divided the median cost for each APC by the median cost for APC 0601 to derive the relative payment weight for each APC.

Beginning with the CY 2007 OPPS (71 FR 67990), we standardized all of the relative payment weights to APC 0606 (Level 3 Clinic Visits) because we deleted APC 0601 as part of the reconfiguration of the clinic visit APCs. We selected APC 0606 as the base because APC 0606 was the mid-level clinic visit APC (that is, Level 3 of five levels). Therefore, in the CY 2012 OPPS/ASC proposed rule (76 FR 42209), for CY 2012, to maintain consistency in using a median for calculating unscaled weights representing the median cost of some of the most frequently provided services, we proposed to continue to use the median cost of the mid-level clinic visit APC (APC 0606) to calculate unscaled weights. Following our standard methodology, but using the proposed CY 2012 median cost for APC 0606, for CY 2012, we assigned APC 0606 a relative payment weight of 1.00 and divided the median cost of each APC by the proposed median cost for APC 0606 to derive the proposed unscaled relative payment weight for each APC. The choice of the APC on which to base the proposed relative weights for all other APCs does not affect the payments made under the OPPS because we scale the weights for budget neutrality.

Section 1833(t)(9)(B) of the Act requires that APC reclassification and recalibration changes, wage index changes, and other adjustments be made in a budget neutral manner. Budget neutrality ensures that the estimated aggregate weight under the OPPS for CY 2012 is neither greater than nor less than the estimated aggregate weight that would have been made without the changes. To comply with this requirement concerning the APC changes, we proposed to compare the estimated aggregate weight using the CY 2011 scaled relative weights to the estimated aggregate weight using the proposed CY 2012 unscaled relative weights. For CY 2011, we multiplied the CY 2011 scaled APC relative weight applicable to a service paid under the OPPS by the volume of that service from CY 2010 claims to calculate the total weight for each service. We then added together the total weight for each of these services in order to calculate an estimated aggregate weight for the year. For CY 2012, we performed the same process using the proposed CY 2012 unscaled weights rather than scaled weights. We then calculated the weight scaler by dividing the CY 2011 estimated aggregate weight by the

proposed CY 2012 estimated aggregate weight. The service-mix is the same in the current and prospective years because we use the same set of claims for service volume in calculating the aggregate weight for each year. For a detailed discussion of the weight scaler calculation, we refer readers to the OPPS claims accounting document available on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS/*. We included payments to CMHCs in our comparison of estimated unscaled weight in CY 2012 to estimated total weight in CY 2011 using CY 2010 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we adjusted the unscaled relative weights for purposes of budget neutrality. The proposed CY 2012 unscaled relative payment weights were adjusted by multiplying them by a proposed weight scaler of 1.4647 to ensure that the proposed CY 2012 relative weights are budget neutral.

Section 1833(t)(14) of the Act provides the payment rates for certain ''specified covered outpatient drugs.'' That section states that ''Additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion factor, weighting and other adjustment factors for 2004 and 2005 under paragraph (9) but shall be taken into account for subsequent years.'' Therefore, the cost of those specified covered outpatient drugs (as discussed in section V.B.3. of the proposed rule and this final rule with comment period) was included in the proposed budget neutrality calculations for the CY 2012 OPPS.

We did not receive any public comments on the proposed methodology for calculating scaled weights from the median costs for the CY 2012 OPPS. Therefore, for the reasons set forth in the proposed rule (76 FR 42209), we are finalizing our proposed methodology without modification, including updating of the budget neutrality scaler for this final rule with comment period as we proposed. Under this methodology, the final unscaled payment weights were adjusted by a weight scaler of 1.3588 for this final rule with comment period. The final scaled relative payment weights listed in Addenda A and B to this final rule with comment period (which are referenced in section XVII. of this final rule with comment period and available via the Internet on the CMS Web site) incorporate the final recalibration adjustments discussed in sections II.A.1. and II.A.2. of this final rule with comment period.

B. Conversion Factor Update

Section 1833(t)(3)(C)(ii) of the Act requires us to update the conversion factor used to determine payment rates under the OPPS on an annual basis by applying the OPD fee schedule increase factor. For purposes of section 1833(t)(3)(C)(iv) of the Act, subject to sections 1833(t)(17) and 1833(t)(3)(F) of the Act, the OPD fee schedule increase factor is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under section 1886(b)(3)(B)(iii) of the Act. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689), consistent with current law, based on IHS Global Insight, Inc.'s second quarter 2011 forecast of the FY 2012 market basket increase, the FY 2012 IPPS market basket update is 3.0 percent. However, sections 1833(t)(3)(F) and 1833(t)(3)(G)(ii) of the Act, as added by section 3401(i) of the Public Law 111–148 and as amended by section 10319(g) of such law and further amended by section 1105(e) of Public Law 111–152, provide adjustments to the OPD fee schedule update for CY 2012.

Specifically, section 1833(t)(3)(F) requires that the OPD fee schedule increase factor under subparagraph (C)(iv) be reduced by the adjustments described in section 1833(t)(3)(F) of the Act. Specifically, section 1833(t)(3)(F)(i) of the Act requires that the OPD fee schedule increase factor under subparagraph (C)(iv) be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act for 2012 and subsequent years. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the ''MFP adjustment''). We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51690 through 51692) for a discussion of the calculation of the MFP adjustment. The final MFP adjustment for FY 2012 is 1.0 percentage point.

We proposed that if more recent data are subsequently available after the publication of the proposed rule (for example, a more recent estimate of the market basket and MFP adjustment), we would use such data, if appropriate, to determine the CY 2012 market basket update and the MFP adjustment in the CY 2012 final rule. Consistent with this proposal, in this CY 2012 OPPS/ASC final rule with comment period, we reduced the OPD fee schedule increase factor for CY 2012 by the final MFP adjustment of 1.0 percentage point for FY 2012. Because the OPD fee schedule increase factor is based on the IPPS hospital inpatient market basket percentage increase, we believe that it is appropriate to apply the same MFP adjustment that is used to reduce the IPPS market basket increase to the OPD fee schedule increase factor. Consistent with the FY 2012 IPPS/LTCH PPS final rule, we applied the updated final FY 2012 market basket percentage increase and the MFP adjustment to the OPD fee schedule increase factor for the CY 2012 OPPS. We believe that it is appropriate to apply the MFP adjustment, which is calculated on a fiscal year basis, to the OPD fee schedule increase factor, which is used to update the OPPS payment rates on a calendar year basis, because we believe that it is appropriate for the numbers associated with both components of the calculation (the underlying OPD fee schedule increase factor and the productivity adjustment) to be aligned so that changes in market conditions are aligned.

In addition, section 1833(t)(3)(F)(ii) of the Act requires that the OPD fee schedule increase factor under subparagraph (C)(iv) be reduced by the adjustment described in subparagraph (G) for each of 2010 through 2019. For CY 2012, section 1833(t)(3)(G)(ii) of the Act provides a 0.1 percentage point reduction to the OPD fee schedule increase factor under subparagraph (C)(iv). Therefore, as we proposed, we are applying a 0.1 percentage point reduction to the OPD fee schedule increase factor.

We note that section 1833(t)(F) of the Act provides that application of this subparagraph may result in the increase factor under subparagraph (C)(iv) being less than 0.0 for a year, and may result in payment rates under the payment system under this subsection for a year being less than such payment rates for the preceding year. As described in further detail below, we are applying an OPD fee schedule increase factor of 1.9 percent for the CY 2012 OPPS (3.0 percent, which is the final estimate of the hospital market basket increase, less the 1.0 percentage point MFP adjustment, less the 0.1 percentage point additional adjustment).

In the CY 2012 OPPS/ASC proposed rule (76 FR 42210), we proposed to revise 42 CFR 419.32(b)(1)(iv)(B) by adding a new paragraph (3) to reflect the requirement in section 1833(t)(3)(F)(i) of the Act that, for CY 2012, we reduce the OPD fee schedule increase factor by the

multifactor productivity adjustment as determined by CMS, and to reflect the requirement in section 1833(t)(3)(G)(ii) of the Act, as required by section 1833(t)(3)(F)(ii) of the Act, that we reduce the OPD fee schedule increase factor by 0.1 percentage point for CY 2012. We also proposed to amend § 419.32(b)(1)(iv)(A) to indicate that the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act is further reduced by the adjustments necessary to satisfy the requirements in sections 1833(t)(3)(F) and (t)(3)(G) of the Act.

We did not receive any public comments on our proposed adjustments to the OPD fee schedule increase factor or on the proposed changes to § 419.32(b)(1)(iv)(B) to add a new paragraph (3). We also did not receive any public comments on our proposed change to § 419.32(b)(1)(iv)(A). For the reasons discussed above, we are adjusting the OPD fee schedule increase factor and are making the two changes to § 419.32 as proposed.

To set the OPPS conversion factor for CY 2012, we increased the CY 2011 conversion factor of $68.876 by 1.9 percent. In accordance with section 1833(t)(9)(B) of the Act, we further adjusted the conversion factor for CY 2012 to ensure that any revisions we make to the updates for a revised wage index and rural adjustment are made on a budget neutral basis. We calculated an overall budget neutrality factor of 1.0005 for wage index changes by comparing total estimated payments from our simulation model using the FY 2012 IPPS final wage indices to those payments using the current (FY 2011) IPPS wage indices, as adopted on a calendar year basis for the OPPS.

For CY 2012, we are not making a change to our rural adjustment policy. Therefore, the budget neutrality factor for the rural adjustment is 1.0000.

For CY 2012, we are finalizing a payment adjustment policy for dedicated cancer hospitals, as discussed in section II.F. of this final rule with comment period. Consistent with the final cancer hospital payment adjustment policies discussed in section II.F. of this final rule with comment period, we calculated a CY 2012 budget neutrality adjustment factor of 0.9978 by comparing the estimated total payments under section 1833(t) of the Act, including the cancer hospital adjustment under section 1833(t)(18)(B) and 1833(t)(2)(E) of the Act, to hospitals described in section 1886(d)(1)(B)(v) of the Act to the estimated total payments under section 1833(t) of the Act if there were no cancer hospital adjustment, including TOPS that would otherwise be made to hospitals described in section 1886(d)(1)(B)(v) of the Act. As discussed in section II.F. of this final rule with comment period, in terms of dollars, the budget neutrality payment reduction is estimated to be $71 million for CY 2012; that is, we estimate that total payments with a cancer hospital payment adjustment would increase total payments by $71 million and this amount needs to be offset by adjusting other payments. Therefore, we applied a budget neutrality adjustment factor of 0.9978 to the conversion factor to make the hospital adjustment budget neutral.

For this final rule with comment period, we estimate that pass-through spending for both drugs and biologicals and devices for CY 2012 will equal approximately $89 million, which represents 0.22 percent of total projected CY 2012 OPPS spending. Therefore, the conversion factor is also adjusted by the difference between the 0.15 percent estimate of pass-through spending for CY 2011 and the 0.22 percent estimate of CY 2012 pass-through spending, resulting in an adjustment for CY 2012 of 0.07 percent. Finally, estimated payments for outliers remain at 1.0 percent of total OPPS payments for CY 2012.

The OPD fee schedule increase factor of 1.9 percent for CY 2012 (that is, the estimate of the hospital market basket increase of 3.0 percent less the 1.0 percentage point MFP adjustment and less the 0.1 percentage point adjustment which were necessary in order to comply with the requirements of the Affordable Care Act), the required wage index budget neutrality adjustment of approximately 1.0005, the cancer hospital payment adjustment of 0.9978, and the adjustment of 0.07 percent of projected OPPS spending for the difference in the pass-through spending result in a conversion factor for CY 2012 of $70.016. This conversion factor for CY 2012 of $70.016 reflects the full OPD fee schedule increase, after including the adjustments which were necessary in order to comply with the requirements of the Affordable Care Act.

As we stated in the proposed rule, hospitals that fail to meet the reporting requirements of the Hospital OQR Program would continue to be subject to a further reduction of additional 2.0 percentage points from the OPD fee schedule increase factor adjustment to the conversion factor that would be used to calculate the OPPS payment rates made for their services as required by section 1833(t)(17) of the Act. For a complete discussion of the Hospital OQR requirements and the payment reduction for hospitals that fail to meet those requirements, we refer readers to section XIV. E. of the proposed rule and this final rule with comment period. To calculate the CY 2012 reduced market basket conversion factor for those hospitals that fail to meet the requirements of the Hospital OQR Program for the full CY 2012 payment update, we are making all other adjustments discussed above, but using a reduced OPD fee schedule update factor of −0.1 percent (that is, the OPD fee schedule increase factor of 1.9 percent further reduced by 2.0 percentage points as required by section 1833(t)(17)(A)(i) of the Act for failure to comply with the Hospital OQR requirements). This resulted in a reduced conversion factor for CY 2012 of $68.616 for those hospitals that fail to meet the Hospital OQR requirements (a difference of −$1.40 in the conversion factor relative to those hospitals that met the Hospital OQR requirements).

We did not receive any public comments on our proposed methodology for calculating the CY 2012 conversion factor.

In summary, for CY 2012, we are using a final conversion factor of $70.016 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using median costs. We did not receive any public comments on this proposal. Therefore, for the reasons we discuss above, we are amending § 419.32(b)(1)(iv)(B) by adding a new paragraph (3) to reflect the reductions to the OPD fee schedule increase factor that are required for CY 2012 in order to satisfy the statutory requirements of sections 1833(t)(3)(F) and (t)(3)(G)(ii) of the Act. We also are amending § 419.32(b)(1)(iv)(A) to indicate that the hospital inpatient market basket percentage increase is reduced by the adjustments described in § 419.32(b)(1)(iv)(B). We are using a reduced conversion factor of $68.616 in the calculation of payments for hospitals that fail to comply with the Hospital OQR requirements to reflect the reduction to the OPD fee schedule increase factor that is required by section 1833(t)(17) of the Act for these hospitals.

C. Wage Index Changes

Section 1833(t)(2)(D) of the Act requires the Secretary to determine a wage adjustment factor to adjust, for geographic wage differences, the portion of the OPPS payment rate, which includes the copayment standardized amount, that is attributable to labor and labor-related cost. This portion of the OPPS payment rate is called the OPPS

labor-related share. This adjustment must be made in a budget neutral manner and budget neutrality is discussed in section II.B. of this final rule with comment period.

The OPPS labor-related share is 60 percent of the national OPPS payment. This labor-related share is based on a regression analysis that determined that, for all hospitals, approximately 60 percent of the costs of services paid under the OPPS were attributable to wage costs. We confirmed that this labor-related share for outpatient services is appropriate during our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553). Therefore, in the CY 2012 OPPS/ASC proposed rule (76 FR42211), we did not propose to revise this policy for the CY 2012 OPPS. We refer readers to section II.H. of this final rule with comment period for a description and example of how the wage index for a particular hospital is used to determine the payment for the hospital.

As discussed in section II.A.2.c. of this final rule with comment period, for estimating national median APC costs, we standardize 60 percent of estimated claims costs for geographic area wage variation using the same FY 2012 pre-reclassified wage index that the IPPS uses to standardize costs. This standardization process removes the effects of differences in area wage levels from the determination of a national unadjusted OPPS payment rate and the copayment amount.

As published in the original OPPS April 7, 2000 final rule with comment period (65 FR 18545), the OPPS has consistently adopted the final fiscal year IPPS wage index as the calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences. Thus, the wage index that applies to a particular acute care short-stay hospital under the IPPS also applies to that hospital under the OPPS. As initially explained in the September 8, 1998 OPPS proposed rule, we believed that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In accordance with section 1886(d)(3)(E) of the Act, the IPPS wage index is updated annually.

The Affordable Care Act contains provisions that affect the final FY 2012 IPPS wage index values, including revisions to the reclassification wage comparability criteria that were finalized in the FY 2009 IPPS final rule (73 FR 48568 through 48570), and the application of rural floor budget neutrality on a national, rather than State-specific, basis through a uniform, national adjustment to the area wage index (76 FR 26021). In addition, section 10324 of the Affordable Care Act requires CMS to establish an adjustment to create a wage index floor of 1.00 for hospitals located in States determined to be frontier States.

Section 10324 of the Affordable Care Act specifies that, for services furnished beginning CY 2011, the wage adjustment factor applicable to any HOPD that is located in a frontier State (as defined in section 1886(d)(3)(E)(iii)(II) of the Act) may not be less than 1.00. Further, section 10324 states that this adjustment to the wage index for these outpatient departments should not be made in a budget neutral manner. As such, for the CY 2012 OPPS, as we proposed, we are continuing to adjust the FY 2012 IPPS wage index, as adopted on a calendar year basis for the OPPS, for all hospitals paid under the OPPS, including non-IPPS hospitals (providers that are not paid under the IPPS) located in a frontier State, to 1.00 in instances where the FY 2012 wage index (that reflects Medicare Geographic Classification Review Board (MGCRB) reclassifications, the application of the rural floor, and the rural floor budget neutrality adjustment) for these hospitals is less than 1.00. Similar to our current policy for HOPDs that are affiliated with multicampus hospital systems, we fully expect that the HOPD will receive a wage index based on the geographic location of the specific inpatient hospital with which it is associated. Therefore, if the associated hospital is located in a frontier State, the wage index adjustment applicable for the hospital will also apply for the affiliated HOPD. We refer readers to the FY 2011 and FY 2012 IPPS/LTCH PPS final rules (75 FR 50160 and 76 FR 51581, respectively) for a detailed discussion regarding this provision, including our methodology for identifying which areas meet the definition of frontier States as provided for in section 1886(d)(3)(E)(iii)(II)) of the Act.

In addition to the changes required by the Affordable Care Act, we note that the FY 2012 IPPS wage indices continue to reflect a number of adjustments implemented over the past few years, including, but not limited to, reclassification of hospitals to different geographic areas, the rural floor provisions, an adjustment for occupational mix, and an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment). We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51581 through 51605) for a detailed discussion of all changes to the FY 2012 IPPS wage indices. In addition, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65842 through 65844) and subsequent OPPS rules for a detailed discussion of the history of these wage index adjustments as applied under the OPPS.

Section 3137 of the Affordable Care Act extended, through FY 2010, section 508 reclassifications as well as certain special exceptions. The most recent extension of the provision was included in section 102 of the Medicare and Medicaid Extender Act, which extends, through FY 2011, section 508 reclassifications as well as certain special exceptions. The latest extension of these provisions expired on September 30, 2011, and is no longer applicable effective with FY 2012. As we did for CY 2010, we revised wage index values for certain special exception hospitals from January 1, 2011 through December 31, 2011, under the OPPS, in order to give these hospitals the special exception wage indices under the OPPS for the same time period as under the IPPS. In addition, because the OPPS pays on a calendar year basis, the effective date under the OPPS for all other nonsection 508 and non-special exception providers was July 1, 2011, instead of April 1, 2011, so that these providers also received a full 6 months of payment under the revised wage index comparable to the IPPS.

For purposes of the OPPS, as we proposed, we are continuing our policy in CY 2012 of allowing non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)). We note that, because non-IPPS hospitals cannot reclassify, they are eligible for the out-migration wage adjustment. Table 4J listed in the FY 2012 IPPS/LTCH PPS final rule (and made available via the Internet on the CMS Web site at: *http://www.cms.gov/AcuteInpatientPPS/01_overview.asp*) identifies counties eligible for the out-migration adjustment and hospitals that will receive the adjustment for FY 2012. We note that, beginning with FY 2012, under the IPPS, an eligible hospital that waives its Lugar status in order to receive the out-migration adjustment has effectively waived its deemed urban status and, thus, is rural for all purposes under the IPPS, including being considered rural for the disproportionate share hospital (DSH)

payment adjustment, effective for the fiscal year in which the hospital receives the out-migration adjustment. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599) for a more detailed discussion on the Lugar redesignation waiver for the out-migration adjustment). As we have done in prior years, we are including Table 4J as Addendum L to this final rule with comment period with the addition of non-IPPS hospitals that will receive the section 505 out-migration adjustment under the CY 2012 OPPS. Addendum L is referenced in section XVII. of this final rule with comment period and available via the Internet on the CMS Web site.

As stated earlier in this section, our longstanding policy for OPPS has been to adopt the final wage index used in IPPS. Therefore, for calculating OPPS payments in CY 2012, we used the FY 2012 IPPS wage indices. However, section 1833(t)(2)(D) of the Act confers broad discretionary authority upon the Secretary in determining the wage adjustment factor used under the OPPS. Specifically, this provision provides that ''subject to paragraph (19), the Secretary shall determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions. * * *'' In other prospective payment systems, we do not adopt the adjustments applied to the IPPS wage index, such as the out-migration adjustment, reclassifications, and the rural floor. For the OPPS, using the IPPS wage index as the source of an adjustment factor for geographic wage differences has, in the past, been both reasonable and logical, given the inseparable, subordinate status of the outpatient department within the hospital overall.

However, in recent years, we have become concerned that hospitals converting their status significantly inflate wage indices across a State. In the FY 2008 IPPS final rule (72 FR 47324 and 47325), we discussed a situation where a CAH may have converted back to IPPS status in order to increase the rural floor.

The FY 2012 IPPS/LTCH PPS final rule (76 FR 51824) shows the impact of this CAH conversion. Hospitals in Massachusetts can expect an approximate 8.7percent increase in IPPS payments due to the conversion and the resulting increase of the rural floor. Our concern is that the manipulation of the rural floor is of sufficient magnitude that it requires all hospital wage indices to be reduced approximately 0.62 percent as a result of nationwide budget neutrality for the rural floor (or more than a 0.4 percent total payment reduction to all IPPS hospitals).

In addition to the CAH conversion, we recently received two requests from urban hospitals to convert to rural hospital status under section 1886(d)(8)(E) of the Act, which would inflate other States' rural floors, through the conversion of what would otherwise be urban hospitals to rural status. While we recognize that conversions from urban-to-rural status are permitted under section 1886(d)(8)(E) of the Act, we are concerned with individual urban to rural conversions allowing payment redistributions of this magnitude.

We believe the above discussions demonstrate that the rural floor is resulting in significant disparities in wage index and, in some cases, resulting in situations where all hospitals in a State receive a wage index higher than that of the single highest wage index urban hospital in the State. As stated above, the statute does not require the Secretary to use the IPPS wage adjustment factor to wage adjust OPPS payments and copayments, nor to apply to OPPS payment and copayment calculations the same wage adjustment factor that the law requires be applied to IPPS payments.

In the CY 2012 OPPS/ASC proposed rule (76 FR 42212), we stated that we were considering the adoption of a policy that would address situations where IPPS wage index adjustments, such as the rural floor, result in significant fluctuations in the wage index within a State. One option we proposed would be not to apply the rural floor wage index at all in the OPPS where the rural floor is set by a small number of hospitals in a State and results in a rural floor that benefits all hospitals in the State. Alternatively, we proposed that we could apply within-State rural budget neutrality to the OPPS wage index as we did for both the IPPS and OPPS wage index beginning in FY 2009. In the proposed rule, we sought public comment on whether to: (1) Adopt the IPPS wage index for the OPPS in its entirety including the rural floor, geographic reclassifications, and all other wage index adjustments (our current policy); (2) adopt the IPPS wage index for the OPPS in its entirety except when a small number of hospitals set the rural floor for the benefit of all other hospitals in the State, and, if so, then not apply the rural floor wage index; (3) adopt the IPPS wage index for the OPPS in its entirety except apply rural floor budget neutrality within each State instead of nationally; or (4) adopt another decision rule for when the rural floor should not be applied in the OPPS when we have concerns about disproportionate impact.

We also requested public comments on an option that we were considering adopting for both the IPPS and the OPPS, where we would determine the applicable rural wage index floor using only data from those hospitals geographically rural under OMB and the Census Bureau's MSA designations, and without including wage data associated with hospitals reclassified from urban to rural status under section 1886(d)(8)(E) of the Act. Such a policy would eliminate the incentive to reclassify from urban to rural status primarily to increase rural floors across a State, and would ensure that the rural floor is based upon hospitals located in rural areas.

Comment: Commenters that were in favor of maintaining the current policy (option 1 listed above) of adopting the IPPS wage indices under the OPPS cited several different reasons for their choice. Several commenters believed that hospital inpatient and outpatient departments are ''inseparable'' because they are subject to the same labor cost environment, and, therefore, should have the same wage index where applicable. Other commenters preferred maintaining the current wage index policy and implementing wage index changes in the context of comprehensive wage index reform. These commenters believed that only comprehensive wage index reform can revise the wage index in such as way as ''to minimize volatility of the wage index and remove incentives to game the system.'' Commenters stated that an additional reason for maintaining the current policy was that different wage indices for inpatient and outpatient payments would add a level of administrative complexity that is overly burdensome and unnecessary.

Several commenters expressed a preference for wage index policy option 2 included in the proposed rule (to adopt the IPPS wage index for the OPPS in its entirety except when a small number of hospitals set the rural floor for the benefit of all other hospitals in the State, and, if so, then not apply the rural floor wage index). These commenters typically viewed this option to be the best in terms of addressing current inequities. However, some of the commenters requested that CMS explicitly define a ''small number'' threshold as well as what is considered as a ''benefit'' for all other hospitals in the State. Some commenters that supported option 2 preferred option 2 to option 3 (the adoption of the IPPS wage index policies but application of statewide rather than national budget

neutrality for the rural floor policy). Commenters that preferred option 2 rather than option 3 argued that a national level adjustment was in keeping with Congressional intent, especially given that Congress enacted legislation to establish national budget neutrality for the rural floor in the IPPS under the Affordable Care Act (effective in FY 2011). These commenters also were concerned about CMS deciding when budget neutrality adjustments should be applied at the State versus national levels.

Several commenters favored option 3 because they supported the application of statewide level budget neutrality for the rural floor policy. These commenters favored basing the wage index on Bureau of Labor Statistics (BLS) data rather than hospital cost reports but believed that, in the absence of broader wage index reform, option 3 was the most equitable policy. One commenter, although supportive of systematic wage index reform, stated that CMS ''should not wait for reform to address obvious and significant immediate problems'' and therefore advocated for option 3.

Instead of recommending other policy options, for the fourth potential wage index policy option (adopting another decision rule), most commenters simply requested further detail. Several commenters did not exhibit any preferences for any specific wage index policy options, choosing instead to comment generally about issues of concern. One commenter believed that ''looking at one policy in isolation serves only to address one issue while likely creating other inequities in the system.'' Another commenter was concerned that any new rule could unnecessarily harm rural providers. Another commenter that supported systematic wage index reform advocated not making changes until reports from the Institute of Medicine are completed and the CMS report to Congress, which is due on December 31, 2011, are fully analyzed. Commenters requested further detail to formulate a policy position on the four options presented and urged CMS to include impact analyses for the final rule.

Response: We appreciate the public comments. We acknowledge that there may be inequities in the current application of the wage index policy and its various adjustments. This is why we described various methods and wage index options that we might consider under the OPPS to address manipulation of wage index adjustment policies, and, in this specific case, the rural floor wage index and its national level budget neutrality.

In the CY 2012 OPPS/ASC proposed rule, we referred specifically to the conversion of one CAH to IPPS status to increase the rural floor for the State, which would increase IPPS and OPPS payments to that State, while decreasing IPPS and OPPS payments to hospitals in other States, under a policy in which the rural floor wage index budget neutrality was applied at the national level. Similarly, we are aware of requests from urban hospitals to convert to rural hospital status, which would inflate those States' rural floors. While we recognize that conversions from urban-to-rural status are permitted under section 1886(d)(8)(E) of the Act, we are concerned with individual urban-to-rural conversions that would result in payment redistributions of this magnitude.

However, we agree with the commenters that stated that maintaining the current policy for CY 2012 would be the best option, given the broader wage index reform currently under development and consideration. This includes the Report to Congress with a plan for wage index reform, which is due December 31, 2011, under the Affordable Care Act. We will continue to consider these policy options in future rulemaking, especially in the context of other significant wage index revisions. In response to commenters' recommendations that we provide more detailed impact analysis, we are providing a State level impact table, similar to the table provided in the FY 2012 IPPS/LTCH final rule (76 FR 51824 through 51825), that displays the impact of the rural floor and imputed floor policies with national budget neutrality on OPPS hospitals and their payments by State. This table is included in section XX. of this final rule with comment period.

Comment: A few commenters responded to our request for comments on setting the applicable rural wage index floor using only data from hospitals that are geographically rural according to OMB and MSA designations, and without including wage data associated with hospitals reclassified from urban to rural status under section 1886(d)(8)(E) of the Act. One commenter opposed using data from geographically rural hospitals alone in setting the rural floor because reclassified hospitals are considered rural for all payment policies. Several commenters agreed that wage data associated with hospitals that are reclassified should be excluded from calculation of the rural floor. One commenter questioned why it is necessary to maintain the rural floor wage index policy under the OPPS.

Response: For the reasons stated above, in this final rule with comment period, we are adopting the IPPS wage index and its adjustments for use under the OPPS. However, in the IPPS proposed rule for FY 2013, we may address the issue of including hospitals reclassified from urban to rural status under section 1886(d)(8)(E) of the Act.

Comment: One commenter asked whether an increase similar to the 1.1 percent increase included in the FY 2012 IPPS/LTCH final rule (76 FR 51788) should also apply under the OPPS.

Response: The increase cited by the commenter is limited to IPPS payments. Budget neutrality (including that for the rural floor) is calculated prospectively each year under the OPPS. While we have historically adopted the IPPS wage index when developing the wage indices for calculating payments under the OPPS, the budget neutrality factors that applied to the standardized amount under IPPS as a result of the rural floor were not applied to the OPPS conversion factor, and thus would not have any effect on OPPS budget neutrality.

After consideration of the public comments we received, we are finalizing our policy to adopt the FY 2012 IPPS wage index for the CY 2012 OPPS in its entirety including the rural floor, geographic reclassifications, and all other wage index adjustments.

With the exception of the out-migration wage adjustment table (Addendum L to this final rule with comment period, which is available via the Internet on the CMS Web site), which includes non-IPPS hospitals paid under the OPPS, we are not reprinting the final FY 2012 IPPS wage indices referenced in this discussion of the wage index. We refer readers to the CMS Web site for the OPPS at: *http://www.cms.gov/HospitalOutpatientPPS/.* At this link, readers will find a link to the final FY 2012 IPPS wage index tables.

D. Statewide Average Default CCRs

In addition to using CCRs to estimate costs from charges on claims for ratesetting, CMS uses overall hospital-specific CCRs calculated from the hospital's most recent cost report to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPS during the PPS year. Medicare contractors cannot calculate a CCR for some hospitals because there is no cost report available. For these hospitals, CMS uses the statewide average default CCRs to determine the payments mentioned above until a hospital's Medicare contractor is able to

calculate the hospital's actual CCR from its most recently submitted Medicare cost report. These hospitals include, but are not limited to, hospitals that are new, have not accepted assignment of an existing hospital's provider agreement, and have not yet submitted a cost report. CMS also uses the statewide average default CCRs to determine payments for hospitals that appear to have a biased CCR (that is, the CCR falls outside the predetermined ceiling threshold for a valid CCR) or for hospitals in which the most recent cost report reflects an all-inclusive rate status (Medicare Claims Processing Manual (Pub. 100–04), Chapter 4, Section 10.11). As we proposed in the CY 2012 OPPS/ASC proposed rule (76 FR 42213), we are updating the default ratios for CY 2012 using the most recent cost report data. We discuss our policy for using default CCRs, including setting the ceiling threshold for a valid CCR, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599) in the context of our adoption of an outlier reconciliation policy for cost reports beginning on or after January 1, 2009.

We proposed to continue to use our standard methodology of calculating the statewide average default CCRs using the same hospital overall CCRs that we use to adjust charges to costs on claims data for setting the CY 2012 OPPS relative weights. Table 11 published in the proposed rule listed the proposed CY 2012 default urban and rural CCRs by State and compared them to last year's default CCRs. These proposed CCRs represented the ratio of total costs to total charges for those cost centers relevant to outpatient services from each hospital's most recently submitted cost report, weighted by Medicare Part B charges. We also adjusted ratios from submitted cost reports to reflect final settled status by applying the differential between settled to submitted overall CCRs for the cost centers relevant to outpatient services from the most recent pair of final settled and submitted cost reports. We then weighted each hospital's CCR by the volume of separately paid line-items on hospital claims corresponding to the year of the majority of cost reports used to calculate the overall CCRs. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66680 through 66682) and prior OPPS rules for a more detailed discussion of our established methodology for calculating the statewide average default CCRs, including the hospitals used in our calculations and our trimming criteria.

We did not receive any public comments on our CY 2012 proposal. We are finalizing our proposal to apply our standard methodology of calculating the statewide average default CCRs using the same hospital overall CCRs that we used to adjust charges to costs on claims data for setting the CY 2012 OPPS relative weights. We used this methodology to calculate the statewide average default CCRs listed in Table 11 below.

For this CY 2012 OPPS/ASC final rule with comment period, approximately 47 percent of the submitted cost reports utilized in the default ratio calculations represented data for cost reporting periods ending in CY 2010 and 53 percent were for cost reporting periods ending in CY 2009. For Maryland, we used an overall weighted average CCR for all hospitals in the Nation as a substitute for Maryland CCRs. Few hospitals in Maryland are eligible to receive payment under the OPPS, which limits the data available to calculate an accurate and representative CCR. The weighted CCR is used for Maryland because it takes into account each hospital's volume, rather than treating each hospital equally. We refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65822) for further discussion and the rationale for our longstanding policy of using the national average CCR for Maryland. In general, observed changes in the statewide average default CCRs between CY 2011 and CY 2012 are modest and the few significant changes are associated with areas that have a small number of hospitals.

Table 11 below lists the finalized statewide average default CCRs for OPPS services furnished on or after January 1, 2012.

BILLING CODE 4120–01–P

TABLE 11.—CY 2012 STATEWIDE AVERAGE CCRs

State	Urban/Rural	CY 2012 Default CCR	Previous Default CCR (CY 2011 OPPS Final Rule)
ALASKA	RURAL	0.487	0.479
ALASKA	URBAN	0.321	0.315
ALABAMA	RURAL	0.213	0.212
ALABAMA	URBAN	0.191	0.193
ARKANSAS	RURAL	0.225	0.223
ARKANSAS	URBAN	0.274	0.282
ARIZONA	RURAL	0.236	0.231
ARIZONA	URBAN	0.193	0.202
CALIFORNIA	RURAL	0.189	0.195
CALIFORNIA	URBAN	0.202	0.205
COLORADO	RURAL	0.345	0.350
COLORADO	URBAN	0.225	0.233
CONNECTICUT	RURAL	0.356	0.356
CONNECTICUT	URBAN	0.292	0.291
DISTRICT OF COLUMBIA	URBAN	0.301	0.313
DELAWARE	RURAL	0.280	0.279
DELAWARE	URBAN	0.347	0.362
FLORIDA	RURAL	0.183	0.185
FLORIDA	URBAN	0.170	0.172
GEORGIA	RURAL	0.241	0.246
GEORGIA	URBAN	0.214	0.220
HAWAII	RURAL	0.320	0.356
HAWAII	URBAN	0.306	0.308
IOWA	RURAL	0.297	0.252
IOWA	URBAN	0.272	0.288
IDAHO	RURAL	0.416	0.419
IDAHO	URBAN	0.378	0.384
ILLINOIS	RURAL	0.245	0.251
ILLINOIS	URBAN	0.240	0.239
INDIANA	RURAL	0.298	0.302
INDIANA	URBAN	0.268	0.270

State	Urban/Rural	CY 2012 Default CCR	Previous Default CCR (CY 2011 OPPS Final Rule)
KANSAS	RURAL	0.282	0.286
KANSAS	URBAN	0.209	0.215
KENTUCKY	RURAL	0.223	0.220
KENTUCKY	URBAN	0.245	0.244
LOUISIANA	RURAL	0.256	0.256
LOUISIANA	URBAN	0.226	0.235
MARYLAND	RURAL	0.280	0.284
MARYLAND	URBAN	0.251	0.256
MASSACHUSETTS	URBAN	0.320	0.314
MAINE	RURAL	0.440	0.460
MAINE	URBAN	0.460	0.450
MICHIGAN	RURAL	0.313	0.312
MICHIGAN	URBAN	0.314	0.320
MINNESOTA	RURAL	0.482	0.483
MINNESOTA	URBAN	0.326	0.311
MISSOURI	RURAL	0.248	0.258
MISSOURI	URBAN	0.267	0.264
MISSISSIPPI	RURAL	0.226	0.229
MISSISSIPPI	URBAN	0.186	0.182
MONTANA	RURAL	0.434	0.444
MONTANA	URBAN	0.398	0.399
NORTH CAROLINA	RURAL	0.256	0.254
NORTH CAROLINA	URBAN	0.264	0.264
NORTH DAKOTA	RURAL	0.322	0.351
NORTH DAKOTA	URBAN	0.429	0.360
NEBRASKA	RURAL	0.323	0.328
NEBRASKA	URBAN	0.252	0.259
NEW HAMPSHIRE	RURAL	0.323	0.323
NEW HAMPSHIRE	URBAN	0.292	0.290
NEW JERSEY	URBAN	0.221	0.221
NEW MEXICO	RURAL	0.266	0.277
NEW MEXICO	URBAN	0.286	0.307

State	Urban/Rural	CY 2012 Default CCR	Previous Default CCR (CY 2011 OPPS Final Rule)
NEVADA	RURAL	0.242	0.269
NEVADA	URBAN	0.169	0.178
NEW YORK	RURAL	0.410	0.415
NEW YORK	URBAN	0.350	0.375
OHIO	RURAL	0.324	0.327
OHIO	URBAN	0.241	0.241
OKLAHOMA	RURAL	0.248	0.260
OKLAHOMA	URBAN	0.220	0.208
OREGON	RURAL	0.302	0.306
OREGON	URBAN	0.327	0.340
PENNSYLVANIA	RURAL	0.270	0.275
PENNSYLVANIA	URBAN	0.200	0.210
PUERTO RICO	URBAN	0.490	0.505
RHODE ISLAND	URBAN	0.287	0.284
SOUTH CAROLINA	RURAL	0.222	0.222
SOUTH CAROLINA	URBAN	0.217	0.227
SOUTH DAKOTA	RURAL	0.309	0.316
SOUTH DAKOTA	URBAN	0.253	0.251
TENNESSEE	RURAL	0.212	0.221
TENNESSEE	URBAN	0.201	0.204
TEXAS	RURAL	0.239	0.245
TEXAS	URBAN	0.210	0.216
UTAH	RURAL	0.385	0.386
UTAH	URBAN	0.359	0.362
VIRGINIA	RURAL	0.238	0.241
VIRGINIA	URBAN	0.257	0.263
VERMONT	RURAL	0.415	0.411
VERMONT	URBAN	0.365	0.365
WASHINGTON	RURAL	0.366	0.367
WASHINGTON	URBAN	0.317	0.327
WISCONSIN	RURAL	0.407	0.412
WISCONSIN	URBAN	0.327	0.334

State	Urban/Rural	CY 2012 Default CCR	Previous Default CCR (CY 2011 OPPS Final Rule)
WEST VIRGINIA	RURAL	0.283	0.291
WEST VIRGINIA	URBAN	0.335	0.337
WYOMING	RURAL	0.385	0.393
WYOMING	URBAN	0.302	0.296

BILLING CODE 4120–01–C

E. OPPS Payments to Certain Rural and Other Hospitals

1. Hold Harmless Transitional Payment Changes

When the OPPS was implemented, every provider was eligible to receive an additional payment adjustment (called either transitional corridor payments or transitional outpatient payments (TOPs)) if the payments it received for covered OPD services under the OPPS were less than the payments it would have received for the same services under the prior reasonable cost-based system (referred to as the pre-BBA amount). Section 1833(t)(7) of the Act provides that the TOPs were temporary payments for most providers and intended to ease their transition from the prior reasonable cost-based payment system to the OPPS system. There are two exceptions to this temporary provision, cancer hospitals and children's hospitals. Such a hospital could receive TOPs to the extent its PPS amount was less than its pre-BBA amount in the applicable year. Section 1833(t)(7)(D)(i) of the Act originally provided for TOPs to rural hospitals with 100 or fewer beds for covered OPD services furnished before January 1, 2004. However, section 411 of Pub. L. 108–173 (the Medicare Prescription Drug, Improvement, and Modernization Act of 2003) amended section 1833(t)(7)(D)(i) of the Act to extend these payments through December 31, 2005, for rural hospitals with 100 or fewer beds. Section 411 also extended the TOPs to sole community hospitals (SCHs) located in rural areas for services furnished during the period that began with the provider's first cost reporting period beginning on or after January 1, 2004, and ending on December 31, 2005. Accordingly, the authority for making TOPs under section 1833(t)(7)(D)(i) of the Act, as amended by section 411 of Public Law 108–173, for rural hospitals having 100 or fewer beds and SCHs located in rural areas expired on December 31, 2005.

Section 5105 of Public Law 109–171 (the Deficit Reduction Act of 2005) extended the TOPs for covered OPD services furnished on or after January 1, 2006, and before January 1, 2009, for rural hospitals having 100 or fewer beds that are not SCHs. Section 5105 also reduced the TOPs to rural hospitals from 100 percent of the difference between the provider's OPPS payments and the pre-BBA amount. When the OPPS payment was less than the provider's pre-BBA amount, the amount of payment was increased by 95 percent of the amount of the difference between the two amounts for CY 2006, by 90 percent of the amount of that difference for CY 2007, and by 85 percent of the amount of that difference for CY 2008.

For CY 2006, we implemented section 5105 of Public Law 109–171 through Transmittal 877, issued on February 24, 2006. In the Transmittal, we did not specifically address whether TOPs apply to essential access community hospitals (EACHs), which are considered to be SCHs under section 1886(d)(5)(D)(iii)(III) of the Act. Accordingly, under the statute, EACHs are treated as SCHs. In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010), we stated that EACHs were not eligible for TOPs under Public Law 109–171. However, we stated they were eligible for the adjustment for rural SCHs authorized under section 411 of Public Law 108–173. In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010 and 68228), we updated § 419.70(d) of our regulations to reflect the requirements of Public Law 109–171.

In the CY 2009 OPPS/ASC proposed rule (73 FR 41461), we stated that, effective for services provided on or after January 1, 2009, rural hospitals having 100 or fewer beds that are not SCHs would no longer be eligible for TOPs, in accordance with section 5105 of Public Law 109–171. However, subsequent to issuance of the CY 2009 OPPS/ASC proposed rule, section 147 of Public Law 110–275 amended section 1833(t)(7)(D)(i) of the Act by extending the period of TOPs to rural hospitals with 100 beds or fewer for 1 year, for services provided before January 1, 2010. Section 147 of Public Law 110–275 also extended TOPs to SCHs (including EACHs) with 100 or fewer beds for covered OPD services provided on or after January 1, 2009, and before January 1, 2010. In accordance with section 147 of Public Law 110–275, when the OPPS payment is less than the provider's pre-BBA amount, the amount of payment is increased by 85 percent of the amount of the difference between the two payment amounts for CY 2009.

For CY 2009, we revised our regulations at §§ 419.70(d)(2) and (d)(4) and added a new paragraph (d)(5) to incorporate the provisions of section 147 of Public Law 110–275. In addition, we made other technical changes to § 419.70(d)(2) to more precisely capture our existing policy and to correct an inaccurate cross-reference. We also made technical corrections to the cross-references in paragraphs (e), (g), and (i) of § 419.70.

For CY 2010, we made a technical correction to the heading of § 419.70(d)(5) to correctly identify the policy as described in the subsequent regulation text. The paragraph heading now indicates that the adjustment applies to small SCHs, rather than to rural SCHs.

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60425), we stated that, effective for services provided on or after January 1, 2010, rural hospitals and SCHs (including EACHs) having 100 or fewer beds would no longer be eligible for TOPs, in accordance with section 147 of Public Law 110–275. However, subsequent to issuance of the CY 2010 OPPS/ASC final rule with comment period, section 3121(a) of the Affordable Care Act amended section 1833(t)(7)(D)(i)(III) of the Act by extending the period of TOPs to rural hospitals that are not SCHs with 100 beds or fewer for 1 year, for services provided before January 1, 2011. Section 3121(a) of the Affordable Care Act amended section 1833(t)(7)(D)(i)(III) of the Act and extended the period of TOPs to SCHs (including EACHs) for 1

year, for services provided before January 1, 2011, and section 3121(b) of the Affordable Care Act removed the 100-bed limitation applicable to such SCHs for covered OPD services furnished on and after January 1, 2010, and before January 1, 2011. In accordance with section 3121 of the Affordable Care Act, when the OPPS payment is less than the provider's pre-BBA amount, the amount of payment is increased by 85 percent of the amount of the difference between the two payment amounts for CY 2010. Accordingly, in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71882), we updated § 419.70(d) of the regulations to reflect the TOPs extensions and amendments described in section 3121 of the Affordable Care Act.

Section 108 of the Medicare and Medicaid Extenders Act of 2010 (MMEA) (Pub. L. 111–309) extended for 1 year the hold harmless provision for a rural hospital with 100 or fewer beds that is not an SCH (as defined in section 1886(d)(5)(D)(iii) of the Act). Therefore, for such a hospital, for services furnished before January 1, 2012, when the PPS amount is less than the provider's pre-BBA amount, the amount of payment is increased by 85 percent of the amount of the difference between the two payments. In addition, section 108 of the MMEA also extended for 1 year the hold harmless provision for an SCH (as defined in section 1886(d)(5)(D)(iii) of the Act (including EACHs) and removed the 100-bed limit applicable to such SCHs for covered OPD services furnished on or after January 1, 2010 and before January 1, 2012. Therefore, for such hospitals, for services furnished before January 1, 2012, when the PPS amount is less than the provider's pre-BBA amount, the amount of payment is increased by 85 percent of the amount of the difference between the two payments. Effective for services provided on or after January 1, 2012, a rural hospital with 100 or fewer beds that is not an SCH and an SCH (including EACHs) will no longer be eligible for TOPs, in accordance with section 108 of the MMEA. In the CY 2012 OPPS/ASC proposed rule (76 FR 42216), we proposed to revise our regulations at § 419.70(d) to conform the regulation text to the self-implementing provisions of section 108 of the MMEA described above.

We did not receive any public comments on our proposed policy to update the language in § 419.70(d) of the regulations. For the reasons we specified in the CY 2012 OPPS/ASC proposed rule (76 FR 42215 and 42216), we are finalizing our proposed revisions of § 419.70(d) without modification.

2. Adjustment for Rural SCHs and EACHs Under Section 1833(t)(13)(B) of the Act

In the CY 2006 OPPS final rule with comment period (70 FR 68556), we finalized a payment increase for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding drugs, biologicals, brachytherapy sources, and devices paid under the pass-through payment policy in accordance with section 1833(t)(13)(B) of the Act, as added by section 411 of Pub. L. 108–173. Section 411 gave the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act.

In CY 2007, we became aware that we did not specifically address whether the adjustment applies to EACHs, which are considered to be SCHs under section 1886(d)(5)(D)(iii)(III) of the Act. Thus, under the statute, EACHs are treated as SCHs. Therefore, in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010 and 68227), for purposes of receiving this rural adjustment, we revised § 419.43(g) to clarify that EACHs are also eligible to receive the rural SCH adjustment, assuming these entities otherwise meet the rural adjustment criteria. Currently, three hospitals are classified as EACHs, and as of CY 1998, under section 4201(c) of Public Law 105–33, a hospital can no longer become newly classified as an EACH.

This adjustment for rural SCHs is budget neutral and applied before calculating outliers and copayment. As we stated in the CY 2006 OPPS final rule with comment period (70 FR 68560), we would not reestablish the adjustment amount on an annual basis, but we may review the adjustment in the future and, if appropriate, would revise the adjustment. We provided the same 7.1 percent adjustment to rural SCHs, including EACHs, again in CYs 2008 through 2011. Further, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68590), we updated the regulations at § 419.43(g)(4) to specify, in general terms, that items paid at charges adjusted to costs by application of a hospital-specific CCR are excluded from the 7.1 percent payment adjustment.

For the CY 2012 OPPS, we proposed to continue our policy of a budget neutral 7.1 percent payment adjustment for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs (76 FR 46232). In the CY 2012 OPPS/ASC proposed rule, we indicated that we intend to reassess the 7.1 percent adjustment in the near future by examining differences between urban hospitals' costs and rural hospitals' costs using updated claims data, cost reports, and provider information.

We did not receive any public comments regarding the proposed continuation of the 7.1 rural adjustment. We are finalizing our CY 2012 proposal, without modification, to apply the 7.1 percent payment adjustment to rural SCHs, including EACHs, for all services and procedures paid under the OPPS in CY 2012, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs because we continue to believe that the adjustment is appropriate for application in CY 2012.

F. OPPS Payments to Certain Cancer Hospitals Described by Section 1886(d)(1)(B)(v) of the Act

1. Background

Since the inception of the OPPS, which was authorized by the Balanced Budget Act of 1997 (BBA), Medicare has paid cancer hospitals identified in section 1886(d)(1)(B)(v) of the Act (cancer hospitals) under the OPPS for covered outpatient hospital services. There are 11 cancer hospitals that meet the classification criteria in section 1886(d)(1)(B)(v) of the Act. These 11 cancer hospitals are exempted from payment under the IPPS. With the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999, Congress created section 1833(t)(7) of the Act, ''Transitional Adjustment to Limit Decline in Payment,'' to serve as a permanent payment floor by limiting cancer hospitals' potential losses under the OPPS. Through section 1833(t)(7)(D)(ii) of the Act, a cancer hospital receives the full amount of the difference between payments for covered outpatient services under the OPPS and a ''pre-BBA'' amount. That is, cancer hospitals

are permanently held harmless to their ''pre-BBA'' amount, and they receive transitional outpatient payments (TOPs) to ensure that they do not receive a payment that is lower under the OPPS than the payment they would have received before implementation of the OPPS, as set forth in section 1833(t)(7)(F) of the Act. The ''pre-BBA'' payment amount is an amount equal to the product of the reasonable cost of the hospital for covered outpatient services for the portions of the hospital's cost reporting period (or periods) occurring in the current year and the base payment-to-cost ratio (PCR) for the hospital. The ''pre-BBA'' amount, including the determination of the base PCR, are defined at 42 CFR 419.70(f). TOPs are calculated on Worksheet E, Part B, of the Hospital and Hospital Health Care Complex Cost Report (Form CMS–2552–96 or Form CMS–2552–10, as applicable) each year. Section 1833(t)(7)(I) of the Act exempts TOPs from budget neutrality calculations. Almost all of the 11 cancer hospitals receive TOPs each year. The volume weighted average PCR for the cancer hospitals is 0.83, or the outpatient payment with TOPs to cancer hospitals is 83 percent of reasonable cost.

Section 3138 of the Affordable Care Act amended section 1833(t) of the Social Security Act by adding a new paragraph (18), which instructs the Secretary to conduct a study to determine if, under the OPPS, outpatient costs incurred by cancer hospitals described in section 1886(d)(1)(B)(v) of the Act with respect to APC groups exceed the costs incurred by other hospitals furnishing services under section 1833(t) of the Act, as determined appropriate by the Secretary. In addition, section 3138 of the Affordable Care Act requires the Secretary to take into consideration the cost of drugs and biologicals incurred by such hospitals when studying cancer hospital costliness. Further, section 3138 of the Affordable Care Act provides that if the Secretary determines that cancer hospitals' costs with respect to APC groups are determined to be greater than the costs of other hospitals furnishing services under section 1833(t) of the Act, the Secretary shall provide an appropriate adjustment under section 1833(t)(2)(E) of the Act to reflect these higher costs. Cancer hospitals described in section 1886(d)(1)(B)(v) of the Act remain eligible for TOPs (which are not budget neutral) and outlier payments (which are budget neutral).

2. Study of Cancer Hospitals' Costs Relative to Other Hospitals

It has been our standard analytical approach to use a combination of explanatory and payment regression models to assess the costliness of a class of hospitals while controlling for other legitimate influences of costliness, such as ability to achieve economies of scale, to ensure that costliness is due to the type of hospital and to identify appropriate payment adjustments. We used this approach in our CY 2006 OPPS final rule with comment period to establish the 7.1 percent payment adjustment for rural SCHs (70 FR 68556 through 68561). In our discussion for the CY 2006 OPPS proposed rule, we stated that a simple comparison of unit costs would not be sufficient to assess the costliness of a class of hospitals because the costs faced by individual hospitals, whether urban or rural, are a function of many varying factors, including local labor supply and the complexity and volume of services provided (70 FR 42699).

In constructing our analysis of cancer hospitals' costs with respect to APC groups relative to other hospitals, we considered whether our standard analytical approach to use a combination of explanatory and payment regression models would lead to valid results for this particular study, or whether we should develop a different or modified analytic approach. We note that the analyses presented in the CY 2006 OPPS proposed and final rules were designed to establish an adjustment for a large class of rural hospitals. In contrast, section 3138 of the Affordable Care Act is specifically limited to identifying an adjustment for 11 cancer hospitals to the extent their costs with respect to APC groups exceeded those costs incurred by other hospitals furnishing services under section 1833(t) of the Act. With such a small sample size (11 out of approximately 4,000 hospitals paid under the OPPS), we were concerned that the standard explanatory and payment regression models used to establish the rural hospital adjustment would lead to imprecise estimates of payment adjustments for this small group of hospitals. Further, section 3138 of the Affordable Care Act specifies explicitly that cost comparisons between classes of hospitals must include the cost of drugs and biologicals. In our CY 2006 analysis of rural hospitals, we excluded the cost of drugs and biologicals in our model because the extreme units associated with proper billing for some drugs and biologicals can bias the calculation of a service mix index, or volume weighted average APC relative weight, for each hospital (70 FR 42698). Therefore, we chose not to pursue our standard combination of explanatory and payment regression modeling to determine a proposed cancer hospital adjustment.

As discussed in the CY 2011 OPPS/ASC proposed rule (75 FR 46235), while we chose not to use our standard models to calculate a proposed cancer hospital adjustment, we determined it still would be appropriate to construct our usual provider-level analytical dataset consisting of variables related to assessing costliness with respect to APC groups, including average cost per unit for a hospital and the hospital's average APC relative weight as an indicator of the hospital's resource intensity, as measured by the APC relative weights. We used these variables to calculate univariate statistics that describe the costliness with respect to APC groups and related aspects of cancer hospitals and other hospitals paid under the OPPS. While descriptive statistics cannot control for the myriad factors that contribute to observed costs, we believed that stark differences in cost between cancer hospitals and other hospitals paid under the OPPS that would be observable by examining descriptive univariate statistics would provide some indication of relative costliness. We began our analysis of the cancer hospitals by creating an analytical dataset of hospitals billing under the OPPS for CY 2009 (a total of 3,933) that were included in our claims dataset for establishing the CY 2011 OPPS proposed APC relative weights. This analytical dataset included the 3,933 OPPS hospitals' total estimated cost (including packaged cost), total lines, total discounted units as modeled for CY 2011 OPPS payment, and the average weight of their separately payable services (total APC weight divided by total units) as modeled for the CY 2011 OPPS. We then summarized estimated utilization and payment for each hospital (''hospital-level''). These files consist of hospital-level aggregate costs (including the cost of packaged items and services), total estimated discounted units under the modeled proposed CY 2011 OPPS, total estimated volume of number of occurrences of separately payable HCPCS codes under the modeled proposed CY 2011 OPPS, and total relative weight of separately payable services under the modeled proposed CY 2011 OPPS. After summarizing modeled payment to the hospital-level, we removed 48 hospitals in Puerto Rico

from our dataset because we did not believe that their cost structure reflected the costs of most hospitals paid under the OPPS and because they could bias the calculation of hospital-weighted statistics. We then removed an additional 66 hospitals with a cost per unit of more than 3 standard deviations from the geometric mean (mean of the natural log) because including outliers in hospital-weighted descriptive statistics also could bias those statistics. This resulted in a dataset with 11 cancer hospitals and 3,808 other hospitals.

We included the following standard hospital-level variables that describe hospital costliness in our analysis file: Outpatient cost per discounted unit under the modeled CY 2011 OPPS (substituting a cost per administration, rather than a cost per unit, for drugs and biologicals); each hospital's proposed CY 2011 wage index as a measure of relative labor cost; the service-mix index, or volume-weighted average proposed CY 2011 APC relative weight (including a simulated weight for drugs and biologicals created by dividing the CY 2010 April ASP-based payment amount at ASP+6 percent appearing in Addendum A and B of the proposed rule by the proposed conversion factor of $68.267); outpatient volume based on number of occurrences of HCPCS codes in the CY 2009 claims data; and number of beds. We used these variables because they are key indicators of costliness with respect to APC groups under the modeled OPPS system, and they allowed us to assess the relative costliness of classes of hospitals under the proposed CY 2011 OPPS. A hospital's service mix index is a measure of resource intensity of the services provided by the hospital as measured by the proposed CY 2011 OPPS relative weights, and standardizing the cost per discounted unit by the service mix index creates an adjusted cost per unit estimate that reflects the remaining relative costliness of a hospital remaining after receiving the estimated payments that we proposed to make under the CY 2011 OPPS. In short, if a class of hospitals demonstrates higher cost per unit after standardization by service mix, it is an early indication that the class of hospitals may be significantly more costly in the regression models. We used these data to calculate the descriptive univariate statistics for cancer hospitals appearing in Table 12 below. We note that because drugs and biologicals are such a significant portion of the services that the cancer hospitals provide, and because section 3138 of the Affordable Care Act explicitly requires us to consider the cost of drugs and biologicals, we included the cost of these items in our total cost calculation for each hospital, counting each occurrence of a drug in the modeled proposed CY 2011 data (based on units in CY 2009 claims data). That is, we sought to treat each administration of a drug or biological as one unit.

In reviewing these descriptive statistics, we observed that cancer hospitals had a standardized cost per discounted unit of $150.12 compared to a standardized cost per discounted unit of $94.14 for all other hospitals. That is, cancer hospitals' average cost per discounted unit remained high even after accounting for payment under the modeled proposed CY 2011 payment system, which is not true for all other hospitals. Observing such differences in standardized cost per discounted unit led us to conclude that cancer hospitals are more costly with respect to APC groups than other hospitals furnishing services under the OPPS, even without the inferential statistical models that we typically employ.

TABLE 12.—MEANS AND STANDARD DEVIATIONS FOR KEY VARIABLES BY CANCER AND NON-CANCER OPPS HOSPITALS

Variable	Cancer Hospitals		Non-Cancer Hospitals	
	Mean	Standard Deviation	Mean	Standard Deviation
Outpatient Cost per Unit*	$344.20	(64.68)	$264.11	(165.86)
Unit Cost Standardized by Service Mix Wage Indices	$150.12	(31.64)	$94.14	(81.19)
Wage Index	1.10	(0.13)	0.98	(0.16)
Service Mix Index *	2.19	(0.26)	3.18	(2.25)
Outpatient Volume	192,197	(186,063)	34,578	(43,094)
Beds	173	(162.33)	173	(171.46)
Number of Hospitals	11		3,808	

* Includes drugs and biologicals based on per administration rather than per unit.

3. CY 2011 Proposed Payment Adjustment for Certain Cancer Hospitals

Having reviewed the cost data from the standard analytic database and determined that cancer hospitals are more costly with respect to APC groups than other hospitals furnishing services under the OPPS system, we decided to examine hospital cost report data from Worksheet E, Part B (where TOPs are calculated on the Hospital and Hospital Health Care Complex Cost Report each year) in order to determine whether our findings were further supported by cost report data and to determine an appropriate proposed payment adjustment methodology for CY 2011 based on cost report data. Analyses on

our standard analytic database and descriptive statistics presented in Table 12 above did not consider TOPs in assessing costliness of cancer hospitals relative to other hospitals furnishing services under section 1833(t) of the Act. There were several reasons for this. One reason was that TOPs have no associated relative weight that could be included in an assessment of APC-based payment. TOPs are paid at cost report settlement on an aggregate basis, not on a per service basis, and we would have no way to break these payments down into a relative weight to incorporate these retrospective aggregate payments in the form of a relative weight. The cost report data we selected for the analysis were limited to the OPPS-specific payment and cost data available on Worksheet E, Part B. These data include aggregate OPPS payments, including outlier payments and the cost of medical and other health services. These aggregate measures of cost and payment also include the cost and payment for drugs and biologicals and other adjustments that we typically include in our regression modeling, including wage index adjustment and rural adjustment, if applicable. While these cost report data cannot provide an estimate of cost per unit after controlling for other potential factors that could influence cost per unit, we used this aggregate cost and payment data to examine the cancer hospitals' OPPS PCR and compare these to the OPPS PCR for other hospitals. PCRs calculated from the most recent cost report data available at the time of the CY 2011 OPPS/ASC proposed rule also indicated that costs relative to payments at cancer hospitals were higher than those at other hospitals paid under the OPPS (that is, cancer hospitals have lower PCRs). In order to calculate PCRs for hospitals paid under the OPPS (including cancer hospitals), we used the same extract of cost report data from the Hospital Cost Report Information System (HCRIS) that we used to calculate the CCRs that were used to estimate median costs for the CY 2011 OPPS. We limited the dataset to the hospitals with CY 2009 claims data that we used to model the CY 2011 proposed APC relative weights.

We estimated that, on average, the OPPS payments to the 11 cancer hospitals, not including TOPs, were approximately 62 percent of reasonable cost (that is, we calculated a PCR of 0.615 for the cancer hospitals), whereas we estimated that, on average, the OPPS payments to other hospitals furnishing services under the OPPS were approximately 87 percent of reasonable cost (resulting in a PCR of 0.868).

Based on our findings that cancer hospitals, as a class, have a significantly lower volume weighted average PCR than the volume weighted PCR of other hospitals furnishing services under the OPPS and our findings that the cancer hospitals cost per discounted unit standardized for service mix remains much higher than the standardized cost per discounted unit of all other hospitals, we proposed an adjustment for cancer hospitals to reflect these higher costs, effective January 1, 2011. For purposes of calculating a proposed adjustment, we chose to rely on this straightforward assessment of payments and costs from the cost report data because of the concerns outlined above with respect to the small number of hospitals, and because of the challenges associated with accurately including drug and biological costs in our standard regression models. We believed that an appropriate adjustment would redistribute enough payments from other hospitals furnishing services under the OPPS to the cancer hospitals to give cancer hospitals a PCR that was comparable to the average PCR for other hospitals furnishing services under the OPPS. Therefore, we proposed a hospital-specific payment adjustment determined as the percentage of additional payment needed to raise each cancer hospital's PCR to the weighted average PCR for other hospitals furnishing services under the OPPS (0.868) in the CY 2011 dataset. This would be accomplished by adjusting each cancer hospital's OPPS APC payment by the percentage difference between the hospital's individual PCR (without TOPs) and the weighted average PCR of the other hospitals furnishing services under the OPPS. This cancer hospital payment adjustment proposed for CY 2011 would have resulted in an estimated aggregate increase in OPPS payments to cancer hospitals of 41.2 percent and a net increase in total payments, including TOPs, of 5 percent for CY 2011.

4. Proposed CY 2011 Cancer Hospital Payment Adjustment Was Not Finalized

The public comments associated with the cancer hospital adjustment that we proposed for CY 2011 are detailed in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71886 through 71887). Many commenters urged CMS to consider TOPs when calculating the cancer hospital payment adjustment, stating that the proposed methodology results, largely, in a change in the form of outpatient payments to cancer hospitals by shifting payment from hold harmless payment under the TOPs provision to APC payments. Noting that the majority of cancer care provided in the country is provided by the non-cancer hospitals that would experience a payment reduction under the CY 2011 proposal, commenters also suggested that the associated budget neutral payment reduction of 0.7 percent was not appropriate or equitable to other OPPS hospitals. Commenters also expressed concern that the proposed payment adjustment would increase beneficiary copayments. That is, they believed that the proposed cancer hospital adjustment would increase APC payments and, because beneficiary copayment is a percentage of the APC payment, Medicare beneficiaries seeking services at the 11 designated cancer hospitals would experience higher copayments due to the proposed methodology. These commenters encouraged CMS to implement the adjustment in a way that does not increase beneficiary copayments. As indicated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71887), because the many public comments we received identified a broad range of very important issues and concerns associated with the proposed cancer hospital payment adjustment, we determined that further study and deliberation was necessary and, therefore, we did not finalize the CY 2011 proposed payment adjustment for certain cancer hospitals.

5. Payment Adjustment for Certain Cancer Hospitals for CY 2012

After further review and deliberation of the issues associated with the cancer hospital payment adjustment, in the CY 2012 OPPS/ASC proposed rule, we proposed a cancer hospital payment adjustment reflecting the same approach as we took in the CY 2011 OPPS/ASC proposed rule, that is, an adjustment under which cancer hospitals would receive additional payments (based on estimates) so that each cancer hospital's PCR would be comparable to the weighted average PCR for other hospitals furnishing services under section 1833(t) of the Act. Therefore, for services furnished on and after January 1, 2012, we proposed that, for a cancer hospital with an individual PCR below the weighted average PCR for other hospitals furnishing services under the OPPS in the CY 2012 dataset, we would make a hospital-specific payment adjustment by adjusting the wage-adjusted OPPS payment for covered OPD services (except devices receiving pass-through status because these items and services are always paid at the estimated full cost and, therefore, a

payment adjustment above zero percent is unnecessary) furnished on and after January 1, 2012, by the percent difference between the hospital's individual PCR and the weighted average PCR of other hospitals furnishing services under the OPPS in the CY 2012 dataset. This methodology resulted in estimated percentage payment adjustments for the 11 cancer hospitals that ranged between 10.1 percent and 61.8 percent, with an estimated aggregate increase in OPPS payment to cancer hospitals of 39 percent for CY 2012 and an estimated net increase in total payments, including TOPs, of 9 percent.

Because section 7101 of the Affordable Care Act expanded the 340B drug program to include certain cancer hospitals, we also proposed that the cancer hospital payment adjustment be recalculated each year. The 340B drug program allows certain hospitals to purchase certain outpatient drugs at reduced prices. We understand from commenters that, currently, two cancer hospitals participate in the 340B program. However, inclusion of cancer hospitals in the 340B drug program should lower drug costs at participating cancer hospitals going forward and, therefore, may cause changes in each cancer hospital's PCR compared to the previous year's calculation.

Comment: Many commenters urged CMS to consider TOPs when calculating the cancer hospital payment adjustment. The commenters stated that the proposed methodology to adjust each cancer hospital's OPPS payment by the percentage difference between their individual PCR without TOPs and the weighted average PCR of the other hospitals paid under OPPS results, largely, in a change in the form of outpatient payments to cancer hospitals by shifting payment from hold harmless payments under the TOPs provision to APC payments. This substitution of TOPs for APC payments, in turn, results in savings to the Medicare program which, the commenters asserted, is in violation of the statutory requirement that the policy be budget neutral. The commenters suggested that because the Congressional Budget Office scoring of section 3138 of the Affordable Care Act estimates no Federal budgetary impact, Congress did not intend for savings under this provision.

Commenters also suggested that the associated budget neutral payment reduction to other hospitals is not appropriate or equitable to other hospitals paid under the OPPS. The commenters indicated that it was not the intent of Congress for the provision to impact the non-cancer hospitals in a manner that is disproportionate to the benefits obtained by the cancer hospitals. Many commenters noted that the majority of cancer care provided in the country is provided by the non-cancer hospitals that would experience a payment reduction under the proposal.

Commenters also expressed concern that the proposed payment adjustment would increase beneficiary copayments. That is, they believed that the proposed cancer hospital adjustment would increase APC payments and, because beneficiary copayment is a percentage of the APC payment, Medicare beneficiaries seeking services at the 11 designated cancer hospitals will experience higher copayments due to the proposed methodology. The commenters encouraged CMS to implement the adjustment in a way that does not increase beneficiary copayments, such as providing the adjustment amount in aggregate instead of on a per claim basis through enhanced APC payments.

Commenters indicated that CMS selected an inappropriate benchmark against which to compare each cancer hospital's PCR. Specifically, the commenters indicated that CMS should have taken into account the concentration of outpatient services at the designated cancer hospitals as compared to other PPS hospitals and adjust the PCR benchmark higher. The commenters argued that other PPS hospitals have the ability to improve their Medicare margins through other payment systems, but that cancer hospitals receive the majority of their Medicare payments through the OPPS. These commenters asserted that, because concentration of outpatient services was not considered in establishing the benchmark, the proposed adjustment was not valid. The commenters also indicated that, because outliers were included in the calculation of hospital PCRs, application of the payment adjustment to the APC payment amount will result in PCRs less than the intended target for cancer hospitals with relatively large outlier payments and suggested that the payment adjustment be applied to outlier payments as well as APC payments. In addition, the commenters opposed annual recalculation of the cancer adjustment stating that CMS should not expect significant cost savings at the cancer hospitals as a result of the inclusion of cancer hospitals in the 340B drug program and that the cancer hospitals require payment stability and predictability over the long term. Other commenters supported the proposal to annually recalculate the cancer hospital adjustment, stating that this will ensure more equitable payments. In addition, these commenters indicated that CMS must make the payment adjustment effective for services furnished on or after January 1, 2011, in order to comply with section 3138 of the Affordable Care Act.

Several commenters addressed CMS' study methodology. One commenter suggested that the CMS analysis is inadequate to conclude that costs are higher in cancer hospitals and that an adjustment is warranted. This commenter noted that the CMS analysis did not control for the many factors that might explain differences in costliness or assess to what extent cost differences could be explained by differences in efficiency. This commenter also asserted that the exclusion of TOPs from the comparison of costliness distorts the analysis and makes the findings invalid. Another commenter suggested that CMS examine the costs of cancer patients generally for all hospitals and compare the costs of these 11 hospitals to all hospitals providing cancer care to ensure an adjustment does not reinforce high-cost characteristics of the 11 designated cancer hospitals. This commenter also indicated that additional payments to cancer hospitals should be guided by quality of care and, because the Affordable Care Act requires the 11 cancer hospitals to begin submitting quality data in fiscal year 2014, suggested that the additional payments to cancer hospitals be delayed until these quality data are available to serve as a basis for the payment adjustment.

Response: We analyzed the various issues raised by commenters, and in this final rule with comment period, we are adopting final policies that reflect a number of modifications to our proposed policies. We believe that a number of points raised by the commenters have merit and, consistent with our broad authority under the statute, we are adopting some (but not all) of their recommendations.

As discussed above, section 3138 of the Affordable Care Act added a new section 1833(t)(18) to the Social Security Act, providing for an adjustment under section 1833(t)(2)(E) of the Social Security Act to address higher costs incurred by cancer hospitals. Section 1833(t)(2)(E) of the Act, in turn, directs the Secretary to establish, ''in a budget neutral manner,'' payment ''adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals.''

Under sections 1833(t)(18) and 1833(t)(2)(E) of the Social Security Act, the agency's authority with respect to the cancer hospital adjustment is broad; similarly, under section 1833(t)(2)(E) of the Act, the agency's authority with respect to calculating budget neutrality is broad. In contrast, the provision of the statute for calculating TOPs is prescriptive.

Commenters requested that CMS maintain TOPs at their current level, that is, calculate TOPs by ignoring the cancer hospital payment adjustment under sections 1833(t)(18) and 1833(t)(2)(E) of the Act. Under the statute, however, the calculation of TOPs is directly tied to what is paid under section 1833(t) of the Act. Specifically, under section 1833(t)(7)(D)(ii) of the Act, ''for covered OPD services for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection [1833(t)] shall be increased by the amount of such difference.'' The ''PPS amount'' means, with respect to covered OPD services, ''the amount payable under this title [Title 18] for such services (determined without regard to this paragraph) * * *'' (section 1833(t)(7)(E) of the Act). Under this provision, the cancer hospital payment adjustment is included in the calculation of the ''PPS amount'' because it is an adjustment under sections 1833(t)(18) and 1833(t) (2)(E) of the Act and, therefore, is the ''amount payable under this title.'' To the extent the PPS amount is less than the pre-BBA amount, a cancer hospital would qualify for a TOP.

With respect to the issue of establishing, in a budget neutral manner, the cancer hospital payment adjustment, we agree with the commenters that it is appropriate to consider that, to some extent, the cancer hospital payment adjustment changes the form of payments (from TOPs to cancer hospital adjustment payments). The cancer hospital payment adjustment presents a unique circumstance insofar as the cancer hospital adjustment can result in lower TOPs. Consistent with section 1833(t)(2)(E) of the Act, we agree that, in determining the baseline for the budget neutrality calculation, it is appropriate to consider TOPs that would otherwise be made if there were no cancer hospital payment adjustment. In determining the budget neutrality adjustment factor, we compare estimated CY 2012 total payments with the cancer hospital payment adjustment under sections 1833(t)(18) and 1833(t)(2)(E) of the Act to estimated CY 2012 total payments without a cancer hospital payment adjustment, taking into account TOPs that would otherwise be made in the absence of a cancer hospital payment adjustment. The inclusion of TOPs in the baseline significantly increases the baseline, and accordingly decreases the amount that other payments need to be reduced to offset the increased payments resulting from the cancer hospital payment adjustment. The budget neutrality adjustment factor for the cancer hospital payment adjustment is 0.9978. In percentage terms, the budget neutrality reduction to the conversion factor is 0.2 percent in this final rule with comment period, as opposed to 0.7 percent in the proposed rule. In dollar terms, the budget neutral payment reduction associated with the cancer hospital payment adjustment is an estimated $71 million for CY 2012 based on updated cost report information. That is, the cancer hospital payment adjustment is estimated to increase total payments by $71 million over the baseline (which accounts for TOPs) and this amount must be offset by reductions in other payments (resulting in the 0.2 percent reduction to the conversion factor). For this final rule with comment period, we are adopting the above-described approach of calculating budget neutrality, consistent with our broad authority under the statute, for the reasons stated above and because we believe it will increase equity to hospitals paid under the OPPS that are not cancer hospitals, as urged by the commenters.

In response to commenters who urged us to implement the cancer hospital payment adjustment in a manner that does not increase beneficiary copayments, such as providing the adjustment amount in aggregate instead of on a per claim basis through enhanced APC payments, we reexamined the manner in which the cancer hospital payment adjustment is applied. We have broad discretion in designing the cancer hospital payment adjustment under sections 1833(t)(18)(B) and 1833(t)(2)(E) of the Act. Consistent with this broad authority, we agree that it is appropriate to make the cancer hospital payment adjustment through the form of an aggregate payment determined at cost report settlement to each cancer hospital, as opposed to an adjustment at the APC level, thereby avoiding the higher copayments for beneficiaries associated with providing the adjustment on a claims basis through increased APC payments. Therefore, in order to implement the cancer hospital payment adjustment in a way that does not increase beneficiary copayments as urged by commenters, and in light of the discretion afforded by the statute, we are providing the cancer hospital payment adjustment as an aggregate payment to each cancer hospital at cost report settlement instead of through enhanced APC payments as proposed. As explained further below, the aggregate adjustment adopted in this final rule with comment period (like the proposed APC-level adjustment) is based on the comparison of each cancer hospital's PCR to the weighted average PCR of the other hospitals that furnish services under the OPPS using the most recent submitted or settled cost report available at the time of this final rule with comment period.

In addition, commenters suggested that CMS take into account the cancer hospitals' significant Medicare outpatient concentration (which, based on the comment letter, is the portion of the cancer hospitals' total Medicare payments that are OPPS payments) when establishing an appropriate PCR benchmark. In other words, the commenter argued that CMS should take into account the portion of the cancer hospitals' total Medicare payments that are OPPS payments compared to the non-cancer hospitals' total Medicare payments that are OPPS payments. Section 3138 of the Affordable Care Act provides that if the Secretary determines under section 1833(t)(18)(A) of the Act that costs incurred by cancer hospitals exceed those costs of other hospitals furnishing services under section 1833(t), the Secretary shall provide for an appropriate adjustment to reflect the higher costs. We are not persuaded that Medicare outpatient concentration in and of itself has an impact on the costs incurred for providing OPD services at cancer hospitals relative to other OPPS hospitals that warrants an adjustment in determining the cancer hospital adjustment. Therefore, we are not adopting this suggestion of the commenters.

With respect to commenters that indicated that because outliers were included in the calculation of hospital PCRs, application of the payment adjustment to the APC payment amount will result in PCRs less than the intended target for cancer hospitals with relatively large outlier payments, we examined this issue and believe commenters made a valid argument that cancer hospitals with relatively large outlier payments will be provided less additional payment than intended under the proposed methodology because the payment adjustment would be applied only to the APC portion of

the payment and not to the outlier amounts. If we were to finalize the implementation of the cancer hospital payment adjustment through increased APC payments as proposed, the PCR used to determine the amount of the adjustment would need to be recalculated to exclude outlier payments. This change would provide a larger APC adjustment to cancer hospitals that have large outlier payments relative to other OPPS hospitals. However, because we are providing the cancer hospital payment adjustment in aggregate at cost report settlement and not through adjustments to the APC payment, it is appropriate to continue to include outlier payments in the calculation of the PCRs used to determine the payment adjustment amount.

In response to the commenters who suggested that annual recalculation of the PCRs for purposes of calculating the cancer hospital payment adjustment is not necessary because significant cost savings are not expected at the cancer hospitals as a result of the inclusion of cancer hospitals in the 340B drug program, we believe that annual recalculation of the cancer hospital payment adjustment will provide a timely assessment of the changes in OPPS payments relative to costs due to any reason and, therefore, will enable CMS to provide OPPS payments that are accurate and equitable.

With regard to the implementation date for the cancer hospital payment adjustment, the agency did not finalize the proposed cancer hospital adjustment for CY 2011 for a variety of reasons, as explained in the CY 2011 OPPS/ASC final rule with comment period. Significantly, the majority of all commenters expressed concerns about implementation of the adjustment and, based on the broad range of important issues and concerns raised by them, we did not implement a cancer hospital adjustment for CY 2011. Moreover, the obligation to provide a cancer hospital payment adjustment is triggered only insofar as the Secretary determines under section 1833(t)(18)(A) of the Act that costs incurred by hospitals described in section 1886(d)(1)(B)(v) of the Act exceed those costs incurred by other hospitals furnishing services under this subsection. Several commenters raised concerns about the agency's study of costliness conducted under section 1833(t)(18)(A) of the Act; for example, a commenter suggested that the CMS analysis was inadequate to conclude that costs are higher in cancer hospitals and that an adjustment was warranted. Given the uncertainty surrounding these issues as well as public comments arguing against implementing a cancer hospital payment adjustment for CY 2011, we decided not to do so for CY 2011. We note that, insofar as the cancer adjustment is budget neutral, the lack of a cancer hospital payment adjustment for CY 2011 also means that other payments were not reduced for CY 2011 to offset the increased payments from the adjustment.

Regarding the commenter's concerns related to the agency's study conducted pursuant to section 1833(t)(18)(A) of the Act, as detailed above and in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71883), we determined that we could not use our standard analytical approach, which uses a combination of explanatory and payment regression models while controlling for other legitimate influences of costliness, to assess the costliness of cancer hospitals relative to other OPPS hospitals. Although this kind of analysis would allow us to control for the many factors that might explain differences in costliness, as suggested by the commenter, we believe that this approach would lead to imprecise estimates of costliness due to the small sample size (11 hospitals).

With respect to commenters who suggested that it would be more appropriate for the CMS study on costliness to compare the costs of providing OPD services at the 11 cancer hospitals to the costs of providing services related to cancer care at other hospitals furnishing services under section 1833(t) of the Act, we believe such an approach is not appropriate because section 3138 of the Affordable Care Act does not specify that the comparison be made with regard to particular APC groups related to cancer services.

In addition, with respect to the commenter who believed that the amount of additional payments to cancer hospitals should be guided by quality of care information and, therefore, be delayed until 2014 when the cancer hospitals begin to submit quality data to CMS, we note that section 1833(t)(18) of the Act did not include such a requirement nor did it include quality measures as a requirement for the additional payments to cancer hospitals. Therefore, we do not believe it is appropriate to delay implementation of the cancer hospital payment adjustment until cancer hospitals have submitted quality data to CMS.

After consideration of the public comments we received, we are adopting in this final rule with comment period a number of the commenters' suggestions and a number of changes to our proposed CY 2012 policies regarding the cancer hospital payment adjustment including modifications to our CY 2012 proposal with regard to the calculation of the budget neutrality adjustment associated with the cancer hospital payment adjustment. The budget neutral payment reduction that is associated with the cancer hospital payment adjustment for CY 2012 is calculated as the difference in estimated CY 2012 total payments to cancer hospitals, including the cancer hospital payment adjustment, and estimated CY 2012 total payments to cancer hospitals without the cancer adjustment, including TOPs. Therefore, based on updated cost report data, the budget neutrality adjustment to the OPPS conversion factor is 0.9978, a reduction of 0.2 percent (as opposed to a reduction of 0.7 percent in the proposed rule). In addition, we are providing the CY 2012 cancer hospital payment adjustment to cancer hospitals in the form of an aggregate payment at cost report settlement instead of through an increased adjustment to APC payments on a claims basis, as was proposed.

Consistent with the approach in the proposed rule, the CY 2012 cancer hospital payment adjustment adopted in this final rule with comment period is intended to provide additional payments to cancer hospitals so that the hospital's PCR with the payment adjustment is equal to the weighted average PCR for other hospitals, which we refer to as the ''target PCR.'' In contrast to the approach in the proposed rule, however, in this final rule with comment period, we are adopting a policy under which the amount of the payment adjustment will be made on an aggregate basis at cost report settlement. Under this final rule with comment period, we will examine each cancer hospital's data at cost report settlement, determine the cancer hospital's PCR (before the cancer hospital payment adjustment), and in turn determine the lump sum amount necessary (if any) to make the cancer hospital's PCR equal to the target PCR. To the extent at cost report settlement a cancer hospital's PCR (before the cancer hospital payment adjustment) is above the target PCR, a cancer hospital payment adjustment of zero is given. This is because we believe that this would indicate that the cancer hospital's costs do not exceed the costs incurred by other hospitals furnishing services under the OPPS, and therefore a payment adjustment above zero would not be necessary. We are amending are regulations at § 419.43 to capture the above-described final policy.

Consistent with the approach in the proposed rule, the target PCR is set in advance and is calculated using the most recent submitted or settled cost report data that are available at the time of this final rule with comment period. For CY 2012, the target PCR for purposes of the cancer hospital payment adjustment is 0.91. To calculate the target PCR, we used the same extract of cost report data from HCRIS, as discussed in section II.A of this final rule with comment period, used to estimate median costs for the CY 2012 OPPS. Using these cost report data, we included data from Worksheet E, Part B, for each hospital, using data from each hospital's most recent cost report, whether as submitted or settled. We then limited the dataset to the hospitals with CY 2010 claims data that we use to model the impact of the CY 2012 final APC relative weights (4,018 hospitals) because it is appropriate to use the same set of hospitals that we are using to calibrate the modeled CY 2012 OPPS. The cancer hospitals in this dataset largely had cost report data from cost reporting periods ending in FY 2010. The cost report data for the other hospitals were from cost report periods with fiscal year ends ranging from 2009 to 2010. We then removed the cost report data of the 47 hospitals located in Puerto Rico from our data set because we do not believe that their cost structure reflects the costs of most hospitals paid under the OPPS and, therefore, their inclusion may bias the calculation of hospital-weighted statistics. We also removed 223 hospitals with cost report data that were not complete (missing aggregate OPPS payments (which include outliers), missing aggregate cost data, or missing both), so that all cost reports in the study would have both the payment and cost data necessary to calculate a PCR for each hospital, leading to a final analytic file of 3,748 hospitals with cost report data. We believe that the costs and PPS payments reported on Worksheet E, Part B, for the hospitals included in our CY 2012 modeling is sufficiently accurate for assessing hospital's relative costliness because all of the key elements that we believe are necessary for the analysis (payment and cost) are contained on this worksheet.

Using this smaller dataset of cost report data, we estimated that, on average, the OPPS payments to the 11 cancer hospitals, not including TOPs, are approximately 67 percent of reasonable cost (that is, we calculated a PCR of 0.674 for the cancer hospitals), whereas, we estimated that, on average, the OPPS payments to other hospitals furnishing services under the OPPS are approximately 91 percent of reasonable cost (weighted average PCR of 0.91). Individual cancer hospital's OPPS PCRs range from approximately 0.63 to approximately 0.78. Based on these data, a target PCR of 0.91 will be used to determine the CY 2012 cancer hospital payment adjustment to be paid at cost report settlement. Therefore, the payment amount associated with the cancer hospital adjustment to be determined at cost report settlement will be the additional payment needed to result in a PCR equal to 0.91 for each cancer hospital.

Using the same data described above, we calculated estimates of the percentage difference between each cancer hospital's PCR and the target PCR. Table 13 below indicates estimates in percentage terms of the CY 2012 payment adjustment for each cancer hospital. The actual amount of the CY 2012 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2012 payments and costs. Under the policies in this final rule with comment period, the payment adjustments for cancer hospitals are estimated to result in an aggregate increase in OPPS payments to cancer hospitals of 34.5 percent for CY 2012 and a net increase in total payment, including TOPs, of 9.5 percent. We note that the changes made by section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs will be assessed as usual after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period.

TABLE 13.—ESTIMATED CY 2012 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS (WITHOUT REGARD TOPS) TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider Number	Hospital Name	Percentage increase without TOPs
050146	City of Hope Helford Clinical Research Hospital	15.8%
050660	USC Kenneth Norris Jr. Cancer Hospital	32.8%
100079	University of Miami Hospital & Clinic	28.4%
100271	H. Lee Moffitt Cancer Center & Research Institute	22.4%
220162	Dana-Farber Cancer Institute	44.8%
330154	Memorial Hospital for Cancer and Allied Diseases	39.4%
330354	Roswell Park Cancer Institute	25.2%
360242	James Cancer Hospital & Solove Research Institute	30.9%
390196	Hospital of the Fox Chase Cancer Center	16.0%
450076	University of Texas M. D. Anderson Cancer Center	39.4%
500138	Seattle Cancer Care Alliance	44.7%
Total		**34.5%**

G. Hospital Outpatient Outlier Payments

1. Background

Currently, the OPPS provides outlier payments on a service-by-service basis. For CY 2011, the outlier threshold is met when the cost of furnishing a service or procedure by a hospital exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus a $2,025 fixed-dollar threshold. We introduced a fixed-dollar threshold in CY 2005, in addition to the traditional multiple threshold, in order to better target outliers to those high cost and complex procedures where a very costly service could present a hospital with significant financial loss. If the cost of a service meets both of these conditions, the multiple threshold and the fixed-dollar threshold, the outlier payment is calculated as 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment rate. Before CY 2009, this outlier payment had historically been considered a final payment by longstanding OPPS policy. We implemented a reconciliation process similar to the IPPS outlier reconciliation process for cost reports with cost reporting periods beginning on or after January 1, 2009 (73 FR 68594 through 68599).

It has been our policy for the past several years to report the actual amount of outlier payments as a percent of total spending in the claims being used to model the proposed OPPS. Our current estimate of total outlier payments as a percent of total CY 2010 OPPS payment, using available CY 2010 claims and the revised OPPS expenditure estimate for the 2011 Trustee's Report, is approximately 1.13 percent of the total aggregated OPPS payments. Therefore, for CY 2010, we estimate that we paid at 0.13 percent above the CY 2010 outlier target of 1.0 percent of total aggregated OPPS payments.

As explained in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71887 through 71889), we set our projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS for CY 2011. The outlier thresholds were set so that estimated CY 2011 aggregate outlier payments would equal 1.0 percent of the total estimated aggregate payments under the OPPS. Using CY 2010 claims data and CY 2011 payment rates, we currently estimate that the aggregate outlier payments for CY 2011 will be approximately 1.06 percent of the total CY 2011 OPPS payments. The difference between 1.0 percent and 1.06 percent is reflected in the regulatory impact analysis in section XX. of this final rule with comment period. We note that we provide estimated CY 2012 outlier payments for hospitals and CMHCs with claims included in the claims data that we used to model impacts in the Hospital–Specific Impacts—Provider-Specific Data file on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS/*.

2. Proposed Outlier Calculation

In the CY 2012 OPPS/ASC proposed rule (76 FR 42222), we proposed for CY 2012 to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS for outlier payments. We proposed that a portion of that 1.0 percent, specifically 0.14 percent, would be allocated to CMHCs for PHP outlier payments. This is the amount of estimated outlier payments that would result from the proposed CMHC outlier threshold as a proportion of total estimated outlier payments. As

discussed in section VIII.C. of the proposed rule, for CMHCs, we proposed to continue our longstanding policy that if a CMHC's cost for partial hospitalization services, paid under either APC 0172 (Level I Partial Hospitalization (3 services) for CMHCs) or APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs), exceeds 3.40 times the payment for APC 0173, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 0173 payment rate. For further discussion of CMHC outlier payments, we refer readers to section VIII.C. of this final rule with comment period.

To ensure that the estimated CY 2012 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we proposed that the hospital outlier threshold be set so that outlier payments would be triggered when the cost of furnishing a service or procedure by a hospital exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus a $2,100 fixed-dollar threshold. This proposed threshold reflected the methodology discussed below in this section, as well as the proposed APC recalibration for CY 2012.

We calculated the proposed fixed-dollar threshold for the proposed rule using largely the same methodology as we did in CY 2011 (75 FR 71887 through 71889). For purposes of estimating outlier payments for the proposed rule, we used the hospital-specific overall ancillary CCRs available in the April 2011 update to the Outpatient Provider-Specific File (OPSF). The OPSF contains provider-specific data, such as the most current CCR, which are maintained by the Medicare contractors and used by the OPPS Pricer to pay claims. The claims that we use to model each OPPS update lag by 2 years. For the proposed rule, we used CY 2010 claims to model the CY 2012 OPPS. In order to estimate the proposed CY 2012 hospital outlier payments for the proposed rule, we inflated the charges on the CY 2010 claims using the same inflation factor of 1.0908 that we used to estimate the IPPS fixed-dollar outlier threshold for the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 26024). We used an inflation factor of 1.0444 to estimate CY 2011 charges from the CY 2010 charges reported on CY 2010 claims. The methodology for determining this charge inflation factor is discussed in the FY 2012 IPPS/LTCH PPS proposed rule and final rule (76 FR 26024 and 51792, respectively). As we stated in the CY 2005 OPPS final rule with comment period (69 FR 65845), we believe that the use of these charge inflation factors are appropriate for the OPPS because, with the exception of the inpatient routine service cost centers, hospitals use the same ancillary and outpatient cost centers to capture costs and charges for inpatient and outpatient services.

As noted in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68011), we are concerned that we could systematically overestimate the OPPS hospital outlier threshold if we did not apply a CCR inflation adjustment factor. Therefore, in the CY 2012 OPPS/ASC proposed rule, we proposed to apply the same CCR inflation adjustment factor that we proposed to apply for the FY 2012 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2012 OPPS outlier payments that determine the fixed-dollar threshold. Specifically, for CY 2012, we proposed to apply an adjustment of 0.9850 to the CCRs that were in the April 2011 OPSF to trend them forward from CY 2011 to CY 2012. The methodology for calculating this proposed adjustment was discussed in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 26024 through 26025).

Therefore, to model hospital outlier payments for the CY 2012 OPPS/ASC proposed rule, we applied the overall CCRs from the April 2011 OPSF file after adjustment (using the proposed CCR inflation adjustment factor of 0.9850 to approximate CY 2012 CCRs) to charges on CY 2010 claims that were adjusted (using the proposed charge inflation factor of 1.0908 to approximate CY 2012 charges). We simulated aggregated CY 2012 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiple threshold constant and assuming that outlier payments would continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until the total outlier payments equaled 1.0 percent of aggregated estimated total CY 2012 OPPS payments. We estimated that a proposed fixed-dollar threshold of $2,100, combined with the proposed multiple threshold of 1.75 times the APC payment rate, would allocate 1.0 percent of aggregated total OPPS payments to outlier payments. We proposed to continue to make an outlier payment that equals 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount when both the 1.75 multiple threshold and the proposed fixed-dollar threshold of $2,100 are met. For CMHCs, we proposed that, if a CMHC's cost for partial hospitalization services, paid under either APC 0172 or APC 0173, exceeds 3.40 times the payment for APC 0173, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 0173 payment rate.

Section 1833(t)(17)(A) of the Act, which applies to hospitals as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to report data required for the quality measures selected by the Secretary, in the form and manner required by the Secretary under 1833(t)(17)(B) of the Act, incur a 2.0 percentage point reduction to their OPD fee schedule increase factor, that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that will apply to certain outpatient items and services furnished by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR requirements. For hospitals that fail to meet the Hospital OQR requirements, we proposed to continue our policy that we implemented in CY 2010 that the hospitals' costs would be compared to the reduced payments for purposes of outlier eligibility and payment calculation. For more information on the Hospital OQR Program, we refer readers to section XIV. of this final rule with comment period.

Comment: One commenter opposed the proposed increase to the fixed-dollar threshold, stating that it would reduce the number of cases eligible for outlier payments across the industry. Another commenter supported the proposed policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS for outlier payments and of increasing the fixed-dollar outlier threshold to $2,100.

Response: As indicated above, we introduced a fixed-dollar threshold in order to better target outliers to those high cost and complex procedures where a very costly service could present a hospital with significant financial loss. We maintain the target outlier percentage of 1.0 percent of estimated aggregate total payment under the OPPS and have a fixed-dollar threshold so that OPPS outlier payments are made only when the hospital would experience a significant loss for supplying a particular service. For CY 2012, based on updated data, we have established a fixed-dollar threshold of $1,900 which, together with a multiple threshold of 1.75, will enable us to meet

our target outlier payment of 1 percent of total OPPS spending.

3. Final Outlier Calculation

Consistent with historical practice, we used updated data for this final rule with comment period for our outlier calculation. For CY 2012, we are applying the overall CCRs from the July 2011 Outpatient Provider-Specific File with a CCR adjustment factor of 0.9903 to approximate CY 2012 CCRs to charges on the final CY 2010 claims that were adjusted to approximate CY 2012 charges (using the final 2-year charge inflation factor of 1.0794). These are the same CCR adjustment and charge inflation factors that were used to set the IPPS fixed-dollar threshold for the FY 2012 IPPS/LTCH PPS final rule (76 FR 51792 through 51795). We simulated aggregated CY 2012 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiple threshold constant and assuming that outlier payment would continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until the total outlier payments equaled 1.0 percent of aggregated estimated total CY 2011 OPPS payments. We estimate that a fixed-dollar threshold of $1,900, combined with the multiple threshold of 1.75 times the APC payment rate, will allocate 1.0 percent of estimated aggregated total OPPS payments to outlier payments.

In summary, for CY 2012, we will continue to make an outlier payment that equals 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount when both the 1.75 multiple threshold and the final fixed-dollar threshold of $1,900 are met. For CMHCs, if a CMHC's cost for partial hospitalization services, paid under either APC 0172 or APC 0173, exceeds 3.40 times the payment for APC 0173, the outlier payment is calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 0173 payment rate. We estimate that this threshold will allocate 0.12 percent of outlier payments to CMHCs for PHP outlier payments.

4. Outlier Reconciliation

In the CY 2009 OPPS/ASC final rule with comment period (73 CFR 68599), we adopted as final policy a process to reconcile hospital or CMHC outlier payments at cost report settlement for services furnished during cost reporting periods beginning in CY 2009. OPPS outlier reconciliation more fully ensures accurate outlier payments for those facilities that have CCRs that fluctuate significantly relative to the CCRs of other facilities, and that receive a significant amount of outlier payments (73 FR 68598). As under the IPPS, we do not adjust the fixed-dollar threshold or the amount of total OPPS payments set aside for outlier payments for reconciliation activity because such action would be contrary to the prospective nature of the system. Our outlier threshold calculation assumes that overall ancillary CCRs accurately estimate hospital costs based on the information available to us at the time we set the prospective fixed-dollar outlier threshold. For these reasons, as we have previously discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68596) and as we proposed for CY 2012, we did not incorporate any assumptions about the effects of reconciliation into our calculation of the OPPS fixed-dollar outlier threshold.

H. Calculation of an Adjusted Medicare Payment From the National Unadjusted Medicare Payment

The basic methodology for determining prospective payment rates for HOPD services under the OPPS is set forth in existing regulations at 42 CFR Part 419, subparts C and D. As proposed, for this final rule with comment period, the payment rate for most services and procedures for which payment is made under the OPPS is the product of the conversion factor calculated in accordance with section II.B. of this final rule with comment period and the relative weight determined under section II.A. of this final rule with comment period. Therefore, as proposed, for this final rule with comment period, the national unadjusted payment rate for most APCs contained in Addendum A to this final rule with comment period (which is referenced in section XVII. of this final rule with comment period and available via the Internet on the CMS Web site) and for most HCPCS codes to which separate payment under the OPPS has been assigned in Addendum B to this final rule with comment period (which is referenced in section XVII. of this final rule with comment period and available via the Internet on the CMS Web site) was calculated by multiplying the CY 2012 scaled weight for the APC by the CY 2012 conversion factor.

We note that section 1833(t)(17) of the Act, which applies to hospitals as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to submit data required to be submitted on quality measures selected by the Secretary, in the form and manner and at a time specified by the Secretary, incur a reduction of 2.0 percentage points to their OPD fee schedule increase factor, that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data and that fail to meet the Hospital Outpatient Quality Reporting (OQR) Program (formerly referred to as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP)) requirements. For further discussion of the payment reduction for hospitals that fail to meet the requirements of the Hospital OQR Program, we refer readers to section XVI.D. of this final rule with comment period.

We demonstrate in the steps below how to determine the APC payments that will be made in a calendar year under the OPPS to a hospital that fulfills the Hospital OQR Program requirements and to a hospital that fails to meet the Hospital OQR Program requirements for a service that has any of the following status indicator assignments: ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''U,'' ''V,'' or ''X'' (as defined in Addendum D1 to this final rule with comment period), in a circumstance in which the multiple procedure discount does not apply, the procedure is not bilateral, and conditionally packaged services (status indicator of ''Q1'' and ''Q2'') qualify for separate payment. We note that, although blood and blood products with status indicator ''R'' and brachytherapy sources with status indicator ''U'' are not subject to wage adjustment, they are subject to reduced payments when a hospital fails to meet the Hospital OQR Program requirements.

Individual providers interested in calculating the payment amount that they would receive for a specific service from the national unadjusted payment rates presented in Addenda A and B to this final rule with comment period (which are referenced in section XVII. of this final rule with comment period and available via the Internet on the CMS Web site) should follow the formulas presented in the following steps. For purposes of the payment calculations below, we refer to the national unadjusted payment rate for hospitals that meet the requirements of the Hospital OQR Program as the ''full'' national unadjusted payment rate. We refer to the national unadjusted payment rate for hospitals that fail to meet the requirements of the Hospital OQR Program as the ''reduced'' national

unadjusted payment rate. The reduced national unadjusted payment rate is calculated by multiplying the reporting ratio of 0.980 times the ''full'' national unadjusted payment rate. The national unadjusted payment rate used in the calculations below is either the full national unadjusted payment rate or the reduced national unadjusted payment rate, depending on whether the hospital met its Hospital OQR Program requirements in order to receive the full CY 2012 OPPS fee schedule increase factor of 1.90 percent.

Step 1. Calculate 60 percent (the labor-related portion) of the national unadjusted payment rate. Since the initial implementation of the OPPS, we have used 60 percent to represent our estimate of that portion of costs attributable, on average, to labor. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18496 through 18497) for a detailed discussion of how we derived this percentage. We confirmed that this labor-related share for hospital outpatient services is appropriate during our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553).

The formula below is a mathematical representation of Step 1 and identifies the labor-related portion of a specific payment rate for a specific service.

X is the labor-related portion of the national unadjusted payment rate.

X = .60 * (national unadjusted payment rate)

Step 2. Determine the wage index area in which the hospital is located and identify the wage index level that applies to the specific hospital. The wage index values assigned to each area reflect the geographic statistical areas (which are based upon OMB standards) to which hospitals are assigned for FY 2012 under the IPPS, reclassifications through the MGCRB, section 1886(d)(8)(B) ''Lugar'' hospitals, reclassifications under section 1886(d)(8)(E) of the Act, as defined in § 412.103 of the regulations, and hospitals designated as urban under section 601(g) of Public Law 98–21. We note that the reclassifications of hospitals under section 508 of Public Law 108–173, as extended by sections 3137 and 10317 of the Affordable Care Act, expired on September 30, 2010. Section 102 of the Medicare and Medicaid Extenders Act of 2010 extends Section 508 and certain additional special exception hospital reclassifications from October 1, 2010 through September 30, 2011. Therefore, these reclassifications will not apply to the CY 2012 OPPS. (For further discussion of the changes to the FY 2012 IPPS wage indices, as applied to the CY 2012 OPPS, we refer readers to section II.C. of this final rule with comment period.) As we proposed, we are continuing to apply a wage index floor of 1.00 to frontier States, in accordance with section 10324 of the Affordable Care Act.

Step 3. Adjust the wage index of hospitals located in certain qualifying counties that have a relatively high percentage of hospital employees who reside in the county, but who work in a different county with a higher wage index, in accordance with section 505 of Public Law 108–173. Addendum L to this final rule with comment period (which is referenced in section XVII. of this final rule with comment period and available via the Internet on the CMS Web site) contains the qualifying counties and the associated wage index increase developed for the FY 2012 IPPS and listed as Table 4J in the FY 2012 IPPS/LTCH PPS final rule and available via the Internet on the CMS Web site at: *http://www.cms.gov/AcuteInpatientPPS/01_overview.asp*. This step is to be followed only if the hospital is not reclassified or redesignated under section 1886(d)(8) or section 1886(d)(10) of the Act.

Step 4. Multiply the applicable wage index determined under Steps 2 and 3 by the amount determined under Step 1 that represents the labor-related portion of the national unadjusted payment rate.

The formula below is a mathematical representation of Step 4 and adjusts the labor-related portion of the national payment rate for the specific service by the wage index.

X_a *is the labor-related portion of the national unadjusted payment rate (wage adjusted).*

X_a = .60 * (national unadjusted payment rate) * applicable wage index

Step 5. Calculate 40 percent (the nonlabor-related portion) of the national unadjusted payment rate and add that amount to the resulting product of Step 4. The result is the wage index adjusted payment rate for the relevant wage index area.

The formula below is a mathematical representation of Step 5 and calculates the remaining portion of the national payment rate, the amount not attributable to labor, and the adjusted payment for the specific service.

Y is the nonlabor-related portion of the national unadjusted payment rate.

Y = .40 * (national unadjusted payment rate)

Adjusted Medicare Payment = Y + Xa

Step 6. If a provider is a SCH, set forth in the regulations at § 412.92, or an EACH, which is considered to be a SCH under section 1886(d)(5)(D)(iii)(III) of the Act, and located in a rural area, as defined in § 412.64(b), or is treated as being located in a rural area under § 412.103, multiply the wage index adjusted payment rate by 1.071 to calculate the total payment.

The formula below is a mathematical representation of Step 6 and applies the rural adjustment for rural SCHs.

Adjusted Medicare Payment (SCH or EACH) = Adjusted Medicare Payment * 1.071

We have provided examples below of the calculation of both the full and reduced national unadjusted payment rates that will apply to certain outpatient items and services performed by hospitals that meet and that fail to meet the Hospital OQR Program requirements, using the steps outlined above. For purposes of this example, we use a provider that is located in Brooklyn, New York that is assigned to CBSA 35644. This provider bills one service that is assigned to APC 0019 (Level I Excision/Biopsy). The CY 2012 full national unadjusted payment rate for APC 0019 is $307.74. The reduced national unadjusted payment rate for a hospital that fails to meet the Hospital OQR Program requirements is $301.59. This reduced rate is calculated by multiplying the reporting ratio of 0.980 by the full unadjusted payment rate for APC 0019.

The FY 2012 wage index for a provider located in CBSA 35644 in New York is 1.3142. The labor-related portion of the full national unadjusted payment is $242.66 (.60 * $307.74 * 1.3142). The labor-related portion of the reduced national unadjusted payment is $237.81 (.60 * $301.59 * 1.3142). The nonlabor-related portion of the full national unadjusted payment is $123.10 (.40 * $307.74). The nonlabor-related portion of the reduced national unadjusted payment is $120.63(.40 * $301.59). The sum of the labor-related and nonlabor-related portions of the full national adjusted payment is $365.76 ($242.66 + $123.10). The sum of the reduced national adjusted payment is $358.44 ($237.81 + $120.63).

I. Beneficiary Copayments

1. Background

Section 1833(t)(3)(B) of the Act requires the Secretary to set rules for determining the unadjusted copayment amounts to be paid by beneficiaries for covered OPD services. Section 1833(t)(8)(C)(ii) of the Act specifies that the Secretary must reduce the national

unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed a specified percentage. As specified in section 1833(t)(8)(C)(ii)(V) of the Act, for all services paid under the OPPS in CY 2010, and in calendar years thereafter, the percentage is 40 percent of the APC payment rate.

Section 1833(t)(3)(B)(ii) of the Act provides that, for a covered OPD service (or group of such services) furnished in a year, the national unadjusted copayment amount cannot be less than 20 percent of the OPD fee schedule amount. However, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected to the amount of the inpatient deductible, which for CY 2012 is $1,156.

Section 4104 of the Affordable Care Act eliminated the Part B coinsurance for preventive services furnished on and after January 1, 2011 that meet certain requirements, including flexible sigmoidoscopies and screening colonscopies, and waived the Part B deductible for screening colonoscopies that become diagnostic during the procedure. Our discussion of the changes made by the Affordable Care Act with regard to copayments for preventive services furnished on and after January 1, 2011 may be found in section XII.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 72013).

2. OPPS Copayment Policy

In the CY 2012 OPPS/ASC proposed rule (76 FR42224), we proposed to determine copayment amounts for new and revised APCs using the same methodology that we implemented beginning in CY 2004. (We refer readers to the November 7, 2003 OPPS final rule with comment period (68 FR 63458).) In addition, we proposed to use the same standard rounding principles that we have historically used in instances where the application of our standard copayment methodology would result in a copayment amount that is less than 20 percent and cannot be rounded, under standard rounding principles, to 20 percent. (We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66687) in which we discuss our rationale for applying these rounding principles.) The proposed national unadjusted copayment amounts for services payable under the OPPS that would be effective January 1, 2012, were shown in Addenda A and B to the proposed rule (which were available via the Internet on the CMS Web site). As discussed in section XIV.E. of the proposed rule and this final rule with comment period, for CY 2012, the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies will equal the product of the reporting ratio and the national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.

We did not receive any public comments regarding the proposed methodology for calculating copayments for CY 2012. Therefore, for the reasons set forth in the proposed rule (76 FR 42225), we are finalizing our CY 2012 copayment amounts without modification. We note that we received public comments on the copayments that would apply to beneficiaries who receive services from dedicated cancer hospitals under our proposal to provide an adjustment to payments to these hospitals. Those copayment-related public comments are discussed in section II.F. of this final rule with comment period.

3. Calculation of an Adjusted Copayment Amount for an APC Group

Individuals interested in calculating the national copayment liability for a Medicare beneficiary for a given service provided by a hospital that met or failed to meet its Hospital OQR Program requirements should follow the formulas presented in the following steps.

Step 1. Calculate the beneficiary payment percentage for the APC by dividing the APC's national unadjusted copayment by its payment rate. For example, using APC 0019, $61.55 is 20 percent of the full national unadjusted payment rate of $307.74. For APCs with only a minimum unadjusted copayment in Addenda A and B of this final rule with comment period (which are available via the Internet on the CMS Web site), the beneficiary payment percentage is 20 percent.

The formula below is a mathematical representation of Step 1 and calculates national copayment as a percentage of national payment for a given service.

B is the beneficiary payment percentage.

B = National unadjusted copayment for APC/national unadjusted payment rate for APC

Step 2. Calculate the appropriate wage-adjusted payment rate for the APC for the provider in question, as indicated in Steps 2 through 4 under section II.H. of this final rule with comment period. Calculate the rural adjustment for eligible providers as indicated in Step 6 under section II.H. of this final rule with comment period.

Step 3. Multiply the percentage calculated in Step 1 by the payment rate calculated in Step 2. The result is the wage-adjusted copayment amount for the APC.

The formula below is a mathematical representation of Step 3 and applies the beneficiary percentage to the adjusted payment rate for a service calculated under section II.H. of this final rule with comment period, with and without the rural adjustment, to calculate the adjusted beneficiary copayment for a given service.

Wage-adjusted copayment amount for the APC = Adjusted Medicare Payment * B

Wage-adjusted copayment amount for the APC (SCH or EACH) = (Adjusted Medicare Payment * 1.071) * B

Step 4. For a hospital that failed to meet its Hospital OQR Program requirements, multiply the copayment calculated in Step 3 by the reporting ratio of 0.980.

The unadjusted copayments for services payable under the OPPS that will be effective January 1, 2012, are shown in Addenda A and B to this final rule with comment period (which are referenced in section XVII. of this final rule with comment period and available via the Internet on the CMS Web site). We note that the national unadjusted payment rates and copayment rates shown in Addenda A and B to this final rule with comment period reflect the full CY 2012 OPD fee schedule increase factor discussed in section XIV.E. of this final rule with comment period.

Also as noted above, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected to the amount of the inpatient deductible, which for CY 2012 is $1,156.

III. OPPS Ambulatory Payment Classification (APC) Group Policies

A. OPPS Treatment of New CPT and Level II HCPCS Codes

CPT and Level II HCPCS codes are used to report procedures, services, items, and supplies under the hospital OPPS. Specifically, CMS recognizes the following codes on OPPS claims:

- Category I CPT codes, which describe medical services and procedures;
- Category III CPT codes, which describe new and emerging

technologies, services, and procedures; and

- Level II HCPCS codes, which are used primarily to identify products, supplies, temporary procedures, and services not described by CPT codes.

CPT codes are established by the American Medical Association (AMA) and the Level II HCPCS codes are established by the CMS HCPCS Workgroup. These codes are updated and changed throughout the year. CPT and HCPCS code changes that affect the OPPS are published both through the annual rulemaking cycle and through the OPPS quarterly update Change Requests (CRs). CMS releases new Level II HCPCS codes to the public or recognizes the release of new CPT codes by the AMA and makes these codes effective (that is, the codes can be reported on Medicare claims) outside of the formal rulemaking process via OPPS quarterly update CRs. This quarterly process offers hospitals access to codes that may more accurately describe items or services furnished and/or provides payment or more accurate payment for these items or services in a timelier manner than if CMS waited for the annual rulemaking process. We solicit comments on these new codes and finalize our proposals related to these codes through our annual rulemaking process. As we proposed in the CY 2012 OPPS/ASC proposed rule (76 FR 42225 through 42226), in Table 14 below (also Table 14 of the proposed rule), we summarize our process for updating codes through our OPPS quarterly update CRs, seeking public comments, and finalizing their treatment under the OPPS. We note that because of the timing of the publication of the proposed rule, the codes that were implemented through the July 2011 OPPS quarterly update were not included in Addendum B of the proposed rule (which is available via the Internet on the CMS Web site), while those codes based upon the April 2011 OPPS quarterly update were included in Addendum B.

TABLE 14.—COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April l, 2011	Level II HCPCS Codes	April 1, 2011	CY 2012 OPPS/ASC proposed rule	CY 2012 OPPS/ASC final rule with comment period
July 1, 2011	Level II HCPCS Codes	July 1, 2011	CY 2012 OPPS/ASC proposed rule	CY 2012 OPPS/ASC final rule with comment period
	Category I (certain vaccine codes) and III CPT codes	July 1, 2011	CY 2012 OPPS/ASC proposed rule	CY 2012 OPPS/ASC final rule with comment period
October 1, 2011	Level II HCPCS Codes	October 1, 2011	CY 2012 OPPS/ASC final rule with comment period	CY 2013 OPPS/ASC final rule with comment period
January 1, 2012	Level II HCPCS Codes	January 1, 2012	CY 2012 OPPS/ASC final rule with comment period	CY 2013 OPPS/ASC final rule with comment period
	Category I and III CPT Codes	January 1, 2012	CY 2012 OPPS/ASC final rule with comment period	CY 2013 OPPS/ASC final rule with comment period

This process is discussed in detail below. We have separated our discussion into two sections based on whether we solicited public comments in the CY 2012 OPPS/ASC proposed rule or whether we are soliciting public comments in this CY 2012 OPPS/ASC final rule with comment period. In the CY 2012 OPPS/ASC proposed rule, we noted that we sought public comment in the CY 2011 OPPS/ASC final rule with comment period on the new CPT and Level II HCPCS codes that were effective January 1, 2011. We also sought public comments in the CY 2011 OPPS/ASC final rule with comment period on the new Level II HCPCS codes effective October 1, 2010. These new codes, with an effective date of October 1, 2010, or January 1, 2011, were flagged with comment indicator ''NI'' (New code, interim APC assignment; comments will be accepted on the interim APC assignment for the new code) in Addendum B to the CY 2011 OPPS/ASC final rule with comment period to indicate that we were assigning them an interim payment status and an APC and payment rate, if applicable, which were subject to public comment following publication of the CY 2011 OPPS/ASC final rule with comment period. We are responding to public comments and finalizing our proposed OPPS treatment of these codes in this CY 2012 OPPS/ASC final rule with comment period.

We received comments on several new codes that were assigned to comment indicator ''NI'' in Addendum B of the CY 2011 OPPS/ASC final rule with comment period. We respond to those comments in sections II.A. and III.D. of this final rule with comment period. Table 15 lists the long descriptors for the CPT codes that were assigned to comment indicator ''NI'' for which we received public comments to the CY 2011 OPPS/ASC final rule with comment period and the specific sections where the comments are addressed.

BILLING CODE 4120–01–P

TABLE 15.—COMMENTS TO THE CY 2011 OPPS/ASC FINAL RULE WITH COMMENT PERIOD ON NEW HCPCS CODES ASSIGNED TO COMMENT INDICATOR "NI"

CY 2011 CPT Code	CY 2011 Long Descriptor	Section In This CY 2012 OPPS/ASC Final Rule With Comment Period Where Comments Are Addressed
0242T	Gastrointestinal tract transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report	III.D.2.b. (Gastrointestinal Transit and Pressure Measurement)
31295	Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (eg, balloon dilation), transnasal or via canine fossa	III.D.9.b. (Nasal Sinus Endoscopy)
31296	Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (eg, balloon dilation)	
31297	Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (eg, balloon dilation)	
37221	Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed	II.A.2.d.(6) (Endovascular Revascularization of the Lower Extremity)
37223	Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed	
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	
37235	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed	
64568	Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator	II.A.2.d.(8) (Cranial Neurostimulator and Electrodes)
65778	Placement of amniotic membrane on the ocular surface for wound healing; self-retaining	III.D.5.a. (Placement of Amniotic Membrane)
65779	Placement of amniotic membrane on the ocular surface for wound healing; single layer, sutured	

CY 2011 CPT Code	CY 2011 Long Descriptor	Section In This CY 2012 OPPS/ASC Final Rule With Comment Period Where Comments Are Addressed
74176	Computed tomography, abdomen and pelvis; without contrast material	III.D.7.f. (Computed Tomography of Abdomen/Pelvis)
74177	Computed tomography, abdomen and pelvis; with contrast material(s)	
74178	Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by contrast material(s) and further sections in one or both body regions	
90867	Therapeutic repetitive transcranial magnetic stimulation treatment; planning	III.D.4.c. (Transcranial Magnetic Stimulation Therapy)
90868	Therapeutic repetitive transcranial magnetic stimulation treatment; delivery and management, per session	
92132	Scanning computerized ophthalmic diagnostic imaging, anterior segment, with interpretation and report, unilateral or bilateral	III.D.5.c. (Scanning Ophthalmic Imaging)
92133	Scanning computerized ophthalmic diagnostic imaging, posterior segment, with interpretation and report, unilateral or bilateral; optic nerve	
92134	Scanning computerized ophthalmic diagnostic imaging, posterior segment, with interpretation and report, unilateral or bilateral; retina	

BILLING CODE 4120–01–C

1. Treatment of New Level II HCPCS Codes and Category I CPT Vaccine Codes and Category III CPT Codes for Which We Solicited Public Comments in the CY 2012 Proposed Rule

Through the April 2011 OPPS quarterly update CR (Transmittal 2174, Change Request 7342, dated March 18, 2011) and the July 2011 OPPS quarterly update CR (Transmittal 2234, Change Request 7443, dated May 27, 2011), we recognized several new HCPCS codes for separate payment under the OPPS. Effective April 1 and July 1 of CY 2011, we made effective a total of 22 new Level II HCPCS codes and 14 Category III CPT codes. Specifically, 5 new Level II HCPCS codes were effective for the April 2011 update and another 17 new Level II HCPCS codes were effective for the July 2011 update for a total of 22. Fourteen new Category III CPT codes were effective for the July 2011 update. Of the 22 new Level II HCPCS codes, we recognized for separate payment 16 of these codes, and of the 14 new Category III CPT codes, we recognized for separate payment 12 of these codes, for a total of 28 new HCPCS codes that are recognized for separate payment for CY 2012.

Through the April 2011 OPPS quarterly update CR, we allowed separate payment for each of the five new Level II HCPCS codes. Specifically, as displayed in Table 16 below (Table 15 of the proposed rule), we provided separate payment for the following HCPCS codes:

- HCPCS code C9280 (Injection, eribulin mesylate, 1 mg)
- HCPCS code C9281 (Injection, pegloticase, 1 mg)
- HCPCS code C9282 (Injection, ceftaroline fosamil, 10 mg)
- HCPCS code Q2040 (Injection, incobotulinumtoxin A, 1 unit)
- HCPCS code C9729 (Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with ligamentous resection, discectomy, facetectomy and/or foraminotomy, when performed) any method under indirect image guidance, with the use of an endoscope when performed, single or multiple levels, unilateral or bilateral; lumbar)

We note that HCPCS code Q2040 replaced HCPCS code C9278 (Injection, incobotulinumtoxin A, 1 unit) beginning April 1, 2010. HCPCS code C9278 was effective January 1, 2011, and deleted March 30, 2011, because it was replaced with HCPCS code Q2040. HCPCS code C9278 was assigned to pass-through status beginning January 1, 2011, when the code was implemented. Because HCPCS code Q2040 describes the same drug as HCPCS code C9278, we are continuing its pass-through status and assigning the HCPCS Q-code to the same APC and status indicator as its predecessor HCPCS C-code, as shown in Table 16 below. Specifically, HCPCS code Q2040 is assigned to APC 9278 and status indicator ''G.''

In the CY 2012 OPPS/ASC proposed rule, we solicited public comments on the proposed status indicators and APC assignments of HCPCS codes C9280, C9281, C9282, C9729, and Q2040, which were listed in Table 15 of that proposed rule (76 FR 42226) and now

appear in Table 16 of this final rule with comment period. We did not receive any public comments on the proposed APC assignments and status indicators for HCPCS codes C9280, C9281, C9282, C9729, and Q2040. However, for CY 2012, the HCPCS Workgroup replaced HCPCS C9280, C9281, C9282, and Q2040 with permanent HCPCS J-codes. Specifically, C9280 was replaced with J9179 (Injection, eribulin mesylate, 0.1 mg), C9281 with J2507 (Injection, pegloticase, 1 mg), C9282 with J0712 (Injection, ceftaroline fosamil, 10 mg), and Q2040 with J0588 (Injection, incobotulinumtoxin A, 1 unit). Consistent with our general policy of using permanent HCPCS codes if appropriate rather than using temporary HCPCS codes for the reporting of drugs under the OPPS in order to streamline coding, we are showing the replacement HCPCS codes effective January 1, 2012 in Table 16 that replaced HCPCS C9280, C9281, C9282, and Q2040.

Similarly, for CY 2012, we deleted HCPCS code C9729 on June 30, 2011 because it was replaced with CPT code 0275T. Further discussion of CPT code 0275T can be found below.

Because HCPCS codes J2507, J0712, and J0588 describe the same drugs and the same dosages currently designated by HCPCS codes C9281, C9282, and Q2040, respectively, these drugs will continue their pass-through status in CY 2012. Therefore, we are assigning HCPCS codes J2507, J0712, and J0588 to the same status indicators and APCs as their predecessor HCPCS codes, as shown in Table 16.

However, we note that the replacement code for HCPCS code C9280 does not describe the same dosage descriptor, and consequently, the replacement HCPCS code will be assigned a new APC number. Specifically, C9280 has a dosage descriptor of 1 mg; however, its replacement HCPCS code J9179 has a dosage descriptor of 0.1 mg. Therefore, effective January 1, 2012, HCPCS codes J9179 will be assigned to APC 1426 to maintain data consistency for future rulemaking. Because the predecessor HCPCS code C9280 was assigned to pass-through status, HCPCS code J9179 will continue to be assigned status indicator ''G'' for CY 2012.

We did not receive any public comments on the new Level II HCPCS codes that were implemented in April 2011. We are adopting as final, without modification, our proposal to assign the Level II HCPCS codes listed in Table 16 to the APCs and status indicators as proposed for CY 2012, with the exception of HCPCS code J9179, which will be assigned to APC 1426. Table 16 shows the final APC and status indicator assignments for all five Level II HCPCS codes.

TABLE 16.—LEVEL II HCPCS CODES WITH A CHANGE IN OPPS STATUS INDICATOR OR NEWLY IMPLEMENTED IN APRIL 2011

CY 2011 HCPCS Code	CY 2012 HCPCS Code	CY 2012 Long Descriptor	Final CY 2012 Status Indicator	Final CY 2012 APC
C9280	J9179	Injection, eribulin mesylate, 0.1 mg	G	1426
C9281	J2507	Injection, pegloticase, 1 mg	G	9281
C9282	J0712	Injection, ceftaroline fosamil, 10 mg	G	9282
C9729	0275T	Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (eg, fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; lumbar	T	0208
Q2040*	J0588	Injection, incobotulinumtoxin A, 1 unit	G	9278

*Level II HCPCS code C9278 was deleted March 31, 2011, and replaced with HCPCS code Q2040 effective April 1, 2011.

Through the July 2011 OPPS quarterly update CR, which included HCPCS codes that were made effective July 1, 2011, we allowed separate payment for 11 of the 17 new Level II HCPCS codes. Specifically, as displayed in Table 16 of

the proposed rule (Table 17 of this final rule with comment period), we provided separate payment for the following HCPCS codes:

- HCPCS code C9283 (Injection, acetaminophen, 10 mg)
- HCPCS code C9284 (Injection, ipilimumab, 10 mg)
- HCPCS code C9285 (Lidocaine 70 mg/tetracaine 70 mg, per patch)
- HCPCS code C9365 (Oasis Ultra Tri-Layer Matrix, per square centimeter)
- HCPCS code C9406 (Iodine I–123 ioflupane, diagnostic, per study dose, up to 5 millicuries)
- HCPCS code C9730 (Bronchoscopic bronchial thermoplasty with imaging guidance (if performed), radiofrequency ablation of airway smooth muscle, 1 lobe)
- HCPCS code C9731 (Bronchoscopic bronchial thermoplasty with imaging guidance (if performed), radiofrequency ablation of airway smooth muscle, 2 or more lobes)
- HCPCS code Q2041 (Injection, von willebrand factor complex (human), Wilate, 1 i.u. vwf:rco)
- HCPCS code Q2042 (Injection, hydroxyprogesterone caproate, 1 mg)
- HCPCS code Q2043 (Sipuleucel-t, minimum of 50 million autologous cd54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion)
- HCPCS code Q2044 (Injection, belimumab, 10 mg)

We note that two of the Level II HCPCS Q-codes that were made effective July 1, 2011, were previously described by a HCPCS J-code and a C-code that were assigned to pass-through status under the hospital OPPS. Specifically, HCPCS code Q2041 replaced HCPCS code J7184 (Injection, von willebrand factor complex (human), Wilate, per 100 iu vwf:rco) beginning July 1, 2011. HCPCS code J7184 was assigned to pass-through status when it was made effective January 1, 2011; however, the code is ''Not Payable by Medicare'' because HCPCS code J7184 is replaced with HCPCS code Q2041 effective July 1, 2011. Therefore, HCPCS code J7184 was reassigned to status indicator ''E'' effective July 1, 2011. Because HCPCS code J7184 describes the same drug as HCPCS code Q2041, we continued its pass-through status and assigned HCPCS code Q2041 to status indicator ''G'' effective July 1, 2011. However, because the dosage descriptor for HCPCS code Q2041 is not the same as HCPCS code J7184, we reassigned HCPCS code Q2041 to a new APC to maintain data consistency for future rulemaking. Specifically, HCPCS code Q2041 was assigned to APC 1352 effective July 1, 2011. In addition, HCPCS code Q2043 replaced HCPCS code C9273 (Sipuleucel-t, minimum of 50 million autologous cd54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion) beginning July 1, 2011. HCPCS code C9273 was assigned to pass-through status when it was made effective October 1, 2010. Because HCPCS code Q2043 describes the same product as HCPCS code C9273, we continued its pass-through status and assigned HCPCS code Q2043 to status indicator ''G'' as well as assigned it to the same APC, specifically APC 9273, effective July 1, 2011.

Of the 17 HCPCS codes that were made effective July 1, 2011, we did not recognize for separate payment six HCPCS codes that describe durable medical equipment (DME) because DME is paid under the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule and not the OPPS. These codes were listed in Table 16 of the proposed rule, and were assigned to either status indicator ''Y'' or ''A'' effective July 1, 2011.

In the CY 2012 OPPS/ASC proposed rule, we solicited public comments on the status indicators and APC assignments where applicable for the 17 HCPCS codes that were listed in Table 16 of that proposed rule (76 FR 42227 through 42228) and now appear in Table 17 of this final rule with comment period. We received a comment on the APC assignments for HCPCS codes C9730 and C9731. A summary of the comments and our responses can be found in section III.D.8.b. (Bronchial Thermoplasty) of this final rule with comment period. In addition, we received some comments on the long descriptor for HCPCS code Q2043. A summary of the comments and our responses can be found in section V.A.3. of this final rule with comment period.

With the exception of HCPCS codes C9730, C9731, and Q2043, we received no other public comments on the 14 other Level II HCPCS codes listed in Table 16 of the CY 2011 OPPS/ASC proposed rule. However, for CY 2012, the HCPCS Workgroup replaced several HCPCS C-codes with an A-code, J-code, or Q-code. Specifically, C9283 was replaced with J0131 (Injection, acetaminophen, 10 mg), C9284 with J9228 (Injection, ipilimumab, 1 mg), C9365 with Q4124 (Oasis Ultra Tri-Layer Matrix, per square centimeter), C9406 with A9584 (Iodine I–123 ioflupane, diagnostic, per study dose, up to 5 millicuries), Q2041 with J7183 (Injection, von willebrand factor complex (human), Wilate, 1 i.u. vwf:rco), Q2042 with J1725 (Injection, hydroxyprogesterone caproate, 1 mg), and Q2044 with J0490 (Injection, belimumab, 10 mg).

Because HCPCS codes J0131, J9228, Q4124, A9584, J7183 and J0490 describe the same drugs and the same dosages currently designated by HCPCS codes C9283,C9284, C9365, C9406, Q2041, and Q2044, respectively, these drugs will continue their pass-through status in CY 2012. Therefore, we are assigning HCPCS codes J0131, J9228, Q4124, A9584, J7183 and J0490 to the same status indicators and APCs as their predecessor HCPCS codes, as shown in Table 17. We note that since HCPCS code Q2042 is assigned to status indicator ''K'' (Nonpass-Through Drugs; Paid under OPPS; Separate APC payment), its replacement HCPCS code J1725 will also continue its nonpass-through status in CY 2012.

Further, for CY 2012, the CPT Editorial Panel made effective Category III CPT codes 0276T and 0277T on January 1, 2012. Because Category III CPT codes 0276T and 0277T describe the same procedures as HCPCS code C9730 and C9731, we are deleting HCPCS codes C9730 and C9731 on December 31, 2011, and assigning both CPT codes to the same status indicator and APC assignment as its predecessor HCPCS code, as shown in Table 17.

As stated previously, we did not receive any other public comments on the new Level II HCPCS codes that were implemented in July 2011, other than HCPCS codes C9730, C9731, and Q2043, which are discussed in sections III.D.8.b. and V.A.3., respectively, of this final rule with comment period. We are adopting as final, without modification, our proposal to assign the 17 Level II HCPCS codes listed in Table 12 to the APCs and status indicators as proposed for CY 2012.

Table 17 below includes a complete list of the Level II HCPCS codes that were made effective July 1, 2011, with their final status indicators, APC assignments, and payment rates for CY 2012.

BILLING CODE 4120–01–P

TABLE 17.—NEW LEVEL II HCPCS CODES IMPLEMENTED IN JULY 2011

CY 2011 HCPCS Code	CY 2012 HCPCS Code	CY 2012 Long Descriptor	Final CY 2012 Status Indicator	Final CY 2012 APC
C9283	J0131	Injection, acetaminophen, 10 mg	G	9283
C9284	J9228	Injection, ipilimumab, 1 mg	G	9284
C9285	C9285	Lidocaine 70 mg/tetracaine 70 mg, per patch	G	9285
C9365	Q4124	Oasis Ultra Tri-Layer Matrix, per square centimeter	G	9365
C9406	A9584	Iodine I-123 ioflupane, diagnostic, per study dose, up to 5 millicuries	G	9406
C9730	0276T	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe	T	0415
C9731	0277T	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes	T	0415
K0741	K0741	Portable gaseous oxygen system, rental, includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing, for cluster headaches	Y	NA
K0742	K0742	Portable oxygen contents, gaseous, 1 month's supply = 1 unit, for cluster headaches, for initial months supply or to replace used contents	Y	NA
K0743	K0743	Suction pump, home model, portable, for use on wounds	Y	NA
K0744	K0744	Absorptive wound dressing for use with suction pump, home model, portable, pad size 16 square inches or less	A	NA
K0745	K0745	Absorptive wound dressing for use with suction pump, home model, portable, pad size more than 16 square inches but less than or equal to 48 square inches	A	NA

CY 2011 HCPCS Code	CY 2012 HCPCS Code	CY 2012 Long Descriptor	Final CY 2012 Status Indicator	Final CY 2012 APC
K0746	K0746	Absorptive wound dressing for use with suction pump, home model, portable, pad size greater than 48 square inches	A	NA
Q2041	J7183	Injection, von willebrand factor complex (human), Wilate, 1 i.u. vwf:rco	G	1352
Q2042	J1725	Injection, hydroxyprogesterone caproate, 1 mg	K	1354
Q2043	Q2043	Sipuleucel-t, minimum of 50 million autologous cd54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion	G	9273
Q2044	J0490	Injection, belimumab, 10 mg	G	1353

BILLING CODE 4120–01–C

In the CY 2012 OPPS/ASC proposed rule (76 FR 42228), for CY 2012, we proposed to continue our established policy of recognizing Category I CPT vaccine codes for which FDA approval is imminent and Category III CPT codes that the AMA releases in January of each year for implementation in July through the OPPS quarterly update process. Under the OPPS, Category I vaccine codes and Category III CPT codes that are released on the AMA Web site in January are made effective in July of the same year through the July quarterly update CR, consistent with the AMA's implementation date for the codes. Through the July 2011 OPPS quarterly update CR, we allowed separate payment for 12 of the 14 new Category III CPT codes effective July 1, 2011. Specifically, as displayed in Table 17 of the proposed rule, we allow separate payment for the following Category III CPT codes:

- CPT code 0263T (Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure including unilateral or bilateral bone marrow harvest)
- CPT code 0264T (Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure excluding bone marrow harvest)
- CPT code 0265T (Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; unilateral or bilateral bone marrow harvest only for intramuscular autologous bone marrow cell therapy)
- CPT code 0267T (Implantation or replacement of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed))
- CPT code 0268T (Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed))
- CPT code 0269T (Revision or removal of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed))
- CPT code 0270T (Revision or removal of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed))
- CPT code 0271T (Revision or removal of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed))
- CPT code 0272T (Interrogation device evaluation (in person), carotid sinus baroreflex activation system, including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (eg, battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day))
- CPT code 0273T (Interrogation device evaluation (in person), carotid sinus baroreflex activation system, including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (eg, battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day); with programming)
- CPT 0274T (Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (eg, fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; cervical or thoracic)
- CPT 0275T (Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural

elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (eg, fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; lumbar) (As published in the July 2011 OPPS quarterly update CR, CPT code 0275T replaced Level II HCPCS code C9729 effective July 1, 2011.)

We note that Category III CPT codes 0262T (Implantation of catheter-delivered prosthetic pulmonary valve, endovascular approach) and 0266T (Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)) were assigned to status indicator ''C'' (Inpatient Procedures) under the hospital OPPS beginning July 1, 2011. As we stated in the proposed rule (76 FR 42229), we believe these procedures should only be paid when provided in the inpatient setting because of the clinical circumstances under which these procedures are performed. There are no new Category I Vaccine CPT codes for the July 2011 update.

Furthermore, for CY 2012, the CPT Editorial Panel made effective Category III CPT code 0275T on July 1, 2011. Because Category III CPT code 0275T describes the same procedure as HCPCS code C9729, we deleted HCPCS code C9729 on June 30, 2011. Through the July 2011 OPPS quarterly update CR, we also instructed hospitals to report the procedure previously described by HCPCS code C9729 with Category III CPT code 0275T effective July 1, 2011. Because Category III CPT code 0275T describes the same procedure designated by HCPCS code C9729, we assigned Category III CPT code 0275T to the same status indicator and APC assignment as its predecessor HCPCS code, as shown in Table 16 and Table 18.

We received a comment on the APC assignment and long descriptor for Category III CPT code 0275T. A summary of the comment and our response can be found in section III.D.6.a. (Percutaneous Laminotomy/Laminectomy) of this final rule with comment period. Table 18 lists the Category III CPT codes that were implemented in July 2011, along with their final status indicators, final APC assignments where applicable, and final payment rates for CY 2012.

BILLING CODE 4120–01–P

TABLE 18.—CATEGORY III CPT CODES IMPLEMENTED IN JULY 2011

CY 2012 CPT Code	CY 2012 Long Descriptor	Final CY 2012 Status Indicator	Final CY 2012 APC
0262T	Implantation of catheter-delivered prosthetic pulmonary valve, endovascular approach	C	NA
0263T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure including unilateral or bilateral bone marrow harvest	S	0112
0264T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure excluding bone marrow harvest	S	0112
0265T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; unilateral or bilateral bone marrow harvest only for intramuscular autologous bone marrow cell therapy	S	0112
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)	C	NA
0267T	Implantation or replacement of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)	T	0687

0268T	Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)	S	0039
0269T	Revision or removal of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)	T	0221
0270T	Revision or removal of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)	T	0687
0271T	Revision or removal of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)	T	0688
0272T	Interrogation device evaluation (in person), carotid sinus baroreflex activation system, including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (eg, battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day)	S	0218
0273T	Interrogation device evaluation (in person), carotid sinus baroreflex activation system, including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (eg, battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day); with programming	S	0218

0274T	Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (eg, fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; cervical or thoracic	T	0208
0275T	Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (eg, fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; lumbar	T	0208

BILLING CODE 4120–01–C

In the CY 2012 OPPS/ASC proposed rule (76 FR 42227 through 42229), we solicited public comments on the CY 2012 proposed status indicators and the proposed APC assignments and payment rates, if applicable, for the Level II HCPCS codes and the Category III CPT codes that are newly recognized in April or July 2011 through the respective OPPS quarterly update CRs. These codes were listed in Tables 15, 16, and 17 of the proposed rule. We proposed to finalize their status indicators and their APC assignments and payment rates, if applicable, in this CY 2012 OPPS/ASC final rule with comment period. Because the July 2011 OPPS quarterly update CR was issued close to the publication of the proposed rule, the Level II HCPCS codes and the Category III CPT codes implemented through the July 2011 OPPS quarterly update CR could not be included in Addendum B to the proposed rule, but these codes were listed in Tables 16 and 17, respectively. We proposed to incorporate these codes into Addendum B to this CY 2012 OPPS/ASC final rule with comment period, which is consistent with our annual OPPS update policy. The Level II HCPCS codes implemented or modified through the April 2011 OPPS update CR and displayed in Table 15 were included in Addendum B to the proposed rule (which is available via the Internet on the CMS Web site), where their proposed CY 2012 payment rates were also shown. We did not receive any additional comments on this process. The final status indicators, APC assignments, and payment rates, if applicable, for the Level II HCPCS codes and the Category III CPT codes that are newly recognized in April or July 2011 through the respective OPPS quarterly update CRs are found in Addendum B to this CY 2012 OPPS/ASC final rule with comment period (which is available via the Internet on the CMS Web site).

2. Process for New Level II HCPCS Codes and Category I and Category III CPT Codes for Which We Are Soliciting Public Comments on This CY 2012 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new Category I and III CPT codes and new Level II HCPCS codes that are effective January 1 in the final rule with comment period updating the OPPS for the following calendar year. These codes are released to the public via the CMS HCPCS (for Level II HCPCS codes) and AMA Web sites (for CPT codes), and also through the January OPPS quarterly update CRs. In the past, we also have released new Level II HCPCS codes that are effective October 1 through the October OPPS quarterly update CRs and incorporated these new codes in the final rule with comment period updating the OPPS for the following calendar year. All of these codes are flagged with comment indicator ''NI'' in Addendum B to the OPPS/ASC final rule with comment period to indicate that we are assigning them an interim payment status which is subject to public comment. Specifically, the status indicator and the APC assignment and payment rate, if applicable, for all such codes flagged with comment indicator ''NI'' are open to public comment in the final rule with comment period, and we respond to these comments in the OPPS/ASC final rule with comment period for the next calendar year's OPPS/ASC update. In the CY 2012 OPPS/ASC proposed rule (76 FR 42230), we proposed to continue this process for CY 2012. Specifically, for CY 2012, we proposed to include in Addendum B to this CY 2012 OPPS/ASC final rule with comment period (which is available via the Internet on the CMS Web site) the new Category I and III CPT codes effective January 1, 2012 (including the Category III CPT codes that were released by the AMA in July 2011) that would be incorporated in the January 2012 OPPS quarterly update CR and the new Level II HCPCS codes, effective October 1, 2011, or January 1, 2012, that would be released by CMS in its October 2011 and January 2012 OPPS quarterly update CRs. As proposed, in this final rule with comment period, these codes are flagged with comment indicator ''NI'' in Addendum B to this CY 2012 OPPS/ASC final rule with comment period to indicate that we have assigned them an interim OPPS payment status for CY 2012. As

proposed, in this final rule with comment period, their status indicators and their APC assignments and payment rates, if applicable, are open to public comment and will be finalized in the CY 2013 OPPS/ASC final rule with comment period. We note that the CPT codes that were released by the AMA in July 2011 that were subject to comment in the CY 2012 OPPS/ASC proposed rule, and were listed in Table 17, will not be assigned to comment indicator ''NI'' in Addendum B because comments about these codes will be addressed in this CY 2012 OPPS/ASC final rule with comment period.

Comment: One commenter recommended that, through a Web posting, CMS request public input on the APC assignments of the Category I CPT vaccine codes, Category III CPT codes, and Level II HCPCS codes that are made effective on October 1 or January 1 of subsequent years but are made available to the public by the completion of each year's OPPS proposed rule. The commenter indicated that some of these codes have already been released to the public, either through the CMS or AMA CPT Web site, by July 1 of any given year. This same commenter suggested that the lack of stakeholder input on the interim APC assignments may negatively impact Medicare beneficiaries. In particular, the commenter stated that interim payment assignments have been influential in determining whether hospitals provide services to Medicare beneficiaries or not, and further suggested that if the payment for a procedure or service does not adequately reflect the true costs of furnishing the service, then hospitals may decide not to offer the service to Medicare beneficiaries.

Response: The commenter is correct that Category I Vaccine and Category III CPT codes that are effective January 1 of a subsequent year are released on the AMA CPT Web site on or about July 1. However, some Level II HCPCS codes are not released on the CMS Web site until much later. For the October update, the Level II HCPCS C-codes that are effective October 1 are usually released and posted on the CMS Web site in August or September, depending on the number of OPPS new technology service and pass-through drug and device applications that are evaluated. Therefore, we do not have sufficient time to evaluate the new codes, determine proposed APC assignments, post those proposed assignments to the CMS Web site, accept and consider public comments, and respond to public comments between the time that the new codes become available and the time that we must meet our systems deadlines for our claims processing and payment files for the upcoming quarter. Given the challenges and time constraints in meeting the quarterly CPT and Level II HCPCS systems deadlines, we will continue to assign the new codes that are effective October 1 and January 1 of subsequent year to interim APC assignments. If we were to wait for comments on the interim APC assignments for the new codes before making them effective on October 1 or January 1, this may result in services and items not being paid for separately for a whole year, which would ultimately disadvantage both the hospital outpatient facilities and Medicare beneficiaries.

The OPPS is a prospective payment system that provides payment for groups of services that share clinical and resource use characteristics. It should be noted that, with all new codes, our policy has been to assign the service to an APC based on input from a variety of sources, including but not limited to review of the clinical similarity of the service to existing procedures; input from CMS medical advisors; information from interested specialty societies; and review of all other information available to us, including information provided to us by the public, whether through meetings with stakeholders or additional information that is mailed or otherwise communicated to us.

After consideration of the public comments we received, we are finalizing our proposed policy, without modification, to assign the new CPT and Level II HCPCS codes that are effective October 1 and January 1 of subsequent years to interim APC assignments and request comments on the codes in the annual OPPS/ASC final rule with comment period, as described above.

Comment: Some commenters requested that CMS implement a 1 to 2 year dampening period to minimize significant fluctuations in payments from year to year for newly bundled or packaged procedure codes. One commenter specifically stated that limiting the payment reduction to 10 percent would prevent hospitals from experiencing substantial payment reductions and would allow hospitals reasonable time to appropriately update their chargemasters to reflect the newly packaged codes.

Response: We do not believe it is necessary or appropriate to limit payment reductions for any individual service in order to prevent hospitals from experiencing substantial payment reductions as the commenter indicates. While payment rates for individual services may decrease from year to year, the total estimated payments made to hospitals remains the same because the OPPS is, by statute, a budget neutral payment system. In order to accurately report charges on their claims, hospitals must be cognizant of HCPCS coding changes, specifically with respect to Category I and III CPT codes and Level II HCPCS codes that occur throughout the year, including the quarterly updates (April 1, July 1, and October 1) as well as the annual updates (January 1). In recent years, the CMS and the AMA's CPT Editorial Panel have increasingly created new codes that use a single HCPCS code to report combinations of services that were previously reported by multiple HCPCS codes or multiple units of a single HCPS code. For example, effective January 1, 2010, CMS created HCPCS code G0424 (Pulmonary rehabilitation, including exercise (includes monitoring), per hour, per session) to represent a comprehensive program of pulmonary therapy and the CPT Editorial Panel created CPT code 77338 (Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction per IMRT plan) to report all devices furnished under a single IMRT treatment plan. As we have stated before, we expect hospitals to carefully review each new HCPCS code when setting charges for the forthcoming year. However, in particular, hospitals should be especially careful to thoughtfully establish charges for new codes that use a single code to report multiple services that were previously reported by multiple codes. It is vital in these cases that hospitals carefully establish charges that fully include all of the charges for all of the predecessor services that are reported by the new code. To fail to carefully construct the charge for a new code that reports a combination of services that were previously reported separately, particularly in the first year of the new code, under-represents the cost of providing the service describing by the new code and can have significant adverse impact on future payments under the OPPS for the individual service described by the new code.

B. OPPS Changes—Variations Within APCs

1. Background

Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered hospital outpatient department services. Section 1833(t)(2)(B) of the Act provides that the Secretary may establish groups of covered OPD services within this

classification system, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we developed a grouping classification system, referred to as Ambulatory Payment Classifications (APCs), as set forth in § 419.31 of the regulations. We use Level I and Level II HCPCS codes to identify and group the services within each APC. The APCs are organized such that each group is homogeneous both clinically and in terms of resource use. Using this classification system, we have established distinct groups of similar services. We also have developed separate APC groups for certain medical devices, drugs, biologicals, therapeutic radiopharmaceuticals, and brachytherapy devices.

We have packaged into payment for each procedure or service within an APC group the costs associated with those items or services that are directly related to, and supportive of, performing the main independent procedures or furnishing the services. Therefore, we do not make separate payment for these packaged items or services. For example, packaged items and services include:

(1) Use of an operating, treatment, or procedure room;

(2) Use of a recovery room;

(3) Observation services;

(4) Anesthesia;

(5) Medical/surgical supplies;

(6) Pharmaceuticals (other than those for which separate payment may be allowed under the provisions discussed in section V. of the proposed rule and this final rule with comment period);

(7) Incidental services such as venipuncture;

(8) Guidance services, image processing services, intraoperative services, imaging, supervision and interpretation services, diagnostic radiopharmaceuticals, and contrast media.

Further discussion of packaged services is included in section II.A.3. of this final rule with comment period.

In CY 2008, we implemented composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service (72 FR 66650 through 66652). Under CY 2011 OPPS policy, we provide composite APC payment for certain extended assessment and management services, low dose rate (LDR) prostate brachytherapy, cardiac electrophysiologic evaluation and ablation, mental health services, and multiple imaging services. Further discussion of composite APCs is included in section II.A.2.e. of this final rule with comment period.

Under the OPPS, we generally pay for hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or combination of services is assigned. Each APC weight represents the hospital median cost of the services included in that APC, relative to the hospital median cost of the services included in APC 0606 (Level 3 Hospital Clinic Visits). The APC weights are scaled to APC 0606 because it is the middle level hospital clinic visit APC (the Level 3 hospital clinic visit CPT code out of five levels), and because middle level hospital clinic visits are among the most frequently furnished services in the hospital outpatient setting.

Section 1833(t)(9)(A) of the Act requires the Secretary to review, on a recurring basis occurring no less than annually, and revise the groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. Section 1833(t)(9)(A) of the Act also requires the Secretary to consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the APC groups and the relative payment weights (the APC Panel recommendations for specific services for the CY 2012 OPPS and our responses to them are discussed in the relevant specific sections throughout this final rule with comment period).

Finally, section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median cost (or mean cost as elected by the Secretary) for an item or service in the group is more than 2 times greater than the lowest median cost (or mean cost, if so elected) for an item or service within the same group (referred to as the ''2 times rule''). We use the median cost of the item or service in implementing this provision. The statute authorizes the Secretary to make exceptions to the 2 times rule in unusual cases, such as low-volume items and services (but the Secretary may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act).

2. Application of the 2 Times Rule

In accordance with section 1833(t)(2) of the Act and § 419.31 of the regulations, we annually review the items and services within an APC group to determine, with respect to comparability of the use of resources, if the median cost of the highest cost item or service within an APC group is more than 2 times greater than the median of the lowest cost item or service within that same group. In making this determination, we consider only those HCPCS codes that are significant based on the number of claims. We note that, for purposes of identifying significant HCPCS codes for examination in the 2 times rule, we consider codes that have more than 1,000 single major claims or codes that have both greater than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC median cost to be significant (75 FR 71832). This longstanding definition of when a HCPCS code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 claims is negligible within the set of approximately 100 million single procedure or single session claims we use for establishing median costs. Similarly, a HCPCS code for which there are fewer than 99 single bills and which comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC median. In the CY 2012 OPPS/ASC proposed rule (76 FR 42231), we proposed to make exceptions to this limit on the variation of costs within each APC group in unusual cases, such as low-volume items and services for CY 2012.

During the APC Panel's February 2011 meeting, we presented median cost and utilization data for services furnished during the period of January 1, 2010, through September 30, 2010, about which we had concerns or about which the public had raised concerns regarding their APC assignments, status indicator assignments, or payment rates. The discussions of most service-specific issues, the APC Panel recommendations, if any, and our proposals and final policies for CY 2012 are contained mainly in sections III.C. and III.D. of this final rule with comment period.

In addition to the assignment of specific services to APCs that we discussed with the APC Panel, we also identified APCs with 2 times violations that were not specifically discussed

with the APC Panel but for which we proposed changes to their HCPCS codes' APC assignments in Addendum B to the proposed rule. We note that Addendum B did not appear in the printed version of the **Federal Register** as part of the CY 2012 OPPS/ASC proposed rule. Rather, it was published and made available only via the Internet on the CMS Web site at: *http://www.cms.gov/*. In these cases, to eliminate a 2 times violation or to improve clinical and resource homogeneity, we proposed to reassign the codes to APCs that contain services that are similar with regard to both their clinical and resource characteristics. We also proposed to rename existing APCs or create new clinical APCs to complement proposed HCPCS code reassignments. In many cases, the proposed HCPCS code reassignments and associated APC reconfigurations for CY 2012 included in the proposed rule were related to changes in median costs of services that were observed in the CY 2010 claims data newly available for CY 2012 ratesetting. We also proposed changes to the status indicators for some codes that were not specifically and separately discussed in the proposed rule. In these cases, we proposed to change the status indicators for some codes because we believe that another status indicator would more accurately describe their payment status from an OPPS perspective based on the policies that we proposed for CY 2012. Addendum B of the CY 2012 OPPS/ASC proposed rule identified with a comment indicator ''CH'' those HCPCS codes for which we proposed a change to the APC assignment or status indicator as assigned in the April 2011 Addendum B Update (available via the Internet on the CMS Web site at: *http://www.cms.gov/*). In contrast, Addendum B of this final rule with comment period identifies with the ''CH'' comment indicator the final CY 2012 changes compared to the codes' status as reflected in the October 2011 Addendum B update.

3. Exceptions to the 2 Times Rule

As discussed earlier, we may make exceptions to the 2 times limit on the variation of costs within each APC group in unusual cases such as low volume items and services. Taking into account the APC changes that we proposed for CY 2012 based on the APC Panel recommendations that were discussed mainly in sections III.C. and III.D. of the proposed rule, the other proposed changes to status indicators and APC assignments as identified in Addendum B to the proposed rule (which was available via the Internet on the CMS Web site), and the use of CY 2010 claims data to calculate the median costs of procedures classified in the APCs, we reviewed all the APCs to determine which APCs would not satisfy the 2 times rule. We used the following criteria to decide whether to propose exceptions to the 2 times rule for affected APCs:

- Resource homogeneity;
- Clinical homogeneity;
- Hospital outpatient setting;
- Frequency of service (volume); and
- Opportunity for upcoding and code fragments.

For a detailed discussion of these criteria, we refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18457 and 18458).

Table 18 of the CY 2012 OPPS/ASC proposed rule (76 FR 42232) listed 17 APCs that we proposed to exempt from the 2 times rule for CY 2012 based on the criteria cited above.

For cases in which a recommendation by the APC Panel appeared to result in or allow a violation of the 2 times rule, we generally accepted the APC Panel's recommendation because those recommendations were based on explicit consideration of resource use, clinical homogeneity, site of service, and the quality of the CY 2010 claims data used to determine the APC payment rates that we proposed for CY 2012. The median costs for hospital outpatient services for these and all other APCs that were used in the development of the CY 2012 OPPS/ASC proposed rule and this final rule with comment period can be found on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS/01_overview.asp.*

For the CY 2012 OPPS/ASC proposed rule, we based the listed exceptions to the 2 times rule on claims data for dates of service between January 1, 2010, and December 31, 2010, that were processed before January 1, 2011. For this final rule with comment period, we used claims data for dates of service between January 1, 2010, and December 31, 2010, that were processed on or before June 30, 2011 and updated CCRs, if available. Although we stated in the CY 2012 OPPS/ASC proposed rule (76 FR 42232) that the list of APC exemptions that appeared in Table 18 were based on claims data processed from January 1, 2010, through September 30, 2010, we are clarifying that the listed exceptions were based on claims data processed between January 1, 2010, and December 31, 2010, consistent with past practice of using claims data processed between January 1 and December 31 of an applicable year to determine APCs that are exempted from the 2 times rule. Thus, after considering the public comments we received on the CY 2012 OPPS/ASC proposed rule and making changes to APC assignments based on those comments, we analyzed the CY 2010 claims data used for this final rule with comment period to identify the APCs with 2 times violations. Based on the final CY 2010 claims data, we found that there are 23 APCs with 2 times rule violations, a cumulative increase of 6 APCs from the proposed rule. We applied the criteria as described earlier to identify the APCs that are exceptions to the 2 times rule for CY 2012, and identified additional APCs that meet the criteria for exception to the 2 times rule for this final rule with comment period:

- APC 0076 (Level I Endoscopy Lower Airway)
- APC 0135 (Level III Skin Repair)
- APC 0148 (Level I Anal/Rectal Procedures)
- APC 0262 (Plain Film of Teeth)
- APC 0317 (Level II Miscellaneous Radiology Procedures)
- 0330 (Dental Procedures)
- APC 0341 (Skin Tests)
- APC 0403 (Level I Nervous System Imaging)
- APC 0409 (Red Blood Cell Tests)
- APC 0607 (Level 4 Hospital Clinic Visits)

In addition, we also determined that there are five APCs that no longer violate the 2 times rule:

- APC 0016 (Level IV Debridement & Destruction)
- APC 0105 (Repair/Revision/Removal of Pacemakers, AICDs, or Vascular Devices)
- APC 0245 (Level I Cataract Procedures without IOL)
- APC 0263 (Level I Miscellaneous Radiology)
- APC 0432 (Health and Behavior Services)

We have not included in this count those APCs where a 2 times violation is not a relevant concept, such as APC 0375 (Ancillary Outpatient Services when Patient Expires), with an APC median cost set based on multiple procedure claims; therefore, we have identified only final APCs, including those with criteria-based median costs, such as device-dependent APCs, with 2 times rule violations.

Comment: One commenter supported CMS' proposal to exempt APCs 0016 and 0058 from the 2 times rule. According to the commenter, because the procedures included in both APCs are similar based on clinical homogeneity and resource costs, there is little opportunity to upcode, and therefore, it is appropriate to exempt APCs 0016 and 0058 from the 2 times rule.

Response: We appreciate the commenter's support. Based on our

analysis of the CY 2010 claims used for the final rule with comment period, we found that APC 0016 no longer violated the 2 times rule. However, APC 0058 continued to violate the 2 times rule. The range in median costs for the procedures with significant claims data in APC 0058 is between $49 and $116. Currently, there are only two levels of APCs for services that describe strapping and cast application, which include APC 0058 and APC 0426 (Level II Strapping and Cast Application). In contrast to APC 0058, our claims data show that the range in median costs for the procedures with significant claims data in APC 0426 is between $150 and $197. Because of the range in median costs in APC 0426, we believe that the procedures in APC 0058 should continue to be placed in APC 0058. Therefore, we are finalizing our proposal to continue to exempt APC 0058 from the 2 times rule.

After consideration of the public comment that we received and our review of the CY 2010 costs from claims available for this final rule with comment period, we are finalizing our proposal to exempt 12 original APCs (that appeared in Table 18 of the CY 2012 OPPS/ASC proposed rule with comment period and also appears in Table 19 below) from the 2 times rule for CY 2012, with modification. Specifically, we removed five APCs that no longer violated the 2 times rule and increased the number of APC exceptions from 17 to 23 APCs, as described previously in this section. Our final list of 23 APCs exempted from the 2 times rule is displayed in Table 19 below.

TABLE 19.—FINAL APC EXCEPTIONS TO THE 2 TIMES RULE FOR CY 2012

Final CY 2012 APC	Final CY 2012 APC Title
0057	Bunion Procedures
0058	Level I Strapping and Cast Application
0060	Manipulation Therapy
0076	Level I Endoscopy Lower Airway
0080	Diagnostic Cardiac Catheterization
0135	Level III Skin Repair
0148	Level I Anal/Rectal Procedures
0235	Level I Posterior Segment Eye Procedures
0262	Plain Film of Teeth
0317	Level II Miscellaneous Radiology Procedures
0330	Dental Procedures
0340	Minor Ancillary Procedures
0341	Skin Tests
0347	Level III Transfusion Laboratory Procedures
0367	Level I Pulmonary Test
0369	Level III Pulmonary Tests
0403	Level I Nervous System Imaging
0409	Red Blood Cell Tests
0436	Level I Drug Administration
0604	Level 1 Hospital Clinic Visits
0607	Level 4 Hospital Clinic Visits
0660	Level II Otorhinolaryngologic Function Tests
0667	Level II Proton Beam Radiation Therapy

C. New Technology APCs

1. Background

In the November 30, 2001 final rule (66 FR 59903), we finalized changes to the time period a service was eligible for payment under a New Technology APC. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected.

We note that the cost bands for New Technology APCs range from $0 to $50 in increments of $10, from $50 to $100 in increments of $50, from $100 to $2,000 in increments of $100, and from $2,000 to $10,000 in increments of $500. These cost bands identify the APCs to which new technology procedures and services with estimated service costs that fall within those cost bands are assigned under the OPPS. Payment for each APC is made at the mid-point of the APC's assigned cost band. For example, payment for New Technology APC 1507 (New Technology—Level VII ($500–$600)) is made at $550. Currently, there are 82 New Technology APCs, ranging from the lowest cost band assigned to APC 1491 (New Technology—Level IA ($0–$10)) through the highest cost band assigned to APC 1574 (New Technology—Level XXXVII ($9,500–$10,000). In CY 2004 (68 FR 63416), we last restructured the New Technology APCs to make the cost intervals more consistent across payment levels and refined the cost bands for these APCs to retain two parallel sets of New Technology APCs, one set with a status indicator of ''S''' (Significant Procedures, Not Discounted when Multiple; Paid under OPPS; separate APC payment) and the other set with a status indicator of ''T'' (Significant Procedure, Multiple Reduction Applies; Paid under OPPS; separate APC payment). These current New Technology APC configurations allow us to price new technology services more appropriately and consistently.

Every year we receive many requests for higher payment amounts under our New Technology APCs for specific procedures under the OPPS because they require the use of expensive equipment. We are taking this opportunity to reiterate our response in general to the issue of hospitals' capital expenditures as they relate to the OPPS and Medicare.

Under the OPPS, one of our goals is to make payments that are appropriate for the services that are necessary for the treatment of Medicare beneficiaries. The OPPS, like other Medicare payment systems, is budget neutral and increases are limited to the annual hospital inpatient market basket increase. We believe that our payment rates generally reflect the costs that are associated with providing care to Medicare beneficiaries in cost-efficient settings, and we believe that our rates are adequate to ensure access to services.

For many emerging technologies, there is a transitional period during which utilization may be low, often because providers are first learning about the techniques and their clinical utility. Quite often, parties request that Medicare make higher payment amounts under our New Technology APCs for new procedures in that transitional phase. These requests, and their accompanying estimates for expected total patient utilization, often reflect very low rates of patient use of expensive equipment, resulting in high per use costs for which requesters believe Medicare should make full payment. Medicare does not, and we believe should not, assume responsibility for more than its share of the costs of procedures based on Medicare beneficiary projected utilization and does not set its payment rates based on initial projections of low utilization for services that require expensive capital equipment. For the OPPS, we rely on hospitals to make informed business decisions regarding the acquisition of high cost capital equipment, taking into consideration their knowledge about their entire patient base (Medicare beneficiaries included) and an understanding of Medicare's and other payers' payment policies.

We note that, in a budget neutral environment, payments may not fully cover hospitals' costs in a particular circumstance, including those for the purchase and maintenance of capital equipment. We rely on hospitals to make their decisions regarding the acquisition of high cost equipment with the understanding that the Medicare program must be careful to establish its initial payment rates, including those made through New Technology APCs, for new services that lack hospital claims data based on realistic utilization projections for all such services delivered in cost-efficient hospital outpatient settings. As the OPPS acquires claims data regarding hospital costs associated with new procedures, we regularly examine the claims data and any available new information regarding the clinical aspects of new procedures to confirm that our OPPS payments remain appropriate for procedures as they transition into mainstream medical practice.

2. Movement of Procedures From New Technology APCs to Clinical APCs

As we explained in the November 30, 2001 final rule (66 FR 59902), we generally keep a procedure in the New Technology APC to which it is initially assigned until we have collected sufficient data to enable us to move the procedure to a clinically appropriate APC. However, in cases where we find that our original New Technology APC assignment was based on inaccurate or inadequate information (although it was the best information available at the time), or where the New Technology APCs are restructured, we may, based on more recent resource utilization information (including claims data) or the availability of refined New Technology APC cost bands, reassign the procedure or service to a different New Technology APC that most appropriately reflects its cost.

Consistent with our current policy, in the CY 2012 OPPS/ASC proposed rule (76 FR 42233), we proposed for CY 2012 to retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to a clinically appropriate APC. The flexibility associated with this policy allows us to move a service from a New Technology APC in less than 2 years if sufficient claims data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient claims data upon which to base a decision for reassignment have not been collected. Table 19 of the proposed rule listed the HCPCS codes and associated status indicators that we proposed to reassign from a New Technology APC to a clinically appropriate APC or to a different New Technology APC for CY 2012.

Currently, in CY 2011, there are three procedures described by a HCPCS G-code receiving payment through a New Technology APC. Specifically, HCPCS code G0417 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 21–40 specimens) is assigned to New Technology APC 1506 (New Technology—Level VI ($400—$500)); HCPCS code G0418 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 41–60 specimens) is assigned to New Technology APC 1511 (New

Technology—Level XI ($900–$1,000)); and HCPCS code G0419 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, greater than 60 specimens) is assigned to New Technology APC 1513 (New Technology—Level XIII ($1,100–$1,200)).

Analysis of our hospital outpatient data for claims submitted for CY 2010 indicates that prostate saturation biopsy procedures are rarely performed on Medicare patients. For OPPS claims submitted from CY 2009 through CY 2010, our claims data show that there were only five claims submitted for HCPCS code G0417 in CY 2009 and only one in CY 2010 with a proposed median cost of approximately $532. Our claims data did not show any hospital outpatient claims for HCPCS codes G0418 and G0419 from either CY 2009 or CY 2010.

While we believe that these procedures will always be low volume, given the number of specimens being collected, we believe that we should continue their New Technology payments for another year for HCPCS codes G0417, G0418, and G0419 to see if more claims data become available. For CY 2012, we proposed to revise the APC assignments for these procedures and continue the New Technology APC payments for HCPCS G-codes G0417, G0418, and G0419. Specifically, we proposed to reassign HCPCS code G0417 from APC 1506 to APC 1505 (New Technology–Level V ($300–$400)), HCPCS code G0418 from APC 1511 to APC 1506 (New Technology–Level VI ($400–$500)), and HCPCS G0419 code from APC 1513 to APC 1508 (New Technology–Level VIII ($600–$700)). We stated in the proposed rule that we believe that the proposed revised APC assignments would more appropriately reflect the procedures described by these three HCPCS G-codes, based on clinical and resource considerations. These procedures and their proposed APC assignments are displayed in Table 19 of the proposed rule.

We did not receive any public comments on the APC reassignments for HCPCS codes G0417, G0418, and G0419. Therefore, for the reasons set forth above, we are finalizing our proposal, without modification, to assign HCPCS code G0417 to APC 1505, HCPCS code G0418 to APC 1506, and to assign HCPCS code G0419 to APC 1508. The final CY 2012 payment rates for HCPCS codes G0417, G0418, and G0419 can be found in Addendum B of this final rule with comment period (which is available via the Internet on the CMS Web site). Table 20 below lists the HCPCS codes and associated status indicators that we are reassigning from a New Technology APC to a different New Technology APC for CY 2012.

TABLE 20.—REASSIGNMENT OF PROCEDURES ASSIGNED TO NEW TECHNOLOGY APCs FOR CY 2012

CY 2011 HCPCS Code	CY 2011 Short Descriptor	CY 2011 SI	CY 2011 APC	Final CY 2012 SI	Final CY 2012 APC
G0417	Sat biopsy prostate 21-40	S	1506	S	1505
G0418	Sat biopsy prostate 41-60	S	1511	S	1506
G0419	Sat biopsy prostate: >60	S	1513	S	1508

D. OPPS APC–Specific Policies

1. Cardiovascular Services

a. Cardiovascular Computed Tomography (CCT) (APC 0340 and 0383)

The CPT Editorial Panel created the following new codes for cardiovascular computed tomography (CCT) services effective January 1, 2010: CPT codes 75571 (Computed tomography, heart, without contrast material, with quantitative evaluation of coronary calcium), 75572 (Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology (including 3D image postprocessing, assessment of cardiac function, and evaluation of venous structures, if performed)), 75573 (Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology in the setting of congenital heart disease (including 3D image postprocessing, assessment of LV cardiac function, RV structure and function and evaluation of venous structures, if performed)), and 75574 (Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed)). These Category I CPT codes replaced eight Category III CPT codes that had been in effect through December 31, 2009. For CY 2010, we assigned CPT code 75571 to APC 0340 (Minor Ancillary Procedures), and we assigned CPT codes 75572, 75573, and 75574 to APC 0383 (Cardiac Computed Tomographic Imaging). For CY 2011, we maintained these APC assignments, with final payment rates for APC 0340 and 0383 of $46.23 and $256.86, respectively. For CY 2012, we proposed to maintain the assignments of CPT code 75571 to APC 0340 and CPT codes 75572, 75573, and 75574 to APC 0383. APCs 0340 and 0383 have final CY 2012 median costs of approximately $46 and $262, respectively.

Comment: One commenter was concerned that hospitals may be failing to report the services in APC 0383 with CPT codes 75572, 75573, and 75574, which were effective January 1, 2010, and are continuing to report the related services using the expired Category III CPT codes previously used through December 31, 2009. The commenter requested that CMS analyze the CY 2010 claims data to determine whether the expired CCT codes are being used to report CCT services and, if so, to use those claims in calculating the APC 0383 final median cost. The commenter

also urged CMS to reassign CPT code 75571 from APC 0340 to APC 0282 (Miscellaneous Computed Axial Tomography) for reasons of clinical coherence and resource use similarity to procedures in APC 0282. The commenter contended that APC 0340 contains several procedures that do not require the same equipment or clinical staff as CPT code 75571, while APC 0282 contains services that do have similar clinical and resource characteristics to CPT code 75571.

In addition, the commenter expressed concerns that hospitals do not report their costs in a consistent and accurate way and do not update their chargemasters regularly with charges that reflect appropriate relativity, and offered to work with CMS to develop a standard methodology to address these issues. The commenter also recommended that CMS promote the need to accurately and completely report all services provided.

Response: We believe that the CY 2012 median costs we have calculated for CPT codes 75572, 75573, and 75574 and APC 0383 appropriately reflect valid estimates of the cost of these services. We compared the median costs and single procedure claims based on CY 2009 claims (used for final CY 2011 payment rates) with median costs and single procedure claims based on CY 2010 claims (which we are using for the final CY 2012 payment rates). The final CY 2011 APC 0383 median cost of approximately $254 used 11,323 single bills based on 6 of the category III CPT codes used prior to CPT codes 75572, 75573, and 75574. The final CY 2012 APC 0383 median cost of approximately $262 used 15,253 single bills based on CPT codes 75572, 75573, and 75574. This shows consistency across years in median costs and an increase in the number of single bills used. Therefore, we have no reason to believe that the median costs we have calculated do not reflect valid estimates of the costs of CPT codes 75572, 75573, and 75574, which went into effect on January 1, 2010.

We believe that CPT code 75571 is a minor ancillary procedure and is appropriately assigned to APC 0340, in terms of resources and clinical similarity. CPT code 75571 has a final median cost of approximately $31, and APC 0340 has a final median cost of approximately $46. In contrast, APC 0282 has a final median cost of approximately $107, driven largely by a single major procedure CPT code, that is, CPT code 76380 (Computed tomography, limited or localized follow-up study), with a final median cost of approximately $107. Therefore, CPT code 75571, with a final median cost of approximately $31, would not be an appropriate resource similarity for APC 0282, while CPT code 75571 is similar to other codes in APC 0340 with respect to resource use. Therefore, we believe it is appropriately assigned to APC 0340. We agree with the commenter that accurate reporting of charges for all services will help to ensure that these items are appropriately accounted for in future years' OPPS payment rates. As we often state (73 FR 68535 through 68536; 74 FR 60367; and 75 FR 71835), we encourage stakeholders to carefully review HCPCS code descriptors, as well as any guidance CMS may have provided for specific HCPCS codes. We note that the definition of charges in the regulations at 42 CFR 413.53(b) states that implicit in the use of charges as the basis of apportionment is the objective that charges for services be related to the cost of the services. As new HCPCS codes are developed or existing HCPCS code descriptors are revised from year to year (for example, by redefining units of service), we expect that hospitals' submitted Medicare charges relate appropriately to the costs of those services. Therefore, we do not share the commenter's belief that we should modify our standard ratesetting methodology (for example, by using claims data for deleted codes) in order to calculate the median costs for the services described by CPT codes 75572, 75573, and 75574. We refer readers to the Provider Reimbursement Manual (Pub. 15–2, Part 2, Chapter 40 Hospital and Hospital Health Care, Form CMS 2552–10) for CMS' instructions for reporting costs.

After considering the public comments we received and reviewing our claims data, we are maintaining the assignment of CPT code 75571 to APC 0340, for which we have calculated a final rule median cost of approximately $46 for CY 2012, and we are maintaining the assignment of CPT codes 75572, 75573, and 75574 to APC 0383, for which we have calculated a final rule median cost of approximately $262 for CY 2012.

b. Cardiac Imaging (APC 0377)

For CY 2012, we proposed to assign the following CPT codes to APC 0377 (Level II Cardiac Imaging): 78451(Myocardial perfusion imaging, tomographic (SPECT) (including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); single study, at rest or stress (exercise or pharmacologic)); 78452 (Myocardial perfusion imaging, tomographic (SPECT) (including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection); 78453 (Myocardial perfusion imaging, planar (including qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); single study, at rest or stress (exercise or pharmacologic)); and 78454 (Myocardial perfusion imaging, planar (including qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection). APC 0377 had a proposed national unadjusted payment rate of approximately $677.

The national unadjusted payment for APC 0377 for CY 2011 is approximately $760. However, it is important to note that the national unadjusted payment rate for APC 0377 for CY 2011 was based on CY 2009 claims data and CPT codes 78451, 78452, 78453 and 78454 had not been created in CY 2009. In CY 2009, APC 0377 was populated with CPT codes 78460 (Myocardial perfusion imaging (planar) single study, at rest of stress (exercise and/or pharmacologic), with or without quantification); 78461 (Myocardial perfusion imaging (planar) single study, at rest or stress (exercise and/or pharmacologic), with or without quantification; multiple studies (planar), at rest and/or stress (exercise and/or pharmacologic), and redistribution and/or rest injection, with or without quantification); 78464 (Myocardial perfusion imaging (planar) single study, at rest or stress (exercise and/or pharmacologic), with or without quantification; tomographic (SPECT) single study (including attenuation correction when performed), at rest or stress (exercise and/or pharmacologic), with or without quantification); and 78465 (Myocardial perfusion imaging (planar) single study, at rest or stress (exercise and/or pharmacologic), with or without quantification; tomographic (SPECT) multiple studies (including attenuation correction when performed), at rest or stress (exercise and/or pharmacologic), with or without quantification), which were also cardiac imaging services. Therefore, CY 2009 is the first year in which hospitals established charges for the new CPT codes for CY 2010 on which the CY

2012 proposed rule and final rule medians are based.

Comment: Several commenters expressed concern over the proposed 11 percent payment reduction to APC 0377. Commenters believed that there were irregularities in the hospital cost data that suggest inaccurate reporting of costs associated with procedures in APC 0377, rather than an actual decline in resource use. Commenters particularly pointed out that CPT code 78453 (Myocardial perfusion imaging, planar, single study) has a higher mean and median cost than CPT code 78454 (Myocardial perfusion imaging, planar, multiple studies), according to CMS data. The commenters stated that it is illogical to expect hospitals to use fewer resources for furnishing multiple studies than for furnishing a single study. In light of these irregularities, and the continued decline in the proposed payment, the commenters recommended that CMS reevaluate the data used to set the payment rate for APC 0337, to ensure that the data indeed capture the entire universe of claims for these APCs and reflect all procedure and radiopharmaceutical costs. The commenters further recommended that CMS recalculate median costs for these procedures after additional refinement of the data, including eliminating hospital claims with CCRs of 0.2 or less and, if subsequent review still warrants a payment reduction for either APC, such a reduction should be phased in over several years. Commenters suggested a 1- to 2-year ''dampening period'' beginning with the first year that CMS could utilize claims for ratesetting, given that APC 0377 contains four CPT codes that were new for CY 2010 and replaced previously existing services that were assigned to APC 0377. Commenters stated that hospitals are often slow to update their charge masters following coding changes. Additionally, the commenters recommended that CMS establish a threshold change of 10 percent that triggers an enhanced CMS validation process for all APCs, including accounting for all packaged costs and review of excluded/included claims. The commenters also recommended that CMS limit year-to-year changes in payment rates to a maximum of 5 to 10 percent for a single year, unless CMS or public commenters identify factors responsible for significant fluctuations in cost data, such as the introduction of new technologies or changes in the composition of an APC.

Response: In accordance with sections 1833(t)(2)(B) and 1833(t)(9)(A) of the Act and §§ 419.31 and 419.50 of the regulations, we annually review the items and services within an APC group with respect to comparability of the use of resources and clinical homogeneity. The payment rates, including the relative weights, set annually for these services are based on the claims and cost report data used for ratesetting. For the CY 2012 update, the payment rates for APCs 0337 are based on data from claims submitted during CY 2010 according to the standard OPPS ratesetting methodology. Specifically, we used 502,757 single claims (out of 584,855 total claims) from CY 2012 proposed rule claims data to calculate the proposed rule median cost of approximately $701, and we used 539,100 single claims (out of 640,458 total claims) from CY 2012 final rule claims data to calculate the median cost for APC 0337 of approximately $672, on which we based the CY 2012 national unadjusted payment rate.

We note that the final CY 2012 median cost represents a slight decline from the median cost of approximately $701, upon which the CY 2012 proposed payment rate for this APC was based and the median cost of approximately $752, upon which the final CY 2011 payment rate was based. As we have in the past (75 FR 71916), we note that our cost-finding methodology is based on reducing each hospital's charge for its services to an estimated cost by applying the most discrete hospital-specific CCR available for the hospital that submitted the claim. Therefore, it is the hospital's claims and cost reports that determine the estimated costs that are used to calculate the median cost for each service and, when aggregated into APC groups, the hospital data are used to calculate the median cost for the APC on which the APC payment rate is based. As we have previously, we note that, as part of our standard ratesetting process, we already engage in a standard review process for all APCs that experience significant changes in median costs (74 FR 60365).

We examined our claims data for APC 0377 for the CY 2011 OPPS final rule with comment period, the CY 2012 proposed rule, and this CY 2012 final rule with comment period. Specifically we looked at the following data elements for all single and pseudo single procedure bills for the four CPT codes that are assigned to APC 0377 and that, therefore, are the data points on which the median cost for the APC is based: median CCR; median charge; median line item cost (that is, without packaging); and median amount of packaging (shown in Table 21). We also show in Table 21 the count of single and pseudo single procedure claims for the APC and the total frequency for the APC.

TABLE 21.—SELECTED DATA FOR APC 0377

Single and Pseudo Single Procedure Bills for APC 0377	CY 2011 Final Rule Data	CY 2012 Proposed Rule Data	CY 2012 Final Rule Data
Median line item CCR	0.1780	0.1719	0.1639
Median line item charge	$2,248.00	$3,040.00	$3,045.00
Median line item cost	$386.96	$520.84	$499.05
Median packaged cost	325.79	$128.42	124.54
Count of single and pseudo single bills	494,745	502,757	542,890
Total Frequency	579,047	584,855	640,458
Total APC Median Cost	$751.80	$701.09	$672.37

We observe from this information that the median charge for services that are assigned to APC 0377 has increased from the CY 2011 final rule data (CY 2009 claims containing charges for the deleted codes) to the CY 2012 proposed and final rule data sets (based on charges for the codes that were effective January 1, 2010). The CCRs that are applied to the codes remained the same from the CY 2011 final rule data to the CY 2012 proposed rule data but declined slightly in the CY 2012 final rule data, with the updating of the data with more current cost reports. Therefore, the line item median costs increased between the CY 2011 final rule data and the CY 2012 proposed rule data but declined in the CY 2012 final rule data due to the decrease in the CCRs. We also observe that the packaged cost for codes in APC 0377 declined 61 percent from the CY 2011 final rule data to the CY 2012 proposed rule data and further declined another 3 percent in the CY 2012 final rule data. Therefore, we believe that the reduction in the payment rate for APC 0377 is attributable to the slight decline in the CCRs and the significant decline in the packaged cost.

We acknowledge that some hospitals may charge at different markups over cost for different services. However, as long as the cost report is correctly completed and the charges are mapped to the cost center in which the costs for the service are recorded, the CCRs will represent a valid reflection of the relationship between the costs and the charges. The OPPS, like all other prospective payment systems, assumes that hospitals complete the cost report properly, including mapping the charges for a service to the cost center in which the costs for that service are captured.

We recognize that there is considerable variability in the charges that hospitals established for the four CPT codes that were new for CY 2010 and replaced deleted codes for reporting these services that had been assigned to APC 0377, but it is not uncommon for a high level of variability in the charges for a service to occur. In addition, it is normal that such variability would be carried through to the calculation of estimated costs for the service. Hospitals charges are a reflection of the monetary value that the hospital places on the service, and we do not advise hospitals with regard to what they should charge for a service other than to require that the charges be reasonably related to their cost for the service, and that they must charge all payers the same amount for the same service. (We refer readers to the definition of ''charges'' at 42 CFR 413.53(b).) However, our use of the median charge to establish payment levels was specifically designed to address wide variances in hospital cost accounting systems and billing patterns, and also has consistently been a reliable mechanism for promoting increased consistency without introducing additional regulations.

We recognize that it appears peculiar that the estimated cost for CPT code 78453, which represents the cost of a single myocardial perfusion imaging (MPI) study, would be greater than the estimated cost for CPT code 78454, which represents the cost of multiple myocardial perfusion imaging studies done in a single session. However, our costs are based on the amount of the charge that the hospital established for the service and the hospital's CCR from its Medicare cost report. It is not unusual for hospitals to establish charges that do not comport with our expectation of the charges they would establish based on the definition of the code for the service for which they are establishing charges and on which we based simulated medians. Moreover, because the median cost is the 50th percentile of the array of costs from different hospitals, case-mix and volume differences between different hospitals can also result in seemingly peculiar relativity between median costs.

Based on our review of the claims data and cost report data, we believe our estimated median cost for APC 0377 is a valid estimate of the relative cost of the services under the APC and, therefore, see no reason to adopt an alternative methodology that would eliminate claims from hospitals with CCRs below 0.2 or limit the decline in the median cost to 5 to 10 percent. In addition, based on the significant volume of single bills used to calculate the median cost (539,100 single procedure bills of 640,458 total frequency or 84 percent of the total frequency for the services in the APC), we have no reason to believe that the median cost we have calculated should not be used to establish the payment for APC 0377 and, therefore, will not implement a 1- to 2-year ''dampening period,'' as suggested by the commenters. To the extent that hospitals determine that their charges should be revised to better reflect the resources required to furnish the services currently assigned to APC 0377, the revised charges would be reflected in future years' OPPS payment rates.

Comment: Commenters asked that CMS post to the CMS Web site the data analysis that was made available to the

APC Panel for all APCs for which the APC Panel median costs fluctuated by more than 10 percent compared to the CY 2011 OPPS final rule median costs to allow all interested stakeholders to review and comment on the data.

Response: During the August 10–11, 2011 meeting of the APC Panel, we presented a list of all APCs whose median costs fluctuated by greater than 10 percent when comparing the CY 2011 final rule median costs to CY 2012 proposed rule median costs. While the proposed payment for APC 0377 represented a reduction in payment of 11 percent, the decline in median cost was less than 10 percent; therefore, it was not included on the list presented to the APC Panel during its August 10–11, 2011 meeting. The comparisons of APCs with median costs fluctuating by more than 10 percent is based on median cost data available on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS.* Additionally, the OPPS Limited Data Set (LDS), which contain claims used to establish median cost for use in ratesetting, is available for purchase on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS.* Therefore, interested stakeholders have access to the same data that we examined and presented to the APC Panel.

After considering the public comments we received and examining the reasons for the decline in the median cost for APC 0377, we are declining to make any of the adjustments to the median cost that commenters requested because we believe that the data on which the median cost for APC 0377 is calculated are valid and that the median cost is an appropriate reflection of the 50th percentile of the array of the estimated costs of services assigned to APC 0377. Therefore, we are finalizing our CY 2012 proposal, without modification, to continue to assign CPT codes 78451, 78452, 78453, and 78454 to APC 0377. We are finalizing a payment rate for APC 0377 for CY 2012 based on the CY 2012 OPPS final rule median cost of approximately $672.

c. Insertion/Replacement/Repair of AICD Leads, Generator, and Pacing Electrodes (APC 0108)

We refer readers to section II.A.2.E.(6) of this final rule with comment period for a detailed discussion of this issue.

d. Implantable Loop Recorder Monitoring (APC 0690)

For CY 2012, we proposed to reassign CPT code 93299 (Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular monitor system or implantable loop recorder system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results) from APC 0691 (Level III Electronic Analysis of Devices) to APC 0690 (Level I Electronic Analysis of Devices), with a proposed payment rate of approximately $35.

Comment: Some commenters objected to the reassignment of CPT code 93299 from APC 0691 to APC 0690. They believed that the reassignment will result in inadequate payment to hospitals for the resources required to provide the service and may be a disincentive to hospitals to provide this service.

Response: The calculated median cost for CPT code 93299 based on CY 2010 hospital claims and cost report data available for this final rule with comment period is approximately $38. We are confident that the observed costs in the claims data are representative of the costs of providing this service in CY 2010 because almost all of the claims are single claims (2,249 out of 2,253) that can be used for ratesetting. The calculated median cost of approximately $38 for CPT code 93299 is similar to that of most of the CPT codes in APC 0690, and very close to the overall APC median cost of approximately $35. In contrast, the overall APC median cost for APC 0691 is approximately $168, more than four times the median cost of CPT code 93299. Therefore, we do not agree with commenters that the placement of CPT code 93299 in APC 0690 does not meet the APC recalibration standards of clinical and resource homogeneity and would result in inadequate payment to hospitals. Thus, we are finalizing our proposal, without modification, to reassign CPT code 93299 to APC 0690 for CY 2012.

e. Echocardiography (APCs 0128, 0269, 0270, and 0697)

Under the OPPS, echocardiography services are reported using a combination of CPT codes and HCPCS C-codes. Hospitals report the echocardiography CPT codes when performing echocardiography procedures without contrast. Alternatively, hospitals report the HCPCS C-codes when performing echocardiography procedures with contrast, or without contrast followed by with contrast. In addition to the HCPCS C-codes, hospitals should also report the appropriate units of the HCPCS codes for the contrast agents used in the performance of the echocardiograms.

Currently, there are four APCs that describe echocardiography services

- APC 0128 (Echocardiogram With Contrast)
- APC 0697 (Level I Echocardiogram Without Contrast)
- APC 0269 (Level II Echocardiogram Without Contrast)
- APC 0270 (Level III Echocardiogram Without Contrast)

For CY 2012, we proposed payment rates for these APCs of approximately $564, $219, $384, and $567, respectively.

Comment: Some commenters expressed concern with the proposed payment rate of approximately $384 for CPT code 93306 (Echocardiography, transthoracic real-time with image documentation (2D), includes M-mode recording, when performed, complete, with spectral Doppler echocardiography, and with color flow Doppler echocardiography), stating that the 5-percent decrease in the payment rate could be the result of miscoding. The commenters suggested that hospitals were continuing to bill CPT code 93307 (Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, complete, without spectral or color Doppler echocardiography) in conjunction with CPT codes 93320 (Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); complete) and 93325 (Doppler echocardiography color flow velocity mapping), rather than using CPT code 93306 because they were still adjusting to billing with CPT code 93306. The commenters requested that CMS confirm that the calculation of the median cost for APC 0269, which is the APC that CMS proposed to continue to assign to CPT code 93306, is based on correct coding.

Response: CPT code 93306 was made effective on January 1, 2009. Consistent with our statement in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71947), we find no evidence that would suggest that the fluctuations in cost data for echocardiography APCs are due to incorrect hospital billing practices. For this CY 2012 OPPS/ASC final rule with comment period, which is based on the CY 2010 hospital outpatient claims for ratesetting, our claims show a significant volume of data for CPT code 93306. Specifically, our analysis reveals a CPT median cost of approximately $394 based on 975,213 single claims (out of 990,809 total claims) for CPT code 93306, which represents 90 percent of the claims in APC 0269. Given the significant volume of claims and its CPT median cost of

approximately $394, we believe that CPT code 93306 is appropriately placed in APC 0269, which has a final APC median cost of approximately $393 for CY 2012.

Therefore, after consideration of the public comments that we received, we are finalizing our CY 2012 proposal, without modification, to continue to assign CPT code 93306 to APC 0269. As has been our practice since the implementation of the OPPS, we annually review all the items and services within an APC group to determine, with respect to comparability of the use of resources, for any 2 times rule violations. In making this determination, we review our claims data and determine whether we need to make changes to the current APC assignments for the following year. We will again reevaluate the status indicator and APC assignment for CPT code 93306 for the CY 2013 OPPS rulemaking cycle.

Comment: Several commenters requested that CMS reassign CPT codes 76825 (Echocardiography, fetal, cardiovascular system, real time with image documentation (2d), with or without m-mode recording) and 76826 (Echocardiography, fetal, cardiovascular system, real time with image documentation (2d), with or without m-mode recording; follow-up or repeat study) from the proposed APC 0697 to APC 0269. The commenters believed that fetal echocardiography is just as resource intensive as adult echocardiography. Another commenter stated that the low median cost for these services is the result of low frequency for these services, and suggested that some of the charges reported may be the result of miscoding.

Response: In Addendum B of the CY 2012 OPPS/ASC proposed rule, we flagged CPT codes 76825 and 76826 with comment indicator ''CH'' to indicate that we are reassigning the APC assignments for these codes. Specifically, we proposed to reassign CPT code 76825 from APC 0270 to APC 0697, and reassign CPT code 76826 from APC 0269 to APC 0697. Because these codes have been in existence for almost 20 years, and have been reportable under the hospital OPPS since it was implemented in 2000, we believe that the low frequency of these services is the result of infrequent use of this procedure on Medicare patients. Analysis of our claims data from the past 3 years, specifically from CY 2008, CY 2009, and CY 2010, reveal that these procedures are relatively low volume procedures. CPT code 76825 has had fewer than 330 single claims for ratesetting for each year (327 single claims in CY 2008, 291 single claims in CY 2009, and 282 single claims in CY 2010), with a CPT median cost that has ranged between $89 and $126. Similarly, CPT code 76826 has had fewer than 50 single claims for ratesetting for each year (25 single claims in CY 2008, 23 single claims in CY 2009, and 43 single claims in 2010), with a CPT median cost that has ranged between $85 and $92. Based on our claims data, we believe that CPT codes 76825 and 76826 are more appropriately placed in APC 0697 based on their clinical homogeneity and resource costs to the other procedure assigned to APC 0697. Furthermore, despite the relatively low volumes, the median costs for these services are notably stable and are more consistent with the median costs of the services assigned to lowest level echocardiogram APC, specifically, APC 0697, than to the services assigned to APC 0269, which has an APC median cost of approximately $393.

After consideration of the public comments received on our proposed APC reassignment, we are finalizing our CY 2012 proposal, without modification, to reassign CPT code 76825 from APC 0270 to APC 0697, and to reassign CPT code 76826 from APC 0269 to APC 0697, which has a final CY 2012 median cost of approximately $221.

Commenter: Several commenters expressed concern that the proposed payment rate of approximately $567 for the non-contrast echocardiogram procedures that are assigned to APC 0270 is higher than the proposed payment rate of approximately $564 for the contrast echocardiograms procedures that are assigned to APC 0128. The commenters indicated that it is not appropriate for an APC with contrast enhanced echocardiogram procedures to have a lower median cost and lower payment rate than an APC with non-contrast enhanced echocardiogram procedures. The commenters requested that CMS develop a more consistent and stable payment methodology for echocardiograms that utilize contrast agents because the cost of the contrast agents is approximately $117 and requires significantly more work when compared to non-contrast echocardiogram procedures. One commenter recommended that CMS adopt three APCs for contrast-enhanced echocardiogram procedures to parallel the three APCs that exist for non-contrast enhanced echocardiogram procedures, while another commenter requested data analysis supporting the higher proposed payment rate for APC 0270. Several commenters urged CMS to pay separately for the administration and cost of the contrast agent.

Response: As stated above, we have four separate APCs to which echocardiography services are assigned. Procedures that utilize contrast agents are assigned to APC 0128, while procedures without contrast agents are assigned to one of three APCs, specifically, APC 0270, APC 0269, or APC 0697. As described above, in the CY 2012 OPPS/ASC proposed rule, the proposed payment rates for APCs 0270, APC 0269, and APC 0697 varied between $219 and $567. Analysis of our claims data show that the median costs for two of the non-contrast echocardiogram APCs (APC 0697 and 0269) are lower than the median cost of the contrast echocardiogram APC (APC 0128). Specifically, our claims data show an APC median cost of approximately $221 for APC 0697 and approximately $393 for APC 0269, compared to the median cost of approximately $557 for APC 0128. Our claims data show a higher median cost for one of the non-contrast echocardiography APCs, specifically, APC 0270, which has a median cost of approximately $581. We agree with the commenters that, in general, contrast-based echocardiography procedures would involve more resources than non-contrast echocardiography services. However, we believe that some non-echocardiography procedures are more complex than contrast-based echocardiography procedures despite the lack of contrast use, and as a result, we expect their costs to be higher. As shown by our claims data, the costs involved with the non-contrast echocardiography procedures assigned to APC 0270 are significantly higher than the contrast-based echocardiography procedures that are assigned to APC 0128. As we do every year, we will again review our claims data for these services for the CY 2013 OPPS rulemaking cycle. We find no evidence that would suggest that the median costs calculated for these APCs based on hospital claims and cost report data incorrectly reflect the relative resource costs of providing the services in APC 0128 or APC 0697. We also do not believe that it is necessary to separate APC 0128 into three APCs as one commenter suggested, because the current composition results in no 2 times rule violation and the major procedures in the APC are similar based on resource costs, ranging from approximately $505 to approximately $732.

In addition, payment for the administration of contrast agents as well

as the contrast agent products are included in payment for the associated imaging procedure, as discussed in section V.B.2.d. of this final rule with comment period. In limited circumstances, we pay separately for contrast agents that are approved for pass-through status under the OPPS, as discussed in section V.A. of this final rule with comment period. Payment for pass-through status is limited to a minimum of 2 years but no more than 3 years.

Furthermore, as we stated above, hospitals should report the appropriate units of the HCPCS codes for the contrast agents used in the performance of the echocardiograms procedures. It is extremely important that hospitals report all HCPCS codes, consistent with their descriptors, CPT and/or CMS instructions, and correct coding principles, for all charges for all services they furnish, whether payment for the services is made separately or is packaged. The appropriateness of the OPPS payment rates depend on the quality and completeness of the claims data that hospitals submit for the services they furnish to Medicare beneficiaries.

After consideration of the public comments we received, we are finalizing, without modification, our CY 2012 proposal to continue to calculate our median costs for the non-contrast echocardiography procedures based on APCs 0697, 0269, and 0270, and to calculate our median costs for the contrast-echocardiography procedures based on APC 0128. We believe that continuing this methodology in CY 2012 results in payment rates for the contrast echocardiography and non-contrast echocardiography procedures that appropriately reflect the costs for these services. For a more detailed discussion and history of the OPPS payment for echocardiography services, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66644 through 66646), the CY 2009 OPPS/ASC final rule with comment period (73 FR 68542 through 68544), and the CY 2010 OPPS/ASC final rule with comment period (74 FR 60374 through 60383). Table 22 below shows the procedures and final median costs assigned to the four echocardiography APCs.

TABLE 22.—APC ASSIGNMENTS FOR ECHOCARDIOGRAPHY PROCEDURES FOR CY 2012

APC	HCPCS Code	Short Descriptor	Final CY 2012 Median Cost
0128 (Echocardiogram With Contrast)	C8921	TTE w or w/o fol w/cont, com	$557
	C8922	TTE w or w/o fol w/cont, f/u	
	C8923	2D TTE w or w/o fol w/con,co	
	C8924	2D TTE w or w/o fol w/con,fu	
	C8925	2D TEE w or w/o fol w/con,in	
	C8926	TEE w or w/o fol w/cont,cong	
	C8927	TEE w or w/o fol w/cont, mon	
	C8928	TTE w or w/o fol w/con,stres	
	C8929	TTE w or wo fol wcon,Doppler	
	C8930	TTE w or w/o contr, cont ECG	
0697 (Level I Echocardiogram Without Contrast)	76825	Echo exam of fetal heart	$221
	76826	Echo exam of fetal heart	
	93308	Tte f-up or lmtd	
0269 (Level II Echocardiogram Without Contrast)	93304	Echo transthoracic	$393
	93306	Tte w/doppler complete	
	93307	Tte w/o doppler complete	
	93313	Echo transesophageal	
	93315	Echo transesophageal	
	93350	Stress tte only	
0270 (Level III Echocardiogram Without Contrast)	93303	Echo transthoracic	$581
	93312	Echo transesophageal	
	93316	Echo transesophageal	
	93318	Echo transesophageal intraop	
	93351	Stress tte complete	

2. Gastrointestinal Services

a. Upper Gastrointestinal (GI) Services (APCs 0141, 0419, and 0422)

For CY 2012 we proposed to create new APC 0419 (Level II Upper GI Procedures), an intermediate APC between APC 0141 (Level I Upper GI Procedures) and APC 0422 (Level II Upper GI Procedures, which we proposed to rename ''Level III Upper GI Procedures''). For APC 0141, we calculated a proposed rule median cost for CY 2012 of approximately $603. For proposed new APC 0419, we calculated a proposed rule median cost of approximately $904. For APC 0422, we calculated a proposed rule median cost of approximately $1,833.

For CY 2011, there are two upper gastrointestinal (GI) procedure APCs, APC 0141, which has a CY 2011 national unadjusted payment rate of $611.73, and APC 0422, which has a CY 2011 national unadjusted payment rate of $1,148.75. In the CY 2011 OPPS/ASC proposed rule, we proposed to reconfigure APCs 0141 and APC 0422 by moving several CPT codes from APC 0141 to APC 0422. We had received public comments on the CY 2011 proposed rule objecting to our CY 2011 proposal on the basis that the reconfiguration would reduce the median cost and, therefore, the payment for services to which APC 0422 was assigned and would not maintain the clinical homogeneity of these services. Instead commenters, including the applicable medical specialty societies, asked that we reconfigure APCs 0141 and 0422 to create three APCs by adding a new APC for upper GI procedures. They also recommended a HCPCS configuration that they believed would provide payment rates that would more accurately reflect the median costs of the services in APCs 0141 and 0422. We

finalized our proposed changes to APCs 0141 and 0422 for CY 2011 without establishing a third APC for upper GI procedures for the reasons discussed in the CY 2011 OPPS/ASC final rule with public comment period (75 FR 71907).

However, when we developed the median costs for APCs 0141 and 0422 using CY 2010 claims data for discussion at the APC Panel meeting of February 28–March 1, 2011, we observed that there was a 2 times rule violation for APC 0141 that had not existed for the CY 2010 OPPS. For the APC Panel meeting, we simulated the HCPCS codes and APC median costs that would result from the reconfiguration that was recommended by the stakeholders in their comments on the CY 2011 OPPS/ASC final rule with comment period, and we discussed the results with the APC Panel. The APC Panel recommended that CMS create an intermediate level upper GI procedures APC (APC Panel Recommendation 13). The APC Panel recommendations and report may be found at the APC Panel Web site, located at: *http://www.cms.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp.*

For the reasons we discuss below, as stated in the proposed rule, we accepted the APC Panel recommendation to propose to establish three levels of upper GI procedure APCs and to propose to adopt the reconfiguration recommended by stakeholders because we believe that the proposed reconfiguration will provide payments that are more closely aligned with the median costs of the services. We stated that creating an intermediate APC for upper GI procedures would provide APC median costs that are more closely aligned with the median costs for the many CPT codes for upper GI procedures, and therefore, the APC median costs better reflect the resources required to provide these services as defined by the CPT codes for them. Moreover, we believed that the proposed reconfiguration would resolve the 2 times rule violation that would result in APC 0141 if we were to apply the CY 2011 APC configuration to the CY 2012 proposed rule data. Therefore, we stated in the proposed rule that we believed that we would need to propose to reassign HCPCS codes, regardless of whether we created the intermediate APC for CY 2012. We stated that we believed that the proposed reconfiguration to create the intermediate APC would be the most appropriate means of avoiding a 2 times rule violation that would otherwise exist for CY 2012 and that the resulting median costs would provide payments that are more reflective of the relative costs of the services being furnished.

Therefore, in the CY 2012 OPPS/ASC proposed rule (76 FR 42238), for CY 2012, we proposed to create new APC 0419 (Level II Upper GI Procedures), as recommended by the stakeholders, and we proposed to reassign HCPCS codes previously assigned to APCs 0141 and 0422 to the three APC configuration. Table 23 of the proposed rule contained the proposed HCPCS code reassignments for CY 2012 using the proposed three APC reconfiguration. We believe that this proposed reconfiguration classifies upper GI CPT codes in groups that demonstrate the best clinical and resource homogeneity. For APC 0141, we calculated a proposed rule median cost for CY 2012 of approximately $603. For proposed new APC 0419, we calculated a proposed rule median cost of approximately $904. For APC 0422, we calculated a proposed rule median cost of approximately $1,833.

At its August 10–11, 2011 APC Panel meeting, the APC Panel recommended that CMS adopt the proposed APC reconfiguration for upper gastrointestinal (GI) procedures and the creation of a new APC 0419 (Level II Upper GI Procedures). The Panel further recommended that HCPCS code 43227 (Esophagoscopy, rigid or flexible; with control of bleeding (e.g., injection, bipolar cautery, unipolar cautery, laser, heater probe, stapler, plasma coagulator)) and HCPCS code 43830 (Gastrostomy, open; without construction of gastric tube (e.g., Stamm procedure) (separate procedure)) be reassigned to APC 0422 (proposed to be renames ''Level III Upper GI Procedures'').

Response to APC Panel Recommendation: We do not agree with the APC Panel recommendation to move CPT code 43227 to APC 0422 because CPT code 43227 is a very low volume service with a total frequency of 45 in CY 2010, for which the median cost has varied considerably over the past few years ($1,010 in CY 2011; $725 in CY 2010). We will reassess the placement of CPT code 43227 for CY 2013. However, we agree with the APC Panel's recommendation to move CPT code 43830 to APC 0422 because the median cost for CPT code 43830 of approximately $1,630 is more similar to the median cost for APC 0422 of approximately $1,819 and is less similar to the median cost for APC 0319 of approximately $887. Therefore, we are assigning CPT code 43830 to APC 0422 for the CY 2012 OPPS.

Comment: Many commenters supported the creation of new APC 0419. Commenters indicated that creation of the new intermediate APC would result in APCs for upper GI procedures that are more cohesive with regard to the resources used to provide the services and would provide for more equitable payment for these services. In particular, commenters were pleased to with the proposed reassignment of CPT code 43228 to APC 0422 because they believed that the assignment would enable facilities to cover the cost of the device and provide patients with greater access to the service. One commenter objected to the reconfiguration of these APCs on the basis that some of the services in each APC have median costs that are higher than the median cost for the APC and, therefore, would be paid less than their median cost.

Response: We continue to believe that it is appropriate to create a third level of upper GI procedures and that it is appropriate to assign CPT code 43228 to APC 0422 for the reasons discussed in the proposed rule as summarized at the beginning of this section. Therefore, we are adopting our proposal to create new APC 0419 for CY 2012, and we have assigned CPT code 43228 to APC 0422 for CY 2012. We disagree with the commenter who objected to the reconfiguration of the upper GI procedure APCs on the basis that the medians for some HCPCS codes in each APC were higher than the median cost for the APC. The median cost by definition is the 50th percentile of the array of the costs of single bills. Therefore, the median costs for some HCPCS codes will always fall below the median cost for the APC. A fundamental principle of a prospective payment system like the OPPS is that prospective payment is set at a measure of central tendency that, on average, pays an amount that is appropriately reflective of the relative cost of the services in the group to which the payment rate applies.

Comment: Several commenters objected to the proposed assignment of CPT code 43257 (Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with delivery of thermal energy to the muscle of lower esophageal sphincter and/or gastric cardia, for treatment of gastroesophageal reflux disease) and CPT code C9724 (Endoscopic full thickness placation in the gastric cardia using endoscopic placation system (EPS); includes endoscopy) to APC 0422 and asked that CMS create an APC for transoral surgical endoscopy to which these codes would be assigned. The commenters believe that CPT codes 43257 and C9724 are clinically different

from most other services in APC 0422 because these services provide surgical therapy and that the resources required to furnish them are much greater than the resources required to furnish the other services in APC 0422. Commenters requested the creation of the new level IV upper GI procedure APC that they believed would result in appropriate payment for these procedures and would also improve the accuracy of the payment for the procedures that will remain in APC 0422. Commenters stated that current claims data for CPT code 43257 underestimates the cost of the service because hospitals are using the code incorrectly. They also stated that the CY 2010 claims data for CPT code 43257 reports the cost of a generation 1 Stretta catheter that was sold at a cost of $1,225, although since 2010 hospitals have been using a generation 2 catheter which has an average sales price of $2,450. Therefore, the commenters asserted that the use of CY 2010 claims data will not fully reflect the cost of the devices that will be used in CY 2012. Commenters suggested that CMS designate the new level IV APC that they requested as device dependent, establish procedure-to-device edits, and use only the claims that meet the device edits in setting the rates for the applicable APCs.

Response: We disagree that it is necessary to create a fourth level upper GI APC to which to assign HCPCS codes 43257 and C9724. We believe that CPT codes 43257 and C9724 are clinically similar to the other services assigned to APC 0422 such as CPT codes 43228 (Esophagoscopy, rigid or flexible; with ablation of tumor(s), polyp(s), or other lesion(s), not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique), and 43870 (Closure of gastrostomy, surgical), which are both therapeutic upper GI procedures. Moreover, the final median cost for CPT code 43257 of approximately $1,535 falls below the final median cost for APC 0422 of approximately $1,819. As we discuss in section II.A. of this final rule with public comment, we calculate the median costs of services based on the most recent charges and cost reports that are available to us at the time we are preparing the proposed and final rules. To the extent that the costs for the catheter used to furnish CPT code 43257 increased after CY 2010, those costs will be used to establish payment rates for the years in which the claims are used. With regard to HCPCS code C9724, we note that it is a low volume service for which the median cost has varied widely over the past few years (for example, $1,370 for CY 2009 OPPS; $2,947 for CY 2010 OPPS; and $5,139 for CY 2011 OPPS), and we believe that its median cost of approximately $5,944 and low volume make it unsuited for establishment of a single service APC for CY 2012 OPPS. We note that placement of HCPCS code C9724 in APC 0422 is not a violation of the 2 times rule because HCPCs code C9724 is not a significant procedure to which the 2 times rule applies because it has a single bill frequency of less than 1,000 and also has a single bill frequency that is less than 99 and the single bills represent less than 2 percent of the single bills used to calculate the median cost for APC 0422. We refer readers to section III.B. of this final rule with comment period for additional information regarding the 2 times rule.

After consideration of the comments we received, we are finalizing our proposals to create new APC 0419 (Level II Upper GI Procedures), to rename APC 0422 as ''Level III Upper GI Procedures'', and to reassign the HCPCS codes for upper GI procedures to the three APC configuration (APCs 0141, 0419 and 0422) for CY 2012 OPPS, as shown in Table 23 below. We are not creating a level IV upper GI procedure APC into which to place HCPCS codes 43257 and C9724 because we believe that HCPCS codes 43257 and C9724 are appropriately assigned to APC 0422 for CY 2012. We are not accepting the APC Panel's recommendation that we reassign CPT code 43227 to APC 0422 because it is a very low volume service for which the median cost has not been stable over the past few years. We are accepting the APC Panel's recommendation that we reassign CPT code 43830 to APC 0422, and we have done so for the CY 2012 OPPS.

BILLING CODE 4120–01–P

TABLE 23.--RECONFIGURATION OF UPPER GI PROCEDURE CODES FOR CY 2012

APC	HCPCS Code	SI	DESCRIPTION	Median Cost	Single Bill Frequency	Percent of Single Bills	Total Bill Frequency
0141		T	Level I Upper GI Procedures	591.79	377,123	.	763,297
	43831	T	Place gastrostomy tube	$0.00	0	.	0
	43999	T	Stomach surgery procedure	$217.22	1,929	.	2,373
	43204	T	Esoph scope w/sclerosis inj	$418.08	2	.	7
	43761	T	Reposition gastrostomy tube	$505.61	395	.	658
	43510	T	Surgical opening of stomach	$512.50	2	.	2
	43235	T	Uppr gi endoscopy diagnosis	$521.98	74,801	20	134,072
	43200	T	Esophagus endoscopy	$560.60	1,129	.	6,309
	43239	T	Upper gi endoscopy biopsy	$606.72	272,965	72	547,867
	43202	T	Esophagus endoscopy biopsy	$608.73	495	.	1,365
	43248	T	Uppr gi endoscopy/guide wire	$609.35	17,395	5	40,005
	43236	T	Uppr gi scope w/submuc inj	$640.49	3,598	1	8,942
	43247	T	Operative upper gi endoscopy	$651.27	5,421	1	18,333
	43234	T	Upper gi endoscopy exam	$656.09	568	.	1,006
	43600	T	Biopsy of stomach	$685.79	6	.	16
	43243	T	Upper gi endoscopy & inject	$735.82	174	.	354
	43241	T	Upper gi endoscopy with tube	$760.58	172	.	504
	43499	T	Esophagus surgery procedure	$2,102.26	556	.	1,484

APC	HCPCS Code	SI	DESCRIPTION	Median Cost	Single Bill Frequency	Percent of Single Bills	Total Bill Frequency
0419		T	Level II Upper GI Procedures	887.02	92,633	.	176,640
	91111	T	Esophageal capsule endoscopy	$705.62	113	.	130
	43250	T	Upper gi endoscopy/tumor	$716.68	986	1	3,278
	43201	T	Esoph scope w/submucous inj	$739.21	107	.	287
	43237	T	Endoscopic us exam esoph	$767.86	397	.	759
	43259	T	Endoscopic ultrasound exam	$778.41	14,488	16	23,686
	43251	T	Operative upper gi endoscopy	$791.81	3,066	3	11,680
	43231	T	Esoph endoscopy w/us exam	$792.01	387	.	526
	43246	T	Place gastrostomy tube	$803.98	16,328	18	22,843
	43458	T	Dilate esophagus	$828.33	147	.	1,376
	49446	T	Change g-tube to g-j perc	$849.75	403	.	732
	43244	T	Upper gi endoscopy/ligation	$859.62	5,376	6	7,380
	43255	T	Operative upper gi endoscopy	$862.67	4,041	4	8,073
	49440	T	Place gastrostomy tube perc	$879.79	1,891	2	3,113
	43205	T	Esophagus endoscopy/ligation	$887.78	126	.	152
	43249	T	Esoph endoscopy dilation	$888.34	20,318	22	53,074
	43215	T	Esophagus endoscopy	$893.83	231	.	987
	43245	T	Uppr gi scope dilate strictr	$902.32	2,607	3	5,744
	43217	T	Esophagus endoscopy	$912.55	24	.	108
	43226	T	Esoph endoscopy dilation	$926.00	804	1	1,272
	49441	T	Place duod/jej tube perc	$955.65	151	.	263

APC	HCPCS Code	SI	DESCRIPTION	Median Cost	Single Bill Frequency	Percent of Single Bills	Total Bill Frequency
	43220	T	Esoph endoscopy dilation	$990.70	642	1	1,015
	44100	T	Biopsy of bowel	$1,030.21	4	.	23
	43240	T	Esoph endoscope w/drain cyst	$1,030.53	41	.	104
	43238	T	Uppr gi endoscopy w/us fn bx	$1,035.10	408	.	593
	43232	T	Esoph endoscopy w/us fn bx	$1,046.02	385	.	501
	43242	T	Uppr gi endoscopy w/us fn bx	$1,104.70	13,185	14	17,943
	43258	T	Operative upper gi endoscopy	$1,118.17	5,950	6	10,953
	43227	T	Esoph endoscopy repair	$1,403.93	27	.	45
				.	.	.	.
0422		T	Level III Upper GI Procedures	1819.19	3,030	.	3,924
	43216	T	Esophagus endoscopy/lesion	$1,078.04	14	.	38
	43257	T	Uppr gi scope w/thrml txmnt	$1,535.07	63	2	92
	43870	T	Repair stomach opening	$1,559.24	101	3	166
	43830	T	Place gastrostomy tube	$1,629.55	168	6	318
	43228	T	Esoph endoscopy ablation	$1,832.39	2,643	87	3,231
	C9724	T	EPS gast cardia plic	$5,944.43	41	1	79

BILLING CODE 4120–01–C

b. Gastrointestinal Transit and Pressure Measurement (APC 0361)

The AMA CPT Editorial Panel created CPT code 0242T (Gastrointestinal tract transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report) effective January 1, 2011. For CY 2011, we assigned CPT code 0242T to APC 0361 (Level II Alimentary Tests) with a payment rate of $282.48. For CY 2012, we proposed to maintain the assignment of CPT code 0242T to APC 0361 with a proposed rule median cost of approximately $295, and a proposed payment of $284.80. (The CY 2012 OPPS/ASC final rule median cost for APC 0361 is approximately $286.)

Comment: Several commenters on the CY 2011 final rule with comment period regarding the APC assignment of CPT code 0242T, requested reassignment of CPT code 0242T from APC 0361 to New Technology APC 1510 (New Technology APC—Level X), which has a payment rate of $850. The commenters claimed that CPT code 0242T is not similar to the other procedures assigned to APC 0361 either in terms of clinical similarity or resource costs; therefore, it should be assigned to a New Technology APC because there currently are insufficient utilization and claims data for the service. The commenters believed that CPT code 0242T is significantly different than the other procedures in APC 0361, which

are predominantly indicated to assess the esophagus, while CPT code 0242T is purportedly a unique test that provides transit, pressure, pH, and temperature measurement of the GI tract from the stomach to the colon. The commenters also stated that the resources, including clinical labor, for the procedures in APC 0361 differ from those of CPT code 0242T. The commenters claimed that the manometric tests assigned to APC 0361 measure neuromuscular activity in an anatomically specific, fixed manner, utilizing a reusable catheter, while CPT code 0242T utilizes a disposable capsule and a special meal to capture multiple pressure and transit measurements throughout the GI tract and cost $600 per procedure. Adding other procedure costs to the disposable costs yields total procedure costs in excess of $800, according to the commenters. The commenters point to the past assignment of CPT code 91110 (Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus through ileum, with physician interpretation and report) to a New Technology APC until sufficient claims data were gathered for assignment to a clinical APC, and they request a similar approach to APC assignment for CPT code 0242T.

Response: We disagree that assignment to a clinical APC necessarily implies that there are clinical and cost data for a new service. We routinely make assignments of new CPT codes to clinical APCs before we have claims data that are indicative of their source costs of a procedure. We make these assignments initially using the best currently available information, while reviewing claims data once such data become available and making reassignments accordingly based on those data. We expect to do the same regarding CPT code 0242T.

As was the case when we made the initial assignment for CY 2011, we continue to believe that there are relevant clinical similarities between the CPT code 0242T service and other services in APC 0361 to continue to justify this APC assignment. CPT code 0242T and the services in APC 0361 all involve tests of the alimentary canal. Regarding resource costs, the final rule median cost of APC 0361 is approximately $288, with a median cost range of procedures in the APC from approximately $235 to approximately $680. We do not believe a New Technology APC is warranted for this procedure at this time. We believe that the clinical attributes and CY 2012 median costs of the services found in APC 0361 support the assignment of CPT code 0242T to APC 0361 as an initial assignment. We generally wait until median cost claims data are available before reassignment to a new APC. For CY 2012, we will maintain our assignment of CPT code 0242T to APC 0361, which has a final median cost of approximately $286. We will review this assignment for CY 2013 when some claims data should be available for this procedure.

3. Genitourinary Services

a. Laser Lithotripsy (APC 0163)

For CY 2012, we proposed to continue to assign CPT codes 52353 (Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy (ureteral catheterization is included)) and 50590 ((Fragmenting of kidney stone) to their existing CY 2011 APCs. That is, we proposed to continue to assign CPT code 52353 to APC 0163 (Level IV Cystourethroscopy and other Genitourinary Procedures), which had a proposed payment rate of approximately $2,566, and to continue to assign CPT code 50590 to APC 0169 (Lithotripsy), which had a proposed payment rate of approximately $3,568. CPT code 50590 was made effective January 1, 1986, and describes an extracorporeal shock wave lithotripsy. CPT code 52353 was made effective January 1, 2001, and describes a cystourethroscopy with lithotripsy. Our understanding is that the lithotripsy described in CPT code 52353 is laser lithotripsy.

At the August 2011 APC Panel Meeting, a presenter requested the Panel to recommend to CMS to reassign CPT code 52353 from APC 0163 to the same APC as CPT code 50590, which is APC 0169. The presenter stated that the proposed payment rate for APC 0169 for CY 2012 shows an increase of approximately 23 percent in the OPPS and approximately 25 percent in the ASCs, while the proposed payment rate for APC 0163 shows a 0.3 percent decrease in the OPPS and a 1.3 percent decrease in the ASCs, thereby creating a significant financial advantage for shock wave lithotripsy over ureteroscopy with lithotripsy. The presenter further suggested that placing CPT code 52353 in APC 0169 would be clinically appropriate because both procedures describe lithotripsy of stones in the ureter and kidney, and also because their historical median costs have tracked closely over time. After discussion of the of the median costs observed for both CPT codes 52353 and 50590, the APC Panel made no recommendation on the CY 2012 APC assignment for CPT code 52353.

Comment: Some commenters recommended the reassignment CPT code 52353 to the same APC as CPT code 50590, which is APC 0169. One commenter argued that the reassignment of CPT code 52353 to APC 0169 would avoid potential incentives to use shock wave lithotripsy over ureteroscopy with lithotripsy. This commenter further stated that these two similar and competing procedures should be placed in the same APC so that their OPPS and ASC payment rates will increase, or decrease, consistently in the future.

Response: CPT code 50590 has been assigned to APC 0169 since the OPPS was implemented in 2000. CPT code 52353 was initially assigned to APC 0162 (Level III Cystourethroscopy Procedures) when the CPT code was made effective in 2001. However, in CY 2002, we revised the APC assignment for CPT code 52353 to APC 0163 (Level IV Cystourethroscopy Procedures) based on input from our clinical advisors that the procedure is similar to the other procedures in APC 0163 based on clinical homogeneity and resource costs. Since CY 2002, CPT code 52353 has been assigned to APC 0163.

In addition, we disagree with the commenter that placing these two procedures in two separate APCs creates an incentive to use one procedure over another. We believe that physicians would choose the most appropriate procedure based on a patient's diagnosis and other relevant clinical factors. Further, based on our claims data, we do not believe that placing both procedures in the same APC would be appropriate. Our analysis of the final CY 2012 claims data reveal that shock wave lithotripsy (CPT code 50590) is more commonly performed on Medicare patients than ureteroscopy with lithotripsy (CPT code 52353). Specifically, our data show a CPT median cost of approximately $2,711, based on 3,366 single claims, for CPT code 52353. CPT code 52353 represents 22 percent of the claims within APC 0163, and its CPT median cost of approximately $2,711 is relatively close to the CY 2012 final APC median cost of approximately $2,596 for APC 0163.

In contrast, the CY 2012 final median cost for CPT code 50590, which is in APC 0169, is approximately $3,647, based on 30,178 single claims. This final median cost of approximately $3,647 for CPT code 50590 is higher than the final median cost of approximately $2,711 for CPT code 52353.

Comment: One commenter suggested that the increase in the median cost for CPT code 50590 may be a result of the application of a CCR calculated from costs and charges reported in the nonstandard cost center data for lithotripsy.

Response: The nonstandard lithotripsy cost center 07699 is a feature of the hospital cost report CMS 2552–10. No CMS 2552–10 cost reports were used in determining the payment rates for the CY 2012 OPPS. The CCRs in the CY 2012 OPPS are created from the hospital cost report CMS 2552–96, and there is no standard or nonstandard lithotripsy cost center in the CMS 2552–96 cost report.

Given our claims data for the CY 2012 update for these lithotripsy procedures, we believe that CPT code 52353 is appropriately placed in APC 0163 based on its clinical homogeneity and resource cost compared to other procedures already assigned in APC 0163. As has been our practice since the implementation of the OPPS in 2000, we review, on an annual basis, the APC assignments for the procedures and services paid under the OPPS. We will continue to review on an annual basis the APC assignment for CPT code 52353 and determine whether a reassignment in the APC is necessary.

Therefore, after consideration of the public comments we received, we are finalizing our CY 2012 proposal, without modification, to continue to assign CPT code 52353 to APC 0163, which has a final CY 2012 median cost of approximately $2,596, and to continue to assign CPT code 50590 to APC 0169, which has a final CY 2012 median cost of approximately $3,647.

b. Percutaneous Renal Cryoablation (APC 0423)

For CY 2012, we proposed to continue to assign CPT code 50593 (Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy) to APC 0423 (Level II Percutaneous Abdominal and Biliary Procedures), with a proposed payment rate of approximately $3,969. This CPT code was new in CY 2008; however, the same service was previously described by CPT code 0135T (Ablation renal tumor(s), unilateral, percutaneous, cryotherapy). We note that in CY 2007, based upon the APC Panel's recommendation made at the March 2006 APC Panel meeting, we reassigned CPT code 50593 (then CPT code 0135T) from APC 0163 ((Level IV Cystourethroscopy and other Genitourinary Procedures)) to APC 0423. We expect hospitals, when reporting CPT code 50593, to also report the device HCPCS code, C2618 (Probe, cryoablation), associated with the procedure.

Comment: One commenter disagreed with the proposed continued assignment for CPT code 50593 to APC 0423 because, the commenter stated, this APC includes other procedures that do not require the use of high-cost devices, such as cryoablation probes. The commenter reported that the payment rate of approximately $3,969 for the procedure does not accurately reflect the costs incurred by hospitals that perform this procedure, and, as a result, hospitals are reluctant to perform this procedure. The commenter suggested that CMS determine the payment rate for CPT code 50593 based on its mean cost, rather than on median cost. The commenter stated that the proposed mean cost for APC 0423 is approximately $4,835, and approximately $5,394 for CPT code 50593. Further, the commenter recommended that CMS designate CPT code 50593 as a device-dependent procedure and require hospitals to submit claims with the appropriate HCPCS code, C2618, so that charges can be reported appropriately. The commenter stated that CPT code 50593 cannot be performed without the device, and adding CPT code 50593 to the device-dependent procedure list would result in more accurate claims data for future ratesetting.

Response: First, we believe that CPT code 50593 is appropriately placed in APC 0423 based on clinical and resource costs when compared to other procedures also assigned to APC 0423. As we stated in the CY 2007 OPPS final rule with comment period (71 FR 68049 through 68050), the CY 2008 OPPS/ASC final rule with comment period (72 FR 66709), the CY 2009 OPPS/ASC final rule with comment period (73 FR 68611), the CY 2010 OPPS/ASC final rule with comment period (74 FR 60444), and the CY 2011 OPPS/ASC final rule with comment period (75 FR 71910), we revised the APC assignment for the percutaneous renal cryoablation procedure from APC 0163 to APC 0423 in CY 2007 based on the APC Panel's recommendation to reassign the procedure to APC 0423.

For CY 2012, we proposed to assign four CPT codes to APC 0423. These procedures share similar median costs ranging from approximately $3,733 to approximately $4,493, which are well within the two-fold variation in median cost that is permitted by the law for an OPPS payment group. Therefore, the grouping of these procedures in the same APC does not violate the 2 times rule. We note that all four of these procedures are relatively low volume, with fewer than 1,800 total claims each for CY 2010 and fewer than 700 single claims each for ratesetting. We believe that grouping these clinically similar, low-volume procedures for the percutaneous ablation of renal, liver, or pulmonary tumors in the same payment group helps to promote payment stability for these low volume services.

Secondly, as we stated in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68611), the final APC relative weights and payment rates are based on median hospital costs, not mean costs, for APC groups. The OPPS relies on the relativity of costs for procedures as reported by hospitals in establishing payment rates, and we do not believe it would be appropriate to utilize a different payment methodology based on mean cost for one APC, while the payment rates for the other clinical APCs would be based on median costs. Mean and median costs are two different statistical measures of central tendency and, based on common distributions, mean costs typically are higher than median costs. Therefore, we do not believe it would be appropriate to use a combination of these measures to establish the payment weights for different APCs under the OPPS.

Further, as we stated in the CY 2007 OPPS final rule with comment period (71 FR 68049 through 68050), the CY 2008 OPPS/ASC final rule with comment period (72 FR 66709), the CY 2009 OPPS/ASC final rule with comment period (73 FR 68611), the CY 2010 OPPS/ASC final rule with comment period (74 FR 60444), and the CY 2011 OPPS/ASC final rule with comment period (75 FR 71910), we designate a procedure as device-dependent service based on consideration of all the procedures in a single APC. While all of the procedures assigned to APC 0423 require the use of implantable devices, for many of the procedures, there are no Level II HCPCS codes that describe all of the technologies that may be used in the procedures. Therefore, it would not be possible for us to develop procedure-to-device edits for all of the CPT codes assigned to APC 0423.

Finally, we remind hospitals that we expect all of the HCPCS codes to be reported that appropriately describe the items used to provide services, regardless of whether the HCPCS codes are packaged or paid separately. When reporting CPT code 50593, we expect hospitals to also report the device HCPCS code C2618, which is associated with this procedure. If hospitals use more than one probe in performing the CPT code 50593 procedure, we expect hospitals to report this information on the claim and adjust their charges accordingly. Hospitals should report the number of cryoablation probes used to perform the CPT code 50593 procedure as the units of HCPCS code C2618, which describes these devices, with their charges for the probes. Since CY

2005, we have required hospitals to report device HCPCS codes for all devices used in procedures if there are appropriate HCPCS codes available. In this way, we can be confident that hospitals have included charges on their claims for devices used in procedures when they submit claims for those procedures.

After consideration of the public comment we received, we are finalizing our CY 2012 proposal, without modification, to continue to assign CPT code 50593 to APC 0423, which has a final CY 2012 APC median cost of approximately $4,096.

4. Nervous System Services

a. Revision/Removal of Neurostimulator Electrodes (APCs 0040 and 0687)

As discussed in detail in the CY 2012 OPPS/ASC proposed rule (76 FR 42233 through 42234), for CY 2012, we proposed to move CPT codes 63663 (Revision, including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed) and 63664 (Revision, including replacement, when performed, of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed) from APC 0687 (Revision/Removal of Neurostimulator Electrodes) to APC 0040 (Level I Implantation/Revision/Replacement of Neurostimulator Electrodes). We noted that the proposed CY 2012 median costs for CPT codes 63663 and 63664 of approximately $4,316 and $4,883, respectively, are more consistent with the proposed median cost of APC 0040 of approximately $4,516 than with the proposed median cost of APC 0687 of approximately $1,492. We also proposed to change the title of APC 0040 from ''Percutaneous Implantation of Neurostimulator Electrodes'' to ''Level I Implantation/Revision/Replacement of Neurostimulator Electrodes'' and the title of APC 0061 (Level II Implantation/Revision/Replacement of Neurostimulator Electrodes) from ''Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electrodes'' to ''Level II Implantation/Revision/Replacement of Neurostimulator Electrodes.'' CPT codes 63661 (Removal of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed), 63662 (Removal of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed), 63663, and 63664 were all effective January 1, 2010. We proposed that CPT codes 63661 and 63662 would remain in APC 0687.

In addition, for CY 2012, we proposed to assign CPT 64569 (Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator), effective January 1, 2011, to APC 0687.

Comment: Several commenters supported the proposed reassignment of CPT codes 63663 and 63664 from APC 0687 to APC 0040. The commenters believed that the proposed reassignment places these CPT codes in an APC that is consistent with their median costs. The commenters also supported the retention of CPT code 63661 and 63662 in APC 0687 because their proposed CY 2012 median costs are consistent with the overall proposed APC 0687 median costs. In addition, the commenters agreed with the proposed title changes for APC 0040 and APC 0061. One commenter agreed with the proposed reassignment of CPT codes 63663 and 63664 to APC 0040 but recommended the creation of two new HCPCS codes to allow hospitals to differentiate between revision and replacement procedures and to foster analysis of the cost differences between revision and replacement procedures for purposes of future APC assignments. The commenter also sought device-to-procedure and procedure-to-device edits to ensure device costs are completely captured.

Response: We appreciate the commenters' support for the reassignment of CPT codes 63663 and 63664 from APC 0687 to APC 0040, the continued assignment of CPT codes 63661 and 63664 to APC 0687, and the title changes to APC 0040 and APC 0061. We agree with the commenters that the proposed changes would ensure that all four codes are in APCs that are consistent with their median costs. Therefore, we are finalizing our proposals to reassign CPT codes 63663 and 63664 to APC 0040, to continue to assign CPT codes 63661 and 63662 to APC 0687, and to change the titles of APC 0040 to ''Level I Implantation/Revision/Replacement of Neurostimulator Electrodes'' and APC 0061 to ''Level II Implantation/Revision/Replacement of Neurostimulator Electrodes.''

We do not agree that it is necessary to create new HCPCS codes in order to differentiate between neurostimulator electrode replacement and revision procedures. As we discussed in the CY 2012 OPPS/ASC proposed rule (76 FR 42234), we examined the CY 2010 claims data available for the proposed rule to compare the frequency of claims containing CPT codes 63663 or 63664 that were billed with and without HCPCS code C1778 (Lead, neurostimulator (implantable)) or HCPCS code C1897 (Lead, neurostimulator test kit (implantable)) in order to determine whether they describe mainly device revision or replacement procedures. Because the majority of claims did not contain HCPCS code C 1778 or C1897, these findings suggested that these CPT codes are being used by hospitals to describe mainly device revision procedures, although there were a significant number of cases with device replacement procedures in the claims data. We also note that we implemented claims processing logic to allow CPT codes 63663 and 63664 to satisfy the device-to-procedure edits for HCPCS codes C1778 and C1897, effective January 1, 2012. We cannot implement procedure-to-device edits for CPT codes 63663 and 63664 because they do not always involve the implantation of a device.

Comment: One commenter objected to the proposed assignment of CPT code 64569 to APC 0687. The commenter stated that CPT code 64569 is clinically similar to CPT codes 63663 and 63664, the only difference being CPT code 64569 is an incision-based procedure, while CPT codes 63663 and 63664 are percutaneous. The commenter also argued that assigning CPT code 64569 to APC 0687 would result in significant financial losses for hospitals and presented simulated data using claims for CPT code 63663 and 63664 to estimate a median cost for CPT code 64569 ranging between approximately $5,551 and $7,790.

Response: We are assigning CPT code 64569 to APC 0687, as we proposed, with a CY 2012 final rule median cost of approximately $1,451. We do not agree that CPT code 64569 is inappropriately assigned to APC 0687. Our clinical analysis indicates that CPT code 64569 is similar to the other device revision and replacement procedures in APC 0687. Furthermore, since CPT code 64569 was effective January 1, 2011, we do not have frequency and cost information upon which to make an assessment of whether there is a meaningful difference between the cost of revising the VNS electrodes and generator or replacing them. We do not agree with the commenter that it is possible to derive meaningful estimates of the costs of providing the service described by CPT code 64569 by using data for CPT codes 63663 and 63664 because these codes involve different types of devices. Therefore, we are not

convinced by the commenter that the assignment of the CPT code 64569 to APC 0687 is inappropriate. As we did with the CPT codes 63661 through 63664, we will continue to monitor and analyze the data for CPT code 64569 when it becomes available.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to assign CPT codes 63663 and 63664 to APC 0040 and to assign CPT codes 63661, 63662, and 64569 to APC 0687. We also are finalizing our proposal to change the title of APC 0040 from ''Percutaneous Implantation of Neurostimulator Electrodes'' to ''Level I Implantation/Revision/Replacement of Neurostimulator Electrodes'' and the title of APC 0061 from ''Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electrodes'' to ''Level II Implantation/ Revision/Replacement of Neurostimulator Electrodes.''

b. Magnetoencephalography (MEG) (APCs 0065, 0066, and 0067)

There are three CPT codes associated with MEG: 95965 (Magnetoencephalography (meg), recording and analysis; for spontaneous brain magnetic activity (eg, epileptic cerebral cortex localization)); 95966 (Magnetoencephalography (meg), recording and analysis; for evoked magnetic fields, single modality (eg, sensory, motor, language, or visual cortex localization)); and 95967 (Magnetoencephalography (meg), recording and analysis; for evoked magnetic fields, each additional modality (eg, sensory, motor, language, or visual cortex localization)). For CY 2012 we calculated a proposed rule median cost of approximately $1,821 for CPT code 95965 based on a frequency of 48 single bills out of a total frequency of 50 bills. We proposed to continue to assign CPT code 95965 to APC 0067 (Level III Stereotactic Radiosurgery, MRgFUS, and MEG), which had a proposed rule median cost of approximately $3,368.

At its August 10–11, 2011 meeting, the APC Panel made two recommendations with regard to CPT code 95965. First, the APC Panel recommended that CMS implement appropriate edits requiring hospitals to use the new MEG revenue code, 086X, with CPT codes 95965, 95966, and 95967. We address this recommendation in the context of a comment from the public to which we respond below. Second, the APC Panel recommended that CMS move CPT code 95965 from APC 0067 to APC 0066 (Level II Stereotactic Radiosurgery, MRgFUS, and MEG), for consistency. We agree with this recommendation and have reassigned CPT code 95965 to APC 0066 because the median cost in the data available for this final rule with comment period for CPT code 95965 of approximately $1,741 is similar to the median cost of APC 0066 of approximately $2,521. In contrast, the median cost of APC 0067 of approximately $3,374 is substantially above the median cost for CPT code 95965. We note that the procedure described by CPT code 95965 is a low-volume service for which we have a single bill frequency of 70, compared to a total bill frequency of 75, in our CY 2012 OPPS final rule data. Although it is a low-volume service, single bills represent 93 percent of total frequency for CPT code 95965.

Comment: Commenters stated that the costs of MEG are far higher than the costs of electroencephalograms (EEG) and electrocardiograms (ECG) and that therefore CMS should not use the CCRs from the cost centers for these services to reduce the charges for MEG to costs. Instead, according to commenters, CMS should create a new cost center on the Medicare hospital cost report to isolate the costs of MEG and calculate and apply a CCR from the dedicated MEG cost center to the charges for MEG to secure a more accurate estimated cost for MEG.

Response: We refer readers to section II.A.1.c. of this final rule with comment period for a summary of public comments and responses related to the use of the CCRs for cost centers 3280 (EKG and EEG) as primary and 5400 (Electroencephalography) as secondary, to reduce the charges for MEG to estimated relative costs.

Comment: Commenters urged CMS to require that hospitals use revenue codes that are specific to MEG. One hospital that furnished comments indicated that its MEG services are furnished through the radiology department, but that the department through which MEG services are furnished varies across hospitals. (As indicated previously, the APC Panel recommended that CMS implement appropriate edits requiring hospitals to use the MEG specific revenue codes, 086X, with CPT codes 95965, 95966, and 95967.)

Response: As we indicate in the Section 20.5, Chapter 4, of the Medicare Claims Processing Manual, generally, CMS does not instruct hospitals on the assignment of HCPCS codes to revenue codes for services provided under OPPS because hospitals' assignment of cost vary (available on the CMS Web site at: *http://www.cms.gov/Manuals*; select Internet Only Manuals). Where explicit instructions are not provided, hospitals should report their charges under the revenue code that will result in the charges being assigned to the same cost center to which the cost of those services are assigned in the cost report. We do not believe that establishing edits to require hospitals to report the charges for MEG under the dedicated MEG revenue code series is necessary or appropriate. Medicare pays for a low volume of MEG services for which there are no special requirements that would justify creation of edits that force hospitals to report particular revenue codes for particular CPT codes. Specifically, in the CY 2012 final rule claims data, a small number of hospitals reported one of the three CPT codes for MEG. We believe that it is not reasonable to implement national CPT-to-revenue code edits to enforce the use of MEG-specific revenue codes when a small number of hospitals reported only 144 lines of MEG total for the 3 MEG codes in CY 2010. Specifically, in the final rule single bills on which we are basing the CY 2012 median costs, 4 hospitals reported 31 lines of CPT code 95967; 6 hospitals reported 384 lines of CPT code 95966; and 10 hospitals reported 75 lines of CPT code 95965. The MEG codes were first paid under the OPPS as new technology services in CY 2006 and the total frequency of services and the number of hospitals that furnish the service have always been very low.

For CY 2012, as stated previously, we are accepting the APC Panel's recommendation to reassign CPT code 95965 to APC 0066 because the CY 2012 final rule median cost of CPT code 95965 of approximately $1,741 is more similar to the final median cost of APC 0066 of approximately $2,521 than to the median cost of APC 0067, which is approximately $3,374. We are not accepting the APC Panel's recommendation to implement edits requiring that hospitals that furnish MEG must report the charges for the service using the MEG specific revenue code series 086X for the reasons stated above. For a response to the commenters' requests for a dedicated cost center on the Medicare cost report, we refer readers to section II.A.c. of this final rule with comment period.

c. Transcranial Magnetic Stimulation Therapy (TMS) (APC 0218)

For CY 2011, the CPT Editorial Panel deleted CPT code 0160T (Therapeutic repetitive transcranial magnetic stimulation treatment planning) on December 31, 2010, and replaced it with CPT codes 90867 (Therapeutic repetitive transcranial magnetic

stimulation treatment; planning) effective January 1, 2011. Similarly, CPT code 0161T (Therapeutic repetitive transcranial magnetic stimulation treatment delivery and management, per session) was deleted on December 31, 2010, and was replaced with CPT code 90868 (Therapeutic repetitive transcranial magnetic stimulation treatment; delivery and management, per session) effective January 1, 2011.

In Addendum B to the CY 2011 OPPS/ASC final rule with comment period, CPT codes 90867 and 90868 were assigned to APC 0216 (Level III Nerve and Muscle Tests) with a payment rate of approximately $186 and were flagged with comment indicator ''NI'' to indicate that these codes were new codes for CY 2011 with an interim APC assignment subject to public comment. We stated that we would address any public comments on issues regarding these new codes in this CY 2012 OPPS/ASC final rule with comment period.

In addition, in the CY 2012 OPPS/ASC proposed rule, we proposed to continue to assign CPT codes 90867 and 90868 to APC 0216 for CY 2012.

Comment: One commenter on the CY 2011 OPPS/ASC final rule with comment period agreed with the APC assignment for CPT code 90867 and indicated that APC 0216 is appropriate, based on the resources required to perform TMS planning and its similarity to other procedures with similar resource costs in this APC. However, this same commenter disagreed with the placement of CPT code 90868 in APC 0216. The commenter stated there are no clinically similar procedures in APC 0216 whose resources are comparable to that of TMS treatment delivery, and recommended the reassignment of CPT code 90868 from APC 0216 to APC 0320 (Electroconvulsive Therapy), which has a payment rate of approximately $414 for CY 2011. The commenter asserted that the hospital outpatient claims data for TMS is not reliable and, therefore, should not be used as the basis for the assignment of CPT code 90868 to APC 0216.

Response: Although both CPT codes 90867 and 90868 were new codes for CY 2011, the services they describe are not new because they were previously described by two predecessor CPT codes, specifically Category III CPT codes 0160T and 0161T. CPT code 90867 was previously described by CPT code 0160T, and CPT code 90868 was previously described by CPT code 0161T. Both CPT codes 0160T and 0161T were made effective July 1, 2006, and deleted on December 31, 2010. From July 1, 2006 through December 31, 2010, both CPT codes 0160T and 0161T were assigned to APC 0216.

We do not agree with the commenter that CPT code 90868 should be placed in APC 0320 based on resource similarity. Based on analysis of our hospital outpatient claims data for predecessor CPT codes 0160T and 0161T from CY 2006 through CY 2010, we believe that both CPT codes 90867 and 90868 would be more appropriately placed in APC 0218 (Level II Nerve and Muscle Tests) rather than in the proposed APC 0216. There were no claims data for either procedure (as described by CPT codes 0160T and 0161T) during CY 2006, CY 2007, and CY 2008. For the CY 2011 OPPS/ASC final rule with comment period, we used claims processed during CY 2009 for ratesetting, and our claims data showed a CPT median cost of approximately $176 for CPT code 0160T based on 17 single claims (out of 17 total claims), and a CPT median cost also of approximately $176 for CPT code 0161T based on 68 single claims (out of 69 total claims), which closely resemble the APC median cost of approximately $184 for APC 0216 for the CY 2011 OPPS. However, for this CY 2012 OPPS/ASC final rule with comment period, which is based on the CY 2010 hospital outpatient claims for ratesetting, our claims data show a CPT median cost of approximately $88 for CPT code 0160T (which is now described by CPT code 90867) based on 6 single claims (out of 9 total claims), and a CPT median cost of approximately $105 for CPT code 0161T (which is now described by CPT code 90868) based on 211 single claims (out of 221 total claims). Given our claims data for predecessor CPT codes 0160T and 0161T, we believe that both CPT codes 90867 and 90868 are appropriately placed in APC 0218, which has a final APC median cost of approximately $84 for CY 2012 based on clinical homogeneity and resource costs. We note that the OPPS methodology allows hospitals to actively contribute on an ongoing basis to the ratesetting process and to influence future payment rates for services by submitting correctly coded and accurately priced claims for the services they provide. According to this methodology, it is generally not our policy to judge the accuracy of hospital coding and charging for purposes of ratesetting. We also do not agree with the commenter that the procedure described by CPT code 90868 would fit into APC 0320 from a clinical perspective because the provision of electroconvulsive therapy generally requires more extensive monitoring and services (for example, muscle blockade) than transcranial magnetic treatment delivery and management.

Therefore, after consideration of the public comment we received on the CY 2011 OPPS/ASC final rule with comment period, we are finalizing our CY 2012 proposal, with modification. That is, we are reassigning CPT codes 90867 and 90868 from APC 0216 to APC 0218, which has a final CY 2012 median cost of approximately $84. Given the information reflected in the CY 2012 final rule claims data for predecessor CPT codes 0160T, which shows a median cost of approximately $105, and a median cost of approximately $88 for CPT code 0161T, we believe our claims data show the costs of these procedures are similar to the costs of other procedures assigned to APC 0218. We also believe that these procedures are similar to the other procedures assigned to APC 0218 from a clinical standpoint. We will reevaluate the APC assignment for CPT codes 90867 and 90868 in future OPPS updates as additional information becomes available to us.

5. Ocular and Ophthalmic Services

a. Placement of Amniotic Membrane (APCs 0233 and 0244)

For the CY 2011 update, the AMA CPT Editorial Panel revised the long descriptor for CPT code 65780 (Ocular surface reconstruction; amniotic membrane transplantation, multiple layers) to include the words ''multiple layers'' to further clarify the code descriptor. In addition, the AMA CPT Editorial Panel created two new CPT codes that describe the placement of amniotic membrane on the ocular surface without reconstruction; one describing the placement of a self-retaining (non-sutured/non-glued) device on the surface of the eye, and the other describing a single layer of amniotic membrane sutured to the surface of the eye. Specifically, the AMA CPT Editorial Panel created CPT codes 65778 (Placement of amniotic membrane on the ocular surface for wound healing; self-retaining) and 65779 (Placement of amniotic membrane on the ocular surface for wound healing; single layer, sutured), effective January 1, 2011.

As has been our practice since the implementation of the OPPS in 2000, we review all new procedures before assigning them to an APC. In determining the APC assignments for CPT codes 65778 and 65779, we took into consideration the clinical and resource characteristics involved with placement of amniotic membrane products on the eye for wound healing via a self-retaining device and a sutured,

single-layer technique. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72402), we assigned CPT code 65780 to APC 0244 (Corneal and Amniotic Membrane Transplant) with a CY 2011 payment rate of approximately $2,681. We assigned CPT code 65778 to APC 0239 (Level II Repair and Plastic Eye Procedures) with a payment rate of approximately $559, and CPT code 65779 to APC 0255 (Level II Anterior Segment Eye Procedures) with a payment rate of approximately $519. In addition, we assigned both CPT codes 65778 and 65779 to comment indicator ''NI'' in Addendum B of the CY 2011 OPPS/ASC final rule with comment period to indicate that both codes were new codes for CY 2011 with an interim APC assignment subject to public comment. We further stated that we would address any public comments on issues regarding these new codes in this CY 2012 OPPS/ASC final rule with comment period.

At the APC Panel at the February 28–March 1, 2011 meeting, a presenter requested the reassignment of both new CPT codes 65778 and 65779 to APC 0244, which is the same APC to which CPT code 65780 is assigned. The presenter indicated that, prior to CY 2011, the procedures described by CPT codes 65578 and 65779 were previously reported under the original version of CPT code 65780, which did not specify ''multiple layers,'' and, as such, these new codes should continue to be assigned to APC 0244. Further, the presenter stated that the costs of the new procedures described by CPT codes 65778 and 65779 are very similar to the procedure described by CPT code 65780.

The APC Panel recommended that CMS reassign both CPT codes 65778 and 65779 to APC 0233 (Level III Anterior Segment Eye Procedures), citing clinical similarity to procedures already in APC 0233. Based on clinical as well as resource similarity to the other procedures currently assigned to APC 0233, in the CY 2012 OPPS/ASC proposed rule (76 FR 42237), we proposed to accept the APC Panel's recommendations to reassign CPT code 65778 from APC 0239 to APC 0233 and to reassign CPT code 65779 from APC 0255 to APC 0233. However, based upon our further review and analysis of the clinical characteristics of the procedure described by CPT code 65778, we also proposed to conditionally package CPT code 65778. The service described by CPT code 65778 would rarely be provided as a separate, stand-alone service in the HOPD; it would almost exclusively be provided in addition to and following another procedure or service. Our medical advisors indicated that the procedure described by CPT code 65778 is not significantly different than placing a bandage contact lens on the surface of the eye to cover a corneal epithelial defect. CPT code 65778 describes the simple placement of a special type of bandage (a self-retaining amniotic membrane device) on the surface of the eye, which would most commonly be used in the HOPD to cover the surface of the eye after a procedure that results in a corneal epithelial defect. In fact, the self-retaining amniotic membrane device is structurally similar to a bandage contact lens, except that the central material is amniotic membrane instead of contact lens polymer. Given the characteristics of this procedure, the device used in the procedure, and its likely use in the HOPD, we proposed to conditionally package CPT code 65778 for CY 2012 and reassign its status indicator from ''T'' to ''Q2'' to indicate that the procedure is packaged when it is billed on the same date with another procedure or service that is also assigned to status indicator ''T.'' Otherwise, separate payment would be made for the procedure.

In summary, for CY 2012, we proposed to reassign CPT code 65778 from APC 0239 to APC 0233 with a conditionally packaged status of ''Q2,'' to reassign CPT code 65779 from APC 0255 to APC 0233, which had a proposed median cost of approximately $1,214, and to continue to assign CPT code 65780 to APC 0244, which had a proposed median cost of approximately $2,767.

At the August 2011 APC Panel Meeting, a presenter urged the Panel to recommend to CMS not to conditionally package CPT code 65778 for CY 2012, and instead, assign it to status indicator ''T.'' Based on information presented at the meeting, and after further discussion on the issue, the APC Panel recommended that CMS reassign the status indicator for CPT code 65778 from conditionally packaged ''Q2'' to status indicator ''T.''

Comment: Several commenters urged CMS not to finalize its proposal to conditionally package CPT code 65778 by assigning it to status indicator ''Q2,'' and instead adopt the APC Panel's recommendation to assign it to status indicator ''T.'' One commenter expressed concern that conditionally packaging CPT code 65778 is inappropriate because it will result in no payment for the procedure despite the significant costs hospitals incur in furnishing the service, which includes the cost of the Prokera device (the self-retaining amniotic membrane device) that is used with this procedure. Further, this same commenter disagreed with CMS' assertion that the service described by CPT code 65778 is merely a minor procedure that involves placing a bandage contact lens on the surface of the eye, and stated that the service is a significant, separate procedure that should continue to be separately paid.

Response: We disagree that the procedure described by CPT code 65778 is a significant procedure. The procedure has been described by the manufacturer as ''like inserting a contact lens.'' The manufacturer's Web site states the following about the Prokera self-retaining amniotic membrane device: ''The ProKera® device configuration enables easy insertion in the office, hospital bedside or following surgical procedures to prevent adhesions while delivering the wound repair and wound healing actions of amniotic membrane.'' Because this is a type of specialized bandage that is typically placed on the surface of the eye immediately after a surgery that has resulted in a corneal epithelial defect, we believe that assigning CPT code 65778 to a conditionally packaged status encourages hospitals to use resources more efficiently. We expect hospitals to provide only necessary, high quality care and to provide that care as efficiently as possible. We expect that, for most surgically induced corneal epithelial defects, hospitals will use a conventional eye patch or a standard bandage contact lens to promote faster wound healing and greater patient comfort, and that they will reserve very high cost products, such as the self-retaining amniotic membrane device, for rare and exceptional vision-threatening cases. We believe that the conditional packaging of CPT code 65778 is consistent with this expectation and will encourage efficient hospital outpatient care under these circumstances. Based on the nature of this procedure, we believe that assigning CPT code 65778 to status indicator ''Q2'' is appropriate under the hospital OPPS. Therefore, we are not accepting the APC Panel's recommendation to reassign this procedure to status indicator ''T.''

After consideration of the public comments we received and the APC Panel's August 2011 recommendation, we are finalizing our proposal, without modification, to assign status indicator ''Q2'' to CPT code 65778. When the service is furnished with a separately payable surgical procedure with status indicator ''T'' on the same day, payment for CPT code 65778 is packaged. Otherwise, payment for CPT

code 65778 is made separately through APC 0233, which has a CY 2012 final median cost of approximately $1,164. We also are finalizing our proposal to accept the APC Panel's recommendation to reassign CPT code 65779 from APC 0255 to APC 0233, which has a final CY 2012 median cost of approximately $1,164. Further, we are finalizing our proposal, without modification, to continue to assign CPT code 65780 to APC 0244, which has a final CY 2012 median cost of approximately $2,654.

As has been our practice since the implementation of the OPPS, we annually review all the items and services within an APC group to determine, with respect to comparability of the use of resources, for any 2 times rule violations. In making this determination, we review our claims data and determine whether we need to make changes to the current APC assignments for the following year. In CY 2012, we will again reevaluate the status indicator and APC assignments for CPT codes 65778, 65779, and 65780 for the CY 2013 OPPS rulemaking cycle. The amniotic membrane procedures and their CY 2012 final APC assignments are displayed in Table 24 below.

TABLE 24.—APC ASSIGNMENTS FOR THE AMNIOTIC MEMBRANE PROCEDURES FOR CY 2012

CY 2011 HCPCS Code	CY 2011 Short Descriptor	CY 2011 SI	CY 2011 APC	Final CY 2012 SI	Final CY 2012 APC
65778	Cover eye w/membrane	T	0239	Q2	0233
65779	Cover eye w/membrane suture	T	0255	T	0233
65780	Ocular reconst transplant	T	0244	T	0244

b. Insertion of Anterior Segment Aqueous Drainage Device (APC 0673)

The AMA CPT Editorial Panel created category III CPT code 0253T (Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach, into the suprachoroidal space) effective on January 1, 2011. We assigned CPT code 0253T to APC 234 (Level IV Anterior Segment Eye Procedures) in the OPPS, effective January 1, 2011 with a comment indicator ''NI'' in Addendum B of the CY 2011 OPPS/ASC final rule with comment period (75 FR 72448). For CY 2012, we proposed to continue to assign CPT code 0253T to APC 0234, with a proposed payment rate of approximately $1,754.

Comment: A few commenters requested that CMS reassign CPT code 0253T to APC 0673 (Level V Anterior Segment Eye Procedures), with a proposed CY 2012 payment rate of approximately $2,901. The commenters claimed that CPT code 0253T would be more appropriately placed in APC 0673 based on clinical homogeneity and resource costs. Specifically, the commenters stated that, because CPT code 0253T is a glaucoma treatment with an implantable device, it should be assigned to APC 0673 because, unlike the procedures assigned to APC 0234, the procedures assigned to APC 0673 are primarily glaucoma treatments with an implantable device. Commenters also stated that the procedure described by CPT code 0253T is very similar to the procedure described by CPT code 0191T (Insertion of anterior segment aqueous drainage device, without extraocular reservoir; external approach), which is assigned to APC 0673. Finally, the commenters stated that the cost of the device used in CPT code 0253T is similar to that of other devices used in glaucoma treatment procedures assigned to APC 0673.

Response: After revisiting this issue and reexamining the clinical and resource characteristics of CPT code 0253T, we agree with the commenters that CPT code 0253T is similar clinically and in terms of resource utilization to the procedures currently assigned to APC 0673. In fact, the procedure described by CPT code 0253T is almost the same as the procedure described by CPT code 0191T, which is currently assigned to APC 0673. Also, both of these procedures employ the same type of internally inserted implantable glaucoma drainage device. Therefore, after consideration of the public comments we received, we are modifying our proposal and reassigning CPT code 0253T from APC 0234 to APC 0673, which has a final median cost of approximately $2,911 for CY 2012. We will monitor claims and cost report data related to CPT code 0253T as the data become available for future updates.

c. Scanning Ophthalmic Diagnostic Imaging (APC 0230)

For CY 2011, the CPT Editorial Panel deleted CPT codes 0187T (Scanning computerized ophthalmic diagnostic imaging, anterior segment, with interpretation and report, unilateral) and 92135 (Scanning computerized ophthalmic diagnostic imaging, posterior segment, (e.g., scanning laser) with interpretation and report, unilateral) on December 31, 2010, and replaced them with three new codes effective January 1, 2011. Specifically, CPT code 0187T was replaced with CPT code 92132 (Scanning computerized ophthalmic diagnostic imaging, anterior segment, with interpretation and report, unilateral or bilateral), and CPT code 92135 was replaced with CPT codes 92133 (Scanning computerized ophthalmic diagnostic imaging, posterior segment, with interpretation and report, unilateral or bilateral; optic nerve) and 92134 (Scanning computerized ophthalmic diagnostic imaging, posterior segment, with interpretation and report, unilateral or bilateral; retina).

In Addendum B of the CY 2011 OPPS/ASC final rule with comment period, CPT codes 92132, 92133, and 92134 were assigned to APC 0230 (Level I Eye Tests & Treatments) with a payment rate of approximately $42 and were flagged with comment indicator ''NI'' to indicate that these codes were

new codes for CY 2011 with an interim APC assignment subject to public comment. We stated that we would address any public comments on issues regarding these new codes in this CY 2012 OPPS/ASC final rule with comment period.

In addition, in the CY 2012 OPPS/ASC proposed rule, we proposed to continue to assign CPT codes 92132, 92133, and 92134 to APC 0230.

Comment: One commenter on the CY 2011 OPPS/ASC final rule with comment period requested that CMS reassign CPT codes 92132, 92133, and 92134 from APC 0230 to APC 0698 (Level II Eye Tests & Treatments), which has a CY 2011 payment rate of approximately $67, to account for the long descriptor changes for the new codes. Specifically, the commenter indicated that the predecessor codes, specifically, CPT codes 0187T and 92135 described a unilateral procedure; however, the new codes, specifically, CPT codes 92132, 92133, and 92134, describe a ''unilateral or bilateral'' procedure in the code descriptors. Further, the commenter expressed concern that the new codes are paid at half the CY 2010 payment rate, which the commenter believed is inappropriate since the typical patient encounter involves two tests.

Response: As indicated above, CPT codes 92132, 92133, and 92134 were assigned to APC 0230 effective on January 1, 2011. We assigned these new codes to the same APC and status indicator as their predecessor CPT codes 0187T and 92135. We note that these predecessor CPT codes were active codes for some time. CPT code 92135 was made effective January 1, 1999 and deleted on December 31, 2010, while CPT code 0187T was made effective January 1, 2008, and deleted on December 31, 2010. Given the history of the predecessor codes, we reviewed our claims.

For the CY 2012 update, the payment rates are based on data from claims submitted during CY 2010 according to the standard OPPS ratesetting methodology. Based on our analysis, we found significant claims data for predecessor CPT codes 92135 and 0187T. Our CY 2012 final claims data show that the median cost for CPT code 92135 is approximately $41 based on 191,170 single claims (out of 191,934 total claims), and approximately $44 based on 341 single claims (out of 348 total claims) for CPT code 0187T. We believe that the final rule median costs of approximately $41 and $44 are similar to the final median cost of approximately $48 for APC 0230. We also believe that the resources consumed in performing these procedures are not significantly different for unilateral versus bilateral imaging.

After consideration of the public comment we received on the CY 2011 OPPS/ASC final rule with comment period, we are finalizing our CY 2012 proposal, without modification. Given the significant information reflected in the CY 2012 final rule claims data for predecessor CPT codes 92135 and 0187T, we believe our claims data are sufficient for us to continue to assign these services to APC 0230, which has a final CY 2012 median cost of approximately $45. We will reevaluate the APC assignment for CPT codes 92132, 92133, and 92134 in future OPPS updates as additional information becomes available to us. Also, we expect to have the first claims data available for CPT codes 92132, 92133, and 92134 for the CY 2013 OPPS/ASC rulemaking cycle.

d. Intraocular Laser Endoscopy (APC 0233)

CPT code 66711 (Ciliary body destruction; cyclophotocoagulation, endoscopic) is assigned to APC 0233 (Level III Anterior Segment Eye Procedures) for CY 2011, with a CY 2011 payment rate of $1,233.03. In the CY 2012 OPPS/ASC proposed rule, we proposed continued assignment for CPT code 66711 for CY 2012 to APC 0233, with a proposed payment rate of $1,171.65. The final rule median cost for APC 0233 is approximately $1,164.

Comment: One commenter, the manufacturer of a single use intraocular laser endoscope, indicated that the device used to accomplish CPT code 66711 is used to treat patients with glaucoma and retinal disease. The commenter had previously manufactured a multiple use version of the intraocular laser endoscope, and claimed that the multiple use device had lower per unit costs per use than the new single use device, but that it could no longer be manufactured due to supply constraints of a part used in the manufacturing process. The commenter stated that the most frequent service code used to deliver this service is represented by CPT code 66711, and stated that the multiple procedure discount typically applies, which reduces the OPPS payment rate to approximately $616 for CY 2011. The commenter stated that the procedure is also performed in the ASC setting with a payment rate of approximately $694 for CY 2011, but a multiple procedure discount typically applies, for a payment rate of approximately $347. The commenter requested that CMS use one of several suggested approaches to pay for the higher costs associated with the single use device. One approach the commenter mentioned was to establish a device pass-through category for the single use intraocular laser endoscope, while noting that it had filed an OPPS pass-through application, and that it expected a separate decision on the pass-through application. Another alternative suggested by the commenter was for CMS to use its equitable adjustment authority under section 1833(t)(2)(E) of the SSA, to adjust payment rates when necessary to ensure patients' treatment options are not inappropriately limited as a result of CMS policies. The third option the commenter listed was to temporarily assign the CPT code 66711 procedure to a different clinical APC or to a new technology APC, based on external data provided by the commenter, until Medicare claims data are available for ratesetting.

Response: As stated above, CPT code 66711 is assigned to APC 0233 for CY 2011, which has a CY 2011 final rule median cost of approximately $1,168. CPT code 66711 has a CY 2012 final median cost of approximately $1,430. The commenter stated that the CPT code 66711 procedure will not change with use of the single use laser endoscope over the multi-use endoscope. We do not believe that it is necessary to invoke the equitable adjustment clause in this case. There are several clinical APCs for anterior segment eye procedures that are potential APCs for this type of service, and the particular APC assignment depends in part on the underlying claims data for the procedure. Upon further review of the various procedures in APC 0233 and APC 0234 (Level IV Anterior Segment Eye Procedures), we believe that CPT code 66711 is more clinically similar to the range of procedures in APC 0234 than the procedures in APC 0233. Both APCs 0233 and 0234 consist of anterior segment eye procedures, but APC 0234 includes several intraocular procedures for the treatment of glaucoma, which also describes CPT code 66711. From a resource perspective, CPT code 66711 fits in either APC 0233 or APC 0234, which have CY 2012 final median costs of approximately $1,164 and $1,631, respectively. Therefore, we are reassigning CPT code 66711 to APC 0234 for CY 2012.

We agree with the commenter that we will decide on any device pass-through application by means of our normal process for that payment mechanism.

6. Orthopedic and Musculoskeletal Services

a. Percutaneous Laminotomy/ Laminectomy (APC 0208)

We created new HCPCS code C9729 (Percutaneous laminotomy/ laminectomy (intralaminar approach) for decompression of neural elements, (with ligamentous resection, discectomy, facetectomy and/or foraminotomy, when performed) any method under indirect image guidance, with the use of an endoscope when performed, single or multiple levels, unilateral or bilateral; lumbar), and assigned it to APC 0208 (Laminotomies and Laminectomies) effective April 1, 2011. AMA's CPT Editorial Panel thereafter created CPT code 0275T (Percutaneous laminotomy/ laminectomy (intralaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (eg, fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; lumbar) effective July 1, 2011. We assigned CPT code 0275T to APC 0208 and deleted HCPCS code C9729 effective July 1, 2011. For CY 2011, APC 0208 has a payment rate of $3,535.92. For CY 2012 we proposed to maintain assignment of percutaneous laminotomy/laminectomy (HCPCS code C9729 is used in the CY 2012 proposed rule, while CPT code 0275T is used in this CY 2012 final rule with comment period) to APC 0208, because we believe the service is similar clinically and with regard to resources to other APC 0208 procedures, APC 0208 had a CY 2012 proposed rule median cost of approximately $3,676, and has a final rule median cost of approximately $3,553

Comment: One commenter believed it is appropriate to assign CPT code 0275T to APC 0208, in the case of ''unilateral'' percutaneous laminotomy/laminectomy, but not in the case of bilateral or multiple level procedures, which are, according to the commenter, more resource intensive. The commenter claimed that the phrase ''unilateral or bilateral'' in the CPT code 0275T descriptor suggests to providers that the code must be reported unmodified when the procedure is performed either unilaterally or bilaterally, which will preclude the use of modifier ''50'' when the bilateral approach is employed, even though additional physician and facilities resources are used. Additionally, the commenter believed that the CPT code 0275T descriptor's inclusion of ''single or multiple levels'' will preclude providers from reporting modifier ''51'' with CPT code 0275T, to reflect the additional resources consumed when the procedure is performed on multiple levels of the spine. Therefore, the commenter believed that the APC 0208 payment rate is not adequate when CPT code 0275T is performed bilaterally or on multiple levels. The commenter recommended that, for CY 2012, CMS either allow the use of modifiers when CPT code 0275T is used, or that CMS create a HCPCS G-code that describes the service when performed bilaterally or on multiple levels. The commenter anticipated that the CPT Editorial Panel will take up the issue of bilateral or multiple levels in the CPT code 0275T code descriptor for CY 2013.

Response: Concerning the request for availability of modifiers 50 or 51, or modification to the descriptor for CPT code 0275T, we refer the commenter to the CPT Editorial Panel. CPT code 0275T is the property of the AMA, and CMS may not modify any CPT codes. We also will wait to see if the CPT Editorial Panel changes the descriptor for CY 2013, and we will not create a HCPCS G-code for CY 2012.

CPT code 0275T is a new code effective July 1, 2011 (as was its predecessor code, HCPCS code C9729, which was available for one quarter, beginning April 1, 2011), and as such we have no claims data at this time. For CY 2013, we should have partial CY 2011 data for both HCPCS code C9729 and CPT code 0275T, which we can use to reevaluate any APC assignment for percutaneous laminotomy/laminectomy for CY 2013. These claims data will include the hospital costs related to all of the various clinical options to perform this service, (that is, unilateral versus bilateral, and single versus multiple levels) to the extent they were performed. Based on those claims, we will reevaluate the APC placement of CPT code 0275T.

After consideration of the public comments we received, we are finalizing our proposed assignment of CPT code 0275T to APC 0208 for CY 2012, which is clinically similar to the procedures in APC 0208, and which has a median cost of approximately $3,553.

b. Level II Arthroscopy (APC 0042)

The CY 2012 proposed rule median cost for APC 0042 (Level II Arthroscopy) was approximately $3,485, based on 5,676 single bill claims from the 28 procedures assigned to APC 0042. The CY 2011 final rule median is $3,301, based on 6,297 single bill claims from those 28 arthroscopic procedures. Our CY 2012 final rule data consist of a median cost of approximately $3,996, based on 3,140 single bill claims based on 234 procedures.

Comment: One commenter believed that the procedures currently assigned to APC 0042 have widely varying median costs, which range from approximately $88 to more than $10,000, according to the CY 2012 proposed rule data. The commenter claimed that the APC currently violates the 2 times rule. The commenter recommended that CMS reconfigure APC 0042 and create two additional APCs in order to group procedures similar in clinical features and resources together. The commenter recommended that CMS place the following hip procedures in the reconfigured APC 0042: CPT codes 29861 (Arthroscopy, hip, surgical; with removal of loose body or foreign body), 29914 (Arthroscopy, hip, surgical; with femoroplasty (ie, treatment of cam lesion)), 29915 (Arthroscopy, hip, surgical; with acetabuloplasty (ie, treatment of pincer lesion)), and 29916 (Arthroscopy, hip, surgical; with labral repair). The commenter also recommended that CMS separate the remaining CPT codes in APC 0042 into new APC 0043 (proposed descriptor ''Level III Upper Extremity Arthroscopy'') and APC 0044 (Level IV Lower Extremity Arthroscopy), with respective payment amounts based on the median costs of those service groupings.

Response: We do not agree that the HCPCS codes comprising APC 0042 have widely varying median costs or that there is a 2 times rule violation for services currently assigned to APC 0042, as claimed by the commenter. As we stated in the CY 2012 OPPS/ASC proposed rule (76 FR 42231), in accordance with section 1833(t)(2) of the Act and § 419.31 of the regulations, we annually review the items and services within an APC group to determine, with respect to comparability of the use of resources, if the median cost of the highest cost item or service within an APC group is more than 2 times greater than the median of the lowest cost item or service within that same group. In making this determination, we consider only those HCPCS codes that are significant based on the number of claims. We note that, for purposes of identifying significant HCPCS codes for examination in the 2 times rule, we consider codes that have more than 1,000 single major claims or codes that have both greater than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC median cost to be significant (75 FR

71832). Based on this rule, we have no 2 times rule violations in APC 0042. Using our CY 2012 final rule claims data, the highest significant procedure in APC 0042 is CPT code 29827 (Arthroscopy, shoulder, surgical; with rotator cuff repair) with a final median cost of approximately $4,817, and the lowest significant procedure in the APC is CPT code 29823 (Arthroscopy, shoulder, surgical; debridement, extensive), with a final median cost of approximately $2,959, leading to a ratio of approximately 1.6, well below the 2.0 required for a violation. Furthermore, we do not agree with the commenter's recommendation to establish an arthroscopy APC with the four hip arthroscopy procedures, specifically, CPT codes 29861, 29914, 29915, and 29916, as a viable alternative, because all four of those CPT codes have no CY 2010 median costs. Therefore, there would be no basis for establishing an APC median cost and payment amount for those four procedures. We see no compelling reason to revise the current procedures of APC 0042 for CY 2012 because they are similar both clinically and in terms of resource utilization. We will keep the current HCPCS code configuration of APC 0042 for CY 2012, and will review the APC 0042 and component HCPCS code median costs again next year for clinical and resource similarity.

c. Closed Treatment Fracture of Finger, Toe, and Trunk (APCs 0129, 0138, and 0139)

In Addendum A (Proposed OPPS APCs for CY 2012) of the CY 2012 OPPS/ASC proposed rule, we proposed to continue with the existing group titles for APCs 0129, 0138, and 0139 to read as follows:

- APC 0129 (Level I Closed Treatment Fracture Finger/Toe/Trunk)
- APC 0138 (Level II Closed Treatment Fracture Finger/Toe/Trunk)
- APC 0139 (Level III Closed Treatment Fracture Finger/Toe/Trunk)

We note that Addendum A did not appear in the printed version of the **Federal Register** as part of the CY 2012 OPPS/ASC proposed rule. Rather, it was published and made available only via the Internet on the CMS Web site at: *http://www.cms.gov/*.

Comment: One commenter recommended that CMS remove the words ''Finger/Toe/Trunk'' from the group titles for APCs 0129, 0138, and 0139 because there is no need to make this distinction since there are no other APCs that describe closed treatment fractures.

Response: We appreciate the commenter's suggestion, and we accept this recommendation. We agree that removing the words ''Finger/Toe/Trunk'' from the group titles for APCs 0129, 0138, and 0139 more appropriately describe these APCs.

After consideration of the public comment we received, we are revising the group titles for APCs 0129, 0138, and 0139 to ensure that the title describes all procedures assigned to these APCs. Table 25 shows the final group titles for APCs 0129, 0138, and 0139 for CY 2012.

TABLE 25.—FINAL GROUP TITLES FOR APCs 0129, 0138, AND 0139 FOR CY 2012

APC	Group Title
0129	Level I Closed Treatment Fracture
0138	Level II Closed Treatment Fracture
0139	Level III Closed Treatment Fracture

d. Level I and II Strapping and Cast Application (APCs 0058 and 0426)

In Addendum A (Proposed OPPS APCs for CY 2012) of the CY 2012 OPPS/ASC proposed rule, we proposed to continue with the existing group titles for APCs 0058 and 0426 to read as follows:

- APC 0058 (Level I Strapping and Cast Application)
- APC 0426 (Level II Strapping and Cast Application)

We note that Addendum A did not appear in the printed version of the **Federal Register** as part of the CY 2012 OPPS/ASC proposed rule. Rather, it was published and made available only via the Internet on the CMS Web site at: *http://www.cms.gov/*.

Comment: One commenter stated there is only a single level APC for the strapping procedures; therefore, the designation ''Level I'' is not appropriate in the group title because there is no ''Level II.''

Response: We disagree with the commenter. There is another level APC for the strapping procedures, specifically, APC 0426 which reads ''Level II Strapping and Cast Application.'' Under the OPPS, APC 0426 was made effective January 1, 2005. We remind hospitals that APCs with multiple levels are not always in sequential order and, as a result, may not always appear close to each other in Addendum B.

After consideration of the public comment we received, we are finalizing our CY 2012 proposal, without modification, to continue to title APC 0058 to read ''Level I Strapping and Cast Application'' and APC 0426 to read ''Level II Strapping and Cast Application.''

7. Radiology Services

a. Proton Beam Therapy (APC 0664 and 0667)

For CY 2012, we proposed to continue to assign CPT codes 77520 (Proton treatment delivery; simple, without compensation) and 77522 (Proton treatment delivery; simple, with compensation) to APC 0664 (Level I Proton Beam Radiation Therapy), which had a proposed payment rate of approximately $992. We also proposed to continue to assign CPT codes 77523 (Proton treatment delivery; intermediate) and 77525 (Proton treatment delivery; complex) to APC 0667 (Level II Proton Beam Radiation Therapy), which had a proposed payment rate of approximately $1,298.

Comment: Some commenters appreciated the relative stability in the hospital outpatient proton therapy rates and supported the proposed payments for the proton beam treatment CPT codes.

Other commenters indicated that they were pleased with CMS' proposal to exempt APC 0667 from the 2 times rule based on the list of APCs that appeared in Table 18 of the CY 2012 OPPS/ASC proposed rule, but expressed concern with the proposed decrease in payments for the proton beam therapy APCs.

Response: In accordance with sectionS 1833(t)(2)(B) and 1833(t)(9)(A) of the Act and §§ 419.31 and 419.50 of the regulations, we annually review the items and services within an APC group to determine, with respect to comparability of the use of resources and clinical homogeneity. The payment rates, including the relative weights, set annually for these services are based on review of the claims data used for ratesetting. For the CY 2012 update, the payment rates for APCs 0664 and 0667 are based on data from claims submitted during CY 2010 according to the standard OPPS ratesetting methodology. Specifically, we used 12,263 single claims (out of 13,364 total claims) from CY 2012 proposed rule claims data (and we used 13,437 single claims (out of 14,519 total claims) from CY 2012 final rule claims data) to calculate the median cost upon which the CY 2012 payment rate for APC 0664 is based. In addition, we used 3,379 single claims (out of 3,879 total claims) from CY 2012 proposed rule claims data (and we used 3,638 single claims (out of 4,145 total claims) from CY 2012 final rule claims data) to calculate the median cost for APC 0667.

For CY 2012, we are setting the final payment rate for proton beam therapy based on median costs of approximately $1,184 for APC 0664 and approximately $1,549 for APC 0667. We note that these median costs are higher than the median costs upon which the CY 2012 proposed payment rates for these APCs were based ($1,028.10 and $1,344.90, respectively) and higher than the median costs upon which the final CY 2011 payment rates were based ($1,020.72 and $1,335.24, respectively). As we have in the past (75 FR 71916), we note that our cost-finding methodology is based on reducing each hospital's charge for its services to an estimated cost by applying the most discrete hospital-specific CCR available for the hospital that submitted the claim. Therefore, it is the hospitals' claims and cost reports that determine the estimated costs that are used to calculate the median cost for each service and, when aggregated into APC groups, the hospital data are used to calculate the median cost for the APC on which the APC payment rate is based.

After consideration of the public comments we received, we are finalizing our CY 2012 proposal, without modification, to pay for proton beam therapy through APCs 0664 and 0667, with payment rates based upon the most current claims and cost report data for these services. Specifically, we will continue to assign CPT codes 77520 and 77522 to APC 0664, with a final CY 2012 APC median cost of approximately $1,184, and CPT codes 77523 and 77525 to APC 0667, with a final CY 2012 APC median cost of approximately $1,549 because we continue to believe these placements are appropriate in light of the resource cost and clinical intensity of the services describe by these CPT codes.

b. Stereotactic Radiosurgery (SRS) Treatment Delivery Services (APCs 0065, 0066, 0067, and 0127)

For CY 2012, we proposed to continue to assign CPT code 77371 (Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; multi-source Cobalt 60 based) to APC 0127 (Level IV Stereotactic Radiosurgery, MRgFUS, and MEG), with a proposed payment rate of approximately $7,368. We also proposed to continue to recognize four existing HCPCS G-codes that describe linear accelerator-based SRS treatment delivery services for separate payment in CY 2012. Specifically, we proposed the following: to assign HCPCS code G0173 (Linear accelerator based stereotactic radiosurgery, complete course of therapy in one session) and HCPCS code G0339 (Image-guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment) to APC 0067 (Level III Stereotactic Radiosurgery, MRgFUS, and MEG), with a proposed payment rate of approximately $3,251; to assign HCPCS code G0251 (Linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, maximum five sessions per course of treatment) to APC 0065 (Level I Stereotactic Radiosurgery, MRgFUS, and MEG), with a proposed payment rate of approximately $864; and to assign HCPCS code G0340 (Image-guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment) to APC 0066 (Level II Stereotactic Radiosurgery, MRgFUS, and MEG), with a proposed payment rate of approximately $2,447. Further, we proposed to continue to assign SRS CPT codes 77372 (Radiation treatment delivery, stereotactic radiosurgery (SRS) (complete course of treatment of cerebral lesion(s) consisting of 1 session); linear accelerator based) and 77373 (Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions) status indicator ''B'' (Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x)) under the OPPS, to indicate that these CPT codes are not payable under the OPPS.

Comment: One commenter requested that CMS continue to recognize HCPCS codes G0173, G0251, G0339, and G0340 for CY 2012 as proposed and supported the proposed assignment of status indicator ''B'' to CPT codes 77372 and 77373. The commenter also recommended that CMS revise the code descriptors for HCPCS code G0173, G0251, G0339, and G0340 to distinguish between robotic and nonrobotic gantry-based SRS systems. Based on analysis of claims data for HCPCS codes G0339 and G0340, the commenter found that 41 and 42 percent of the claims submitted for HCPCS codes G0339 and G0340, respectively, during CY 2010 were paid to hospitals without image-guided robotic SRS systems. The commenter suggested specific code descriptor changes for the four HCPCS G-codes to ensure submission of correctly coded claims. Alternatively, the commenter requested that CMS provide guidance on the reporting of the existing SRS HCPCS G-codes if no change is made to the HCPCS code descriptors.

Response: As we have stated in the past (75 FR 71915), these HCPCS G-codes for SRS have been in effect for several years and, based on questions brought to our attention by hospitals, we have no reason to believe that hospitals are confused about the reporting of these codes. Moreover, based on our analysis of the hospital outpatient claims data that we use for ratesetting, we see resource differences reflected in the median costs of the four HCPCS G-codes that are reasonably consistent with our expectations for different median costs for the services based on the current code descriptors. We continue to believe it would be confusing to hospitals if we were to revise the code descriptors for HCPCS codes G0173, G0251, G0339, and G0340 at this point in time and could lead to instability in our median costs and inaccurate payments for some services. Therefore, we believe that modifying the

HCPCS G-code descriptors is not necessary for us to continue to provide appropriate payment for the services they describe. Further, we have provided instruction on the reporting of these SRS codes in Chapter 4, Section 200.3 of the Medicare Claims Processing Manual of the Internet-Only Manual.

After consideration of the public comment we received, we are finalizing our CY 2012 proposals, without modification, to maintain the existing CY 2011 APC assignments for the SRS HCPCS codes for CY 2012. Specifically, we are continuing to assign HCPCS G-codes G0173 and G0339 to APC 0067, which has a final CY 2012 APC median cost of approximately $3,374; HCPCS G-code G0251 to APC 0065, which has a final CY 2012 APC median cost of approximately $903; HCPCS G-code G0340 to APC 0066, which has a final CY 2012 APC median cost of approximately $2,521; and CPT code 77371 to APC 0127, which has a final CY 2012 APC median cost of approximately $7,461 because we continue to believe these placements are appropriate in light of the resource cost and clinical intensity of the services describe by these CPT codes. In addition, we are finalizing our proposals, without modification, to continue to assign CPT codes 77372 and 77373 to status indicator ''B'' under the OPPS.

c. Adrenal Imaging (APC 0408)

For CY 2012, we proposed to reassign CPT code 78075 (Adrenal imaging, cortex and/or medulla) from APC 0408 (Level III Tumor/Infection Imaging), which had a proposed payment rate of approximately $953, to APC 0414 (Level II Tumor/Infection Imaging), which had a proposed payment rate of approximately $485.

Comment: Commenters questioned CMS' rationale for the proposal to reassign CPT code 78075 from APC 0408 to APC 0414, citing a lack of clinical reasoning to justify its movement as well as CPT code 78075's cost similarity to a clinically similar procedure assigned to APC 0408. Commenters requested that CMS reevaluate the reassignment of CPT code 78075 and consider maintaining its placement in APC 0408. Commenters further recommended that CMS provide rationale in all proposed rules when any CPT code placement change is proposed.

Response: After revisiting this issue and analyzing the final CY 2012 median cost for CPT code 78075, we agree with commenters' assertion that CPT code 78075 should remain in APC 0408 and, therefore, we will continue to assign CPT code 78075 to APC 0408 for CY 2012 based on its final median cost of approximately $997 (calculated using 99 single claims out of 127 total claims), which is similar to the APC median cost of APC 0408 of approximately $958. . We note that the proposed rule does not include service-specific discussions for each separately paid HCPCS code reassignment or for each APC. Rather, we discuss the general methodology used to calculate the median costs upon which the proposed payment rates are based (76 FR 42183 through 42190) and the principles applied in determining APC configurations (76 FR 42230 through 42232). We discuss specific APCs or services in the proposed rule only when we have a specific reason to do so, such as when we apply a nonstandard ratesetting methodology to calculate a proposed payment rate for a particular item or service. In most cases, a proposed reduction of a median cost for an APC or for a HCPCS code that is calculated from actual charges and cost data will not result in a service specific discussion in the propose rule. The number of APCs and the volume of HCPCS codes for which median costs are calculated prohibit a detailed explanation of each in the proposed rule.

After consideration of the public comments we received, we are modifying our CY 2012 proposal to reassign CPT code 78075 to APC 0414 and will instead continue to assign it to APC 0408, with a final CY 2012 APC median cost of approximately $958.

d. Positron Emission Tomography (PET) Imaging (APC 0308) (Created From Myocardial Positron Emission Tomography (PET) Imaging (APC 0307) and Non-Myocardial Positron Emission Tomography (PET) Imaging (APC 0308))

For CY 2012, we proposed to continue to assign CPT codes 78459 (Myocardial imaging, positron emission tomography (PET), metabolic evaluation), 78491 (Myocardial imaging, positron emission tomography (PET), perfusion; single study at rest or stress), and 78492 (Myocardial imaging, positron emission tomography (PET), perfusion; multiple studies at rest and/or stress) to APC 0307 (Myocardial Position Emission Tomography (PET) Imaging), for which we proposed a national unadjusted payment rate of approximately $921. The CY 2011 national unadjusted payment rate is approximately $1,107.

For CY 2012, we proposed to continue to assign CPT codes 78608 (Brain imaging, positron emission tomography (PET); metabolic evaluation), 78811 (Tumor imaging, positron emission tomography (PET) imaging; limited area (eg, chest, head/neck)), 78812 (Tumor imaging, positron emission tomography (PET) imaging; skull base to mid-thigh), 78813 (Tumor imaging, positron emission tomography (PET) imaging; whole body), 78814 (Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; limited area (eg, chest, head/neck)), 78815 (Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh), and 78816 (Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body) to APC 0308 (Non-Myocardial Positron Emission Tomography (PET) imaging), for which we proposed a national unadjusted payment rate of $1,015. The CY 2011 national unadjusted payment rate for APC 0308 is approximately $1,042.

Comment: Commenters objected to the proposed decrease in the payment rate for APC 0307. Commenters were concerned with the volatility of the payment rates from one year to the next and the proposed reduction in the payment rate for CY 2012, particularly in view of the reduction in the payment rate from CY 2010 to CY 2011. The commenters urged CMS to validate the costs estimated from the CY 2010 hospital claims and cost report data for the limited number of hospitals reporting CPT codes 78459, 78491, and 78492 to determine the reason for the proposed change in payment. Several commenters asked that CMS limit to 5 to 10 percent the amount of decrease in the payment rate for CY 2012 compared to CY 2011 because they believed that the reduction CMS proposed for myocardial PET for CY 2012 would jeopardize access to the service. One commenter asked that CMS combine APC 0307 and APC 0308 into one single PET imaging APC because the commenter believed that myocardial PET and non-myocardial PET are clinically similar and have similar resource requirements. The commenter also believe that merging the APCs would result in more appropriate payment for myocardial PET services and would increase the stability of payment for myocardial PET services.

Several commenters indicated that they believed that aberrant CCRs for a few hospitals that furnish myocardial PET services are affecting the median cost for APC 0307 and that the

methodology must be flawed to permit this to occur. Commenters stated that their analyses of the claims data showed that 4 of the top 25 hospitals contribute 34 percent of all single bills used in ratesetting for CPT code 78492 and that these hospitals have substantially lower calculated costs as compared to their peer institutions. The commenters believed that the CCRs of these institutions are aberrantly low and have skewed the data and lowered the overall median cost for APC 0307 due to the significant percentage of single bills attributable to them. The commenter recommended that CMS delete claims from hospitals with a CCR lower than 0.15 or 0.20 from ratesetting for APC 0307 to remove the effect of these hospitals on the APC 0307 median cost. In contrast, another commenter asked that CMS ensure that claims from every hospital that furnished a service assigned to APC 0307 are included in the calculation of the median for APC 0307.

One commenter stated that the median cost for myocardial PET services is decreasing because they are performed at a relatively small number of hospitals and because hospitals do not always align the costs and charges for the service properly in their accounts and, therefore, the CCRs that result from the cost reports understate the cost of the services. Commenters also stated that they were concerned that hospitals had not charged appropriately for the services and the radiopharmaceutical that is needed to furnish the service. Some commenters objected to the absence of a strict definition of what costs should be included in each cost center because this results in a wide variance in the calculation of costs. One commenter stated that the absence of CMS guidance to hospitals with regard to how to charge for services results in the potential for hospitals to set charges at 4 to 5 times the cost for established procedures but to establish charges at 1.5 times the cost for new, more expensive procedures. One commenter urged CMS to remind hospitals to accurately report all myocardial PET costs on their Medicare cost reports to improve the accuracy of the CCRs in the futures, while another commenter suggested that CMS establish a new cost center or CCRs for PET to moderate the fluctuations in the median cost calculation for PET services.

Response: We agree that myocardial PET and non-myocardial PET have similar clinical characteristics and, currently, appear to have somewhat similar resource requirements. Therefore, for CY 2012, we are deleting the myocardial PET APC (APC 0307) and are reassigning CPT codes 78459, 78491, and 78492 to APC 0308, which we have renamed ''Positron Emission Tomography (PET) Imaging.'' The CY 2012 final rule median cost for newly reconfigured APC 0308 is approximately $1,038.

We were influenced in this decision by a significant unexpected and unusual decrease in the median cost for CPT code 78492 between the proposed rule data and the final rule data for the CY 2012 OPPS. CPT code 78492 comprises approximately 98 percent of the volume of the 3 myocardial PET services that were assigned to APC 0307 and therefore largely would control the median cost for APC 0307 if it had been retained for CY 2012 OPPS. The proposed rule median cost for CPT code 78492 was approximately $954, but the final rule median cost for CPT code 78492 is approximately $778, a decrease of approximately 18 percent from the proposed rule median cost and a decrease of approximately 29 percent from the CY 2011 OPPS median cost of approximately $1,096. APC 0307 had a median cost of approximately $1,096 for CY 2011, a median cost of approximately $954 for the CY 2012 proposed rule, and had we not deleted it for this final rule, APC 0307 would have had a median cost of approximately $809, a 15-percent decrease from the median cost on which the CY 2012 proposed payment rate was based.

We examined the claims and cost report data for the single procedure claims for CPT code 78492 to determine why it declined substantially from the CY 2011 OPPS final rule data and the CY 2012 proposed rule and yet further between the CY 2012 proposed rule and the CY 2012 final rule data. We believe that there are multiple reasons that the median cost for APC 0307 declined from CY 2011 to CY 2012. Specifically, we looked at the following elements for CPT code 78492 across the three data sets: Line item CCRs; line item charges; line item costs; packaged costs; number of hospitals billing the service; and number of single bills. Our findings are contained in Table 26 below.

TABLE 26.—SELECT DATA FOR CPT CODE 78492

Single and "Pseudo" Single Bill Data for CPT Code 78492	CY 2011 Final Rule Data	CY 2012 Proposed Rule Data	CY 2012 Final Rule Data
Median Line Item CCR	0.1708	0.1350	0.1272
Median Line Item Charge	3,858.75	4,051.70	4,051.70
Median Line Item Cost	$649.85	$539.07	$492.02
Median Packaged Cost	$391.06	$327.69	$273.43
Hospitals Reporting	48	60	64
Single Bills	3,910	8,617	9,727
Total Frequency	5,922	10,531	11,912

We note three significant observations from these data for CPT code 78492, which is the myocardial PET imaging service that represents 98 percent of the volume of APC 0307. First, the median line item CCR for CPT code 78492

decreased 21 percent from the CY 2011 final rule claims data to the CY 2012 proposed rule claims data, although the median charge increased only 5 percent over the same time between the two data sets. Similarly, the median line item CCR for CPT code 78492 decreased 5.8 percent from the CY 2012 proposed rule data to the CY 2012 final rule data, although the line item charge remained the same in both data sets. Therefore, the median line item CCR for CPT code 78492 decreased 25.5 percent from the CT 2011 final rule data to the CY 2012 final rule data although the median line item charge increased only 5 percent over the same period, thus resulting in a significant decrease in the CY 2012 final rule line item median cost compared to both the CY 2011 line item median cost and the CY 2012 line item median cost. Secondly the estimated median cost of the packaged radiopharmaceutical and other supplies necessary to furnish the service decreased in each data set. Specifically, the estimated median packaged cost decreased by 16.2 percent from the CY 2011 final rule data to the CY 2012 proposed rule data and by 16.6 percent from the CY 2012 proposed rule data to the CY 2012 final rule data, or a decrease of 30.1 percent from the CY 2012 final rule data to the CY 2012 final rule data. Third, we observed that the number of hospitals that furnished the service increased in a significant proportion and that the volume of services furnished increased by 25 percent from CY 2009 (CY 2011 final rule data) to CY 2010 (CY 2012 proposed and final rule data sets) and by an additional 6.7 percent from the CY 2012 proposed rule data set to the CY 2012 final rule data set, or a total increase from CY 2009 to CY 2010 of 33.3 percent.

We are particularly concerned with the volatility that is displayed in the data, particularly from the CY 2012 proposed rule data to the CY 2012 final rule data. In particular, there seems to be a transition in CCRs underway that should stabilize itself once the number of hospitals that furnish the service is stable and once the volume of services being furnished each year is stable. We believe that the CCR changes are increasing the instability in the median costs for CY 2012 and that combining the two APCs is a reasonable response for the CY 2012 final rule, particularly because both former APC 0307 and APC 0308 are for PET imaging services and because it is reasonable to expect that the costs would be similar. However, we will reevaluate the relative resource utilization of the services after the cost center transitions are complete. In general, large volumes of services enhance stability of median costs, and we believe that by reassigning CPT codes 78459, 78491 and 78492 to APC 0308, we can lessen the volatility of payment changes for these services for CY 2012. There are many legitimate reasons why costs for these services may go down (for example, hospitals are becoming more efficient as they provide greater volumes of these services without incurring additional substantial costs for equipment and staff, the radiopharmaceuticals used to provide these services are furnished by use of a generator that produces a dose periodically for 28 days and, therefore, additional doses are no more costly during the life of the generator, among others). If we determine that the per unit costs for providing myocardial PET have genuinely decreased over time and stabilized, we believe that it is appropriate that our payment rates would reflect these diminishing costs.

With regard to the comments that we should exclude claims from hospitals with CCRs less than 0.15 or 0.20, we note that we applied our standard policy regarding calculation of CCRs to the calculation of the median cost of myocardial PET services for the proposed and final rule data for the CY 2012 OPPS. Specifically, as we discuss in detail in the claims accounting description that accompanies this final rule with comment period, we excluded claims from hospitals whose CCRs were flagged as invalid. These included claims for hospitals without a CCR, for hospitals paid an all inclusive rate, for CAHs, for hospitals with obviously erroneous CCRs (greater than 90 or less than .0001), and for hospitals with CCRs that were identified as outliers (3 standard deviations from the geometric mean after removing error CCRs). This longstanding practice has resulted in enhancing the number of claims we use for ratesetting, while eliminating claims that cannot be reduced to cost or for which hospital CCRs are clearly erroneous. In the case of myocardial PET services, the commenter indicated that the claims that the commenter requested be deleted from the set of claims used for ratesetting comprise 34 percent of the set of single bills and were submitted by hospitals with CCRs lower than 0.15. Assuming that the commenter's statement is correct, we believe that to remove 34 percent of the claims (more than 1 in every 3 single bills) from hospitals because their CCRs are lower than 0.15 would result in a skewed set of single bills and that the resulting median cost would not be an accurate representation of the relative cost of the service furnished by the full population of providers that furnish the service. These claims would be retained in the dataset used to set median costs under our standard process because they would not be affected by the standard claim trims. We refer readers to section II.A.2.c. of this final rule with comment period for discussion of our policy with regard to trimming of claim records before median cost calculation. The OPPS is a system of averages in which the measure of central tendency is used as the basis for the payment for a service, and to delete 34 percent of the data points would necessarily result in a median cost that would be a less accurate, if perhaps higher, reflection of the cost of the service. We believe that the low CCRs that are of concern to the commenter may be only one element in the transition in the data for these codes. For CY 2012, we believe that deleting APC 0307 and reassigning CPT codes 78459, 78491, and 78492 to APC 0308 is a more reasonable response than deleting 34 percent of the single bills for the procedures. Similarly, we do not believe that it is necessary to create a service-specific cost center for the purpose of calculating a PET-specific CCR because correct and consistent reporting of the costs of PET services on the Medicare hospital cost report and accurate crosswalking of the charges for PET to the cost center in which the costs are housed will result in appropriate estimates of the cost of PET services when the CCR for the cost center is applied to the charges for the services.

With regard to what the commenter viewed as the absence of CMS guidance regarding what cost centers should be used to record the costs of services and how hospitals should charge for services, we note that CMS provides extensive instructions on how cost reports should be completed in the Provider Reimbursement Manual. However, hospitals charges are a reflection of the monetary value that the hospital establishes for service it is furnishing and the only CMS restriction on hospital charges is that charges must be reasonably related to cost and that the same amount must be charged to all payers for the same service (we refer readers to the definition of ''charges'' for cost reporting purposes in 42 CFR 413.53(b)). We recognize that some hospitals may charge at different markups over cost for similar services. However, as long as the cost report is correctly completed and the charges are mapped to the cost center in which the costs for the service are recorded, the CCRs should represent a valid reflection

of the relationship between the costs and the charges in the aggregate for services for which the cost is reported in that cost center. The OPPS, like all other prospective payment systems, assumes that hospitals complete the cost report properly, including mapping the charges for a service to the cost center in which the costs for that service are captured. Therefore, when the appropriate CCR is applied to the charge for a service for which the costs are housed in the cost center from which the CCR is calculated, the result should be a reasonable estimate of the cost of the service.

With regard to the comment that we should limit the decline in payment for APC 0307 in CY 2012 to 5 to 10 percent compared to the payment for these services in CY 2011, we do not believe that it is appropriate to limit the decrease in payment in such an arbitrary manner for CY 2012. Moreover, for the reasons we discuss above, we have deleted APC 0307 for CY 2012. Accordingly, we also believe that there will be no adverse impact on access to care as a result of deleting APC 0307 and reassigning CPT codes 78459, 78491 and 78492 to APC 0308.

Comment: One commenter asked CMS to explain why it proposed to pay more for the non-myocardial PET APC (APC 0308) than for the myocardial PET APC (APC 0307).

Response: We proposed to pay more for non-myocardial PET (APC 0308) than for myocardial PET (APC 0307) because the proposed rule median cost we calculated for APC 0308 of approximately $1,051 was higher than the proposed rule median cost we calculated for APC 0307 of approximately $954. We calculated both median costs using our longstanding standard cost estimation methodology which applied each hospital's most current, hospital-specific and departmental-specific CCR to that hospital's charge for services furnished in CY 2010. However, we are deleting APC 0307 for CY 2012 and, therefore, all PET imaging services will be paid at the same payment rate for CY 2012, based on the APC 0308 median cost of approximately $1,038.

Comment: Commenters noted that the median cost for single myocardial PET scans, represented by CPT code 78491, has been higher than the median cost for multiple scans, represented by CPT code 78492 in CYs 2007, 2009 and 2010. The commenters believed that this is evidence indicating that the data on which CMS is basing the payment rate are flawed. One commenter also stated that the CY 2012 proposed payment rate for APC 0307 is below the mean cost for each of the codes assigned to APC 0307 (CPT codes 78459, 78491, and 78492) and is also below the median cost for three of the codes in APC 0307 that comprise 10,929 of the 11,060 total claims for the APC.

Response: We do not believe that the presence of a median cost for multiple scans that is greater than the median cost for a single scan indicates that the data are flawed. There are many reasons that the median cost for a single scan could be higher than the median cost for multiple scans, including different charging practices and cost structures across hospitals and different hospital utilization of single versus multiple scans. Our standard ratesetting methodology converts the hospital's charge to cost by application of the most specific departmental or overall hospital-specific CCR and after trimming claims for which the cost exceeds +/− 3 standard deviations from the geometric mean, and calculates the 50th percentile, that is, the median cost, the array of costs. Variation in hospital patterns of utilization combined with differential hospital charging practices can result in valid relative costs, as we define them for the OPPS, in which the median cost for single scans exceeds the median cost for multiple scans.

With respect to the commenter's observation that the proposed rule mean cost for APC 0307 as it was proposed is higher than its proposed rule median cost, we note that it is very common for the mean cost to be higher than the median cost for services that are paid under the OPPS because there is frequently a wide range between the minimum cost and the maximum cost. For example, for CPT code 78492, the CY 2012 proposed rule minimum cost on a single bill was approximately $175 and the maximum cost was approximately $7,828, although the median cost was approximately $954 and the mean cost was approximately $1,186. Therefore, it is clear that the cost of most of the single bills were closer to $175 than they were to $7,827, but when all of the single bill costs were averaged, the mean cost (approximately $1,186) was greater than the median cost (approximately $954). We do not understand what is meant by the commenter's additional statement that the CY 2012 proposed rule median cost for APC 0307 ''is also below the median cost for three of the codes in APC 0307 that comprise 10,929 of the 11,060 total claims for the APC'' because there were only three codes in APC 0307. CPT codes 78459, 78491, and 78492 were the only CPT codes assigned to now deleted APC 0307. We note that it is not surprising that the median cost for APC 0307 in the CY 2012 proposed rule data was equal to the median cost for CPT code 78492 because CPT code 78492 contained 98 percent of the single bills in APC 0307 (deleted for CY 2012) and, therefore, CPT code 78492 would be likely to control the median cost in the array of single procedure bills.

Comment: One commenter objected to the absence of a CMS presentation and explanation of the change in median cost for APC 0307 at either the winter or summer APC Panel meetings in 2011 and to the limited amount of information furnished in the proposed rule.

Response: We do not discuss all services paid under the OPPS at the APC Panel meetings. The APC Panel meetings offer the opportunity for any member of the public to make presentations on any issue of interest that is within scope of the Panel's charter and for CMS to seek Panel comment and advice on issues for which CMS believes such comment and advice would be useful. The winter APC Panel meeting generally reviews concerns of the public with regard to the final rule for that year and provides an opportunity for the public and CMS to seek the Panel's comment and advice on issues for the forthcoming year's OPPS. The summer APC Panel meeting occurs during the comment period of the proposed rule and is generally limited to hearing the views of the public on the proposed rule for the upcoming year. No member of the public asked to make a presentation on the payment rate for APC 0307 at either the Panel's winter or the summer meetings in 2011. Moreover, we had no clinical or resource-related question related to APC 0307 for which we believed that APC Panel input would be useful. Therefore, like many other topics applicable to the CY 2012 OPPS, there was no discussion of the proposed payment for APC 0307 for CY 2012.

We also note that the proposed rule does not include service-specific discussions of the calculation of median cost for each separately paid HCPCS code or for each APC. Rather, we discuss the general methodology used to calculate the median costs on which the proposed payment rates are based and the principles applied in determining APC configurations. We discuss specific APCs or services in the proposed rule only when we have a specific reason to do so, such as when we apply a nonstandard ratesetting methodology to calculate a proposed payment rate for a particular item or service. In most cases, a proposed reduction of a median cost for an APC or for a HCPCS code that is calculated from actual charges and cost

data does not result in a service-specific discussion in the proposed rule. The number of APCs and the volume of HCPCS codes for which median costs are calculated prohibit a detailed explanation of each change in a median cost in the proposed rule because annual changes to hospital charges and costs generally result in changes to median costs for each HCPCS code and, therefore, for each APC each year.

Comment: Commenters objected to the proposed decrease in the payment rate for non-myocardial PET imaging services assigned to APC 0308.

Response: For CY 2012, the payment rate for APC 0308 is based on data from claims submitted during CY 2010 according to the standard OPPS ratesetting methodology after the reassignment of CPT codes 78459, 78491, and 78492 to APC 0308 for the reasons we discuss above. Specifically, we used 249,026 single procedure bills (out of 289,786 total claims) from CY 2012 final rule claims data to calculate the final median cost upon which the CY 2012 payment rate for APC 0308 is based. For CY 2012, we are setting the final payment rate for all PET imaging services (including CPT codes 78459, 78491 and 78492 that were in APC 0307 for CY 2011) based on final rule median costs of approximately $1,038 for APC 0308. This median cost results in a modest decline in the final CY 2012 median cost for PET imaging services compared to the CY 2011 median cost for non-myocardial PET imaging services. We note that our cost-finding methodology is based on converting each hospital's charge for its services to an estimated cost by applying the most discrete hospital-specific CCR available for the hospital that submitted the claim. Therefore, it is each hospital's claims and cost reports that determine the estimated costs that are used to calculate the median cost for each service and, when aggregated into APC groups, the hospital data are used to calculate the median cost for the APC on which the APC payment rate is based.

In summary, based on our review of the claims and cost report data and our assessment of the similarity of the services in APCs 0307 and 0308, we have reassigned CPT codes 78459, 78491, and 78492 to APC 0308, for which we have calculated a median cost of approximately $1,038 for CY 2012. We have revised the description of APC 0308 to be ''Positron Emission Tomography (PET) Imaging,'' so that it will describe both non-myocardial PET and myocardial PET services, and we have deleted APC 0307 for CY 2012 for the reasons we discuss previously in this section. We have made no other reassignments to APC 0308 nor have we removed codes that are assigned to APC 0308 for CY 2011 from APC 0308 for CY 2012.

We will reassess whether it continues to be appropriate to assign both the non-myocardial PET and the myocardial PET services to the same APC for CY 2013 based on the CY 2013 OPPS cost data. We would propose to make any reassignments that we may believe to be necessary through the standard annual notice-and-comment rulemaking process.

e. Device Construction for Intensity Modulated Radiation Therapy (IMRT) (APC 0305)

CPT code 77338 (Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction per IMRT plan) was new for CY 2010. The service was previously reported using multiple units of CPT code 77334 (Treatment devices, design and construction; complex (irregular blocks, special shields, compensators, wedges, molds or casts)). For CY 2012, the first year of claims data for CPT code 77338, we proposed to assign CPT code 77338 to APC 0305 (Level II Therapeutic Radiation Treatment Preparation), with a proposed median cost of approximately $266 because we calculated a proposed rule median cost for CPT code 77338 of approximately $186 based on a single bill frequency of 32,547 (out of a total bill frequency of 41,663) in the CY 2010 claims data that we used to establish the proposed payment rates for the CY 2012 OPPS.

For CY 2011, we had assigned CPT code 77338 to APC 0310 (Level III Therapeutic Radiation Treatment Preparation) based on a simulated median cost of approximately $792 that we calculated using CY 2009 claims data for CPT code 77334, the predecessor code to CPT code 77338. Using CY 2009 claims data, we estimated that hospitals would furnish 4 units of CPT code 77334 per IMRT treatment plan and that the estimated CY 2009 cost per unit for CPT code 77334 was $198, thus resulting in an estimated cost per IMRT plan of $792. Based on this simulated median cost for CPT code 77338, we assigned the code to APC 0310 which had a CY 2011 median cost of approximately $917. We stated that, for the CY 2012 OPPS, we planned to use our standard cost estimation process using the CY 2010 claims data and the most recent cost report data to establish a median cost for CPT code 77338, and that, based on that data, we would assess whether placement of CPT code 77338 in APC 0310 would remain appropriate for the CY 2012 OPPS (75 FR 71916).

Using the claims data from CY 2010, upon which we proposed to base the CY 2012 OPPS payment rates, we proposed to move CPT code 77338 from APC 0310 to APC 0305 for CY 2012 because its presence in APC 0310 would have created a 2 times rule violation. We refer readers to section III.B. of this final rule with comment period for discussion of the 2 times rule. Specifically, the proposed rule median cost for APC 0310 of approximately $953 was more than twice the median cost of approximately $186 that we calculated for CPT code 77338, and the single bill frequency for CPT code 77338 of 32,547 caused it to meet the criteria as a significant procedure in APC 0310. To resolve the 2 times rule violation, we proposed to move CPT code 77338 to APC 0305 for CY 2012 OPPS.

Comment: Commenters objected to our proposal to move CPT code 77338 from APC 0310 to APC 0305. They believed that even if assigned to APC 0310, the code is being underpaid because the predecessor code CPT code 77334 would have been charged 3 to 9 units for the initial IMRT treatment and that additional units would be charged 3 to 9 units for the successive IMRT treatments. Therefore, the commenters stated that if CPT code 77334 had not been replaced by CPT code 77338, they would have charged and been paid approximately $4,625 for 18 total units of CPT code 77334. Commenters stated that it is illogical that the proposed rule median cost of $213 for CPT code 77334, which is for one device, would be greater than the median cost of $186 for CPT code 77338, which is for all devices in an IMRT plan of treatment. One commenter stated that its analysis revealed there is huge variability in hospital charges for CPT code 77338, specifically, that 25 percent of hospitals charge less than $500 and 8.5 percent of hospitals charge more than $5,000 for one unit of CPT code 77338. This commenter noted that this variability is carried through the CMS cost data, with CMS finding costs of less than $100 for 17.5 percent of hospitals and costs of more than $1,000 for 10 percent of hospitals. Another commenter indicated that its analysis of the proposed rule claims data indicated that only 13 percent of hospitals submitted claims in line with CMS expectations of the charges for CPT code 77338. Many commenters stated that it is clear that hospitals require guidance with regard to billing for this service before improved data should be used to establish payment rates. Commenters asked that CMS reassign CPT code

77338 to APC 0301 (Level II Radiation Therapy), or alternatively assign the procedure to an APC that would pay for construction of 10 to 20 devices or assign the code to a new technology APC. Commenters also asked that CMS provide guidance to ensure that hospitals bill appropriately for this new service because they believed that their data analysis shows that median costs are not accurate.

Response: After consideration of the public comments, the nature of the service being reported by CPT code 77338, and our claims data, we are finalizing our placement of CPT code 77338 in APC 0305, consistent with the median cost that we calculated based on the actual charges reported by 965 hospitals for CPT code 77338, converted to cost by application of the CCRs we calculated from the billing hospitals' most recently submitted cost reports. CPT code 77338 has similar clinical characteristics to the services in APC 0305 (Level II Therapeutic Radiation Treatment Preparation). In addition, the final rule median cost for CPT code 77338 of approximately $188 is more similar to the median cost for APC 0305 of approximately $264 than it is similar to the median cost for APC 0310 of approximately $955.

Our examination of the CY 2010 claims that we used to calculate the final median cost of approximately $188 for CPT code 77338 reveals that the median charge in the single bills used for ratesetting for CPT code 77338 was approximately $826. The median CCR that we used to reduce the hospital established charges to costs was 0.23. We used 36,860 single procedure bills from 965 hospitals (out of 47,589 total lines) or approximately 78 percent of the total lines containing actual charges for CPT code 77338, to calculate the final rule median cost for CPT code 77338, which is defined as including all devices required for an IMRT treatment plan.

We recognize that there is considerable variability in the charges that hospitals established for these new codes, but it is not uncommon for there to be a high level of variability in the charges for a service, and it is normal that such variability would be carried through to the calculation of estimated costs for the service. We do not advise hospitals with regard to what they should charge for a service other than to require that the charges be reasonably related to their cost for the service and that they must charge all payers the same amount for the same service. However, our use of the median charges to establish payment levels was specifically designed to address wide variances in hospital cost accounting systems and billing patterns, and has also consistently been a reliable mechanism for promoting increased consistency without introducing additional regulations. We recognize that it is peculiar that the estimated cost for CPT code 77334, which represents the cost of a single device, would be greater than the estimated cost for CPT code 77338, which represents the cost of all devices in a single IMRT plan of treatment, but our estimated costs are based on the amounts of the charges established by hospitals for the service and the hospitals' CCRs, which are calculated from their Medicare cost reports. There are many reasons why this apparent anomaly could exist, including clinical rationales such as the inclusion of labor-intensive physical blocks, shields, and molds in the service described by CPT code 77334, as well as accounting rationales such as the crosswalking of a single collimator setting to the charges for the construction of a physical block, also in the service described by CPT code 77334. It is not unusual for hospitals to establish charges that do not comport with our expectation of the charges they would establish based on the definition of the code for the service for which they are establishing charges and on which we based simulated medians.

The OPPS is based on the expectation that hospital charges reflect the relative resources that are required to furnish the service for which they are requesting a specified amount of payment. This self-selected hospital charge is converted to an estimated cost by the application of a CCR for the billing hospital which is calculated from the billing hospital's own cost report. As described previously, in this case the single bills used to calculate the median cost were submitted in significant volume by 965 hospitals (36,860 single bills were used for ratesetting out of 47,589 total lines). Therefore, we have no reason to believe that the median cost we have calculated from such a robust submission of charge data from a significant number of hospitals should not be used to establish the payment for the service reported by CPT code 77338 for CY 2012. To the extent that hospitals determine that their charges should be revised to better reflect the resources required to furnish the service as defined by CPT code 77338, the revised charges would be reflected in future years' OPPS payment rates. However, for CY 2012, based on the robust set of single procedure bills containing actual charges for CPT code 77338 by 965 hospitals, we believe that it is appropriate to apply our longstanding cost-finding methodology, as we proposed, to calculate the median cost on which the payment for CPT code 77338 is based for CY 2012. We see no basis to ignore our robust set of single procedure claims submitted by a significant number of hospitals by continuing to simulate a median cost for CPT code 77338.

In conclusion, we see no irregularities in our calculation of the median cost for CPT code 77338 based on the actual charges reported on 36,860 single procedure bills submitted by 965 hospitals. Therefore, we are finalizing our assignment of CPT code 77338, which has a final median cost of approximately $188 to APC 0305, which has a final median cost of $264 for CY 2012.

f. Computed Tomography of Abdomen and Pelvis (APC 0331 and 0334)

The AMA CPT Editorial Panel created three codes for computed tomography (CT) of abdominal and pelvis that were effective January 1, 2011, specifically, CPT code 74176 (Computed tomography, abdomen and pelvis; without contrast material); CPT code 74177 (Computed tomography, abdomen and pelvis; with contrast material(s)); and CPT code 74178 (Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by contrast material(s) and further sections in one or both body regions). As with all new CPT codes for CY 2011, these new codes were announced through the publication of the CY 2011 CPT in November 2010, effective on January 1, 2011.

In accordance with our longstanding policy, we made an interim APC assignment for each new code for CY 2011 based on our understanding of the resources required to furnish the service as the service was defined in the new code (75 FR 71898). Specifically, for CY 2011, we assigned new CPT code 74176 to APC 0332 (Computed Tomography without Contrast), which has a CY 2011 payment rate of approximately $194; we assigned CPT code 74177 to APC 0283 (Computed Tomography with Contrast), which has a CY 2011 payment rate of approximately $300; and we assigned CPT code 74178 to APC 0333 (Computed Tomography Without Contrast Followed by with Contrast), which has a CY 2011 payment rate of approximately $334. For CY 2011, we also made these codes eligible for composite payment under the multiple imaging composite APC methodology when they are furnished with other CT

procedures to the same patient on the same day.

As is our standard practice each year, our clinicians review each of the many CPT code changes that will be effective in the forthcoming year and make a decision regarding status indicator and/or APC assignment based on their understanding of the nature of the services furnished. We are unable to include a proposed status indicator and/or APC assignment in the proposed rule for codes that are not announced by the AMA CPT Editorial Board prior to the proposed rule. Therefore, in accordance with our longstanding policy, we include, in the final rule with comment period, an interim status indicator and/or APC assignment for all new CPT codes that are announced by the AMA CPT Editorial Board subsequent to the OPPS/ASC proposed rule to enable payment to be made for new services as soon as the code is effective. In accordance with our longstanding practice, we identified the new codes for abdominal/pelvis CT for CY 2011 in Addendum B of the CY 2011 OPPS/ASC final rule with comment period as having new interim APC assignments by showing a comment indicator of ''NI,'' and we provided a public comment period. As we do with all new CPT codes, we are responding to the public comments in this OPPS/ASC final rule with comment period for CY 2012. This longstanding process enables us to pay for new services as soon as the new CPT codes for them go into effect, despite the fact that they first become publicly available around the same time the final rule with comment period for the upcoming year is made public.

At its February 28–March 1, 2011 meeting, the APC Panel heard public presentations on this issue and recommended that CMS provide more data on the new CPT codes for combined abdomen and pelvis CT as soon as these data are available. In the CY 2012 OPPS/ASC proposed rule (76 FR 42235), we stated that we were accepting this recommendation, and we would provide claims data as soon as the data are available. We noted that, because these codes were effective January 1, 2011, the first available claims data for these codes will be the APC Panel claims data for the CY 2013 OPPS rulemaking. These data will be for dates of service January 1, 2011 through and including September 30, 2011, as processed through the Common Working File on or before September 30, 2011.

As we described in the proposed rule, in general, stakeholders who provided comments on the interim assignment of these codes for CY 2011 stated that the most appropriate approach to establishing payment for these new codes is to assign these procedures to APCs that recognize that each of the new codes reflects the reporting under a single code of two services that were previously reported under two separate codes and that, therefore, payments would be more accurate and better reflective of the relative cost of the services under the OPPS if we were to establish payment rates for the codes for CY 2012 using claim data that reflect the combined cost of the two predecessor codes. They noted that when these services were reported in CY 2010 using two CPT codes, rather than a single code, the services that are being reported under CPT code 74176 were assigned to imaging composite APC 8005 (CT and CTA without Contrast) for which the CY 2010 payment was $419.45. Similarly, the services being reported under CPT code 74177 or CPT code 74178 were assigned to composite APC 8006 (CT and CTA with Contrast) for which the CY 2010 payment was $628.49. They indicated that they believed that simulating the median cost for CPT codes 74176, 74177, and 74178 using historic claims data from the predecessor codes in a manner similar to that used to create the composite APC medians would result in the best estimates of costs for these codes and, therefore, the most accurate payment rate for these codes.

After considering the presentations at the APC Panel meeting, the views of stakeholders who met with us to discuss this issue, and the comments in response to the CY 2011 final rule with public comment period, and after examining our claims data for the predecessor codes, we stated in the proposed rule that we believe that establishment of payment rates for these services based on historic claims data for the combinations of predecessor codes that are now reported by CPT codes 74176, 74177, and 74178 would result in a more accurate and appropriate payment for these services for CY 2012 because it would take into account the full cost of both services that are now reported by a single CPT code. We indicated that we believe that the best way to secure the most appropriate payments for CY 2012 is to use the claims data from the predecessor codes under which the new codes were reported for CY 2010 to simulate median costs for the new codes and to create APCs that are appropriate to the services. To do so should reflect both the full cost of the service as reported by the new code and should also reflect the efficiencies of reporting the service represented by the single new code. Therefore, in the CY 2012 OPPS/ASC proposed rule (76 FR 42234), we proposed to establish two APCs to which we proposed to assign the combined abdominal and pelvis CT services. Specifically, we proposed to create new APC 0331 (Combined Abdominal and Pelvis CT Without Contrast), to which we proposed to assign CPT code 74176 and for which we proposed to base the CY 2012 OPPS payment rate on a median cost of approximately $417. We also proposed to create new APC 0334 (Combined Abdominal and Pelvis CT With Contrast), to which we proposed to assign CPT codes 74177 and 74178 for the CY 2012 OPPS and for which we proposed to base the CY 2012 OPPS payment rate on a median cost of approximately $592. We proposed to create two new APCs to which to assign these codes, rather than one, because CPT code 74176 is furnished without contrast, while CPT codes 74177 and 74178 are furnished with contrast. Section 1833(t)(2)(G) of the Act requires that services with contrast may not be assigned to APCs that contain services without contrast. Therefore, we could not assign CPT code 74176, which does not require contrast, to the same APC as CPT codes 74177 and 74178, which require contrast.

We proposed to create new APC 0331 to which we proposed to assign CPT code 74176 and to create new APC 0334 to which we proposed to assign CPT codes 74177 and 74178 because the proposed methodology for simulating the median costs for CPT codes 74176, 74177, and 74178, which uses claims data for the predecessor codes is unique to these CPT codes. Therefore, we believe that it is appropriate to create APCs comprised only of services for which we calculated medians using claims data for the predecessor codes. We stated in the proposed rule that, to the extent this policy is finalized, we would reassess whether it continues to be appropriate to pay these codes under APCs 0331 and 0334 once the median costs for the proposed CY 2013 OPPS are calculated using our standard methodology, based on hospitals' CY 2011 charges for CPT codes 74176, 74177, and 74178.

To calculate the proposed median costs for proposed APCs 0331 and 0334 for CY 2012, we selected claims that contained one unit of both of the predecessor CPT codes that appear in the CY 2011 CPT for CPT codes 74176, 74177, and 74178. The predecessor codes were limited to the codes in Table 20 of the proposed rule (now Table 27 of this final rule with comment period).

TABLE 27.--CPT CODES THAT WERE COMBINED TO CREATE NEW ABDOMINAL AND PELVIS CPT CODES FOR CY 2011

CPT Code	Descriptor
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

For purposes of selecting claims to be used to calculate simulated median costs, we selected only claims that contained one (and only one) unit of each of the predecessor codes in the allowed combinations identified in Table 21 of the proposed rule (now Table 28 of this final rule with comment period). We used only claims that contained one and only one unit of each of the code combinations because we believe that it represents the best simulation of the definition of the new codes. Where more than one unit of either or both codes were reported, the claim would be paid under an imaging composite APC, not under APC 0331 or 0334. For median calculation, claims that contained more than one unit of either or both codes were assigned to the applicable imaging composite APC. We refer readers to section II.A.2.e.5. of the proposed rule and this final rule with comment period for discussion of the imaging composite APCs.

TABLE 28.--COMBINATIONS OF PREDECESSOR CPT CODES USED TO SIMULATE MEDIAN COSTS FOR THE COMBINED ABDOMINAL AND PELVIS CT CODES THAT ARE NEW FOR CY 2011

Combined Abdominal and pelvis CT code	Predecessor CT Abdomen without contrast	Predecessor CT Pelvis without contrast	Predecessor CT Abdomen with contrast	Predecessor CT Pelvis with contrast
74176	74150	72192	--	--
74177	--	--	74160	72193
74178	74150	--	--	72193
74178	74150	--	--	72194
74178	--	72192	74160	--
74178	--	--	74160	72194
74178	--	72192	74170	--
74178	--	--	74170	72193
74178	--	--	74170	72194

After we selected the claims that contained one and only one unit of each code in each combination, we deleted claims that contained other separately paid HCPCS codes if those codes did not appear on the bypass list (we refer readers to section II.A.1.b. of the proposed rule and this final rule with comment period, and to Addendum N, which was available via the Internet on the CMS Web site). We bypassed the costs for codes that appeared on the

bypass list to create simulated single procedure claims for CPT codes 74176, 74177, and 74178. Using the remaining simulated single procedure claims for the combined abdominal and pelvis CT services, we applied our standard trimming, packaging, and wage standardization methodology to calculate the median cost for each combined abdominal and pelvis CT code for the two proposed APCs. We refer readers to section II.A.2.c. of the proposed rule and this final rule with comment period for discussion of our standard trimming, packaging, and wage standardization methodology.

We found that using the proposed methodology resulted in a simulated median cost for CPT code 74176 of approximately $417, and that, because we proposed that CPT code 74176 would be the only HCPCS code assigned to APC 0331, the simulated median cost for APC 0331 also would be approximately $417. We found that using this proposed methodology, the simulated median cost for CPT code 74177 was approximately $570 and the simulated median cost for CPT code 74178 was approximately $638, and that the simulated median cost for proposed APC 0334 was approximately $592. We proposed to use this simulation methodology to establish proposed median costs for proposed APCs 0331 and 0334 for the CY 2012 OPPS.

We also proposed that, in cases where CPT code 74176 is reported with CT codes that describe CT services for other regions of the body other than the abdomen and pelvis in which contrast is not used, it would be assigned to imaging composite APC 8005 (CT and CTA without Contrast), for which we proposed a median cost of approximately $445 for the CY 2012 OPPS. In cases where CPT code 74177 or 74178 is reported with CT codes that describe CT services for regions of the body other than abdomen and pelvis in which contrast is used, we proposed that the code would be assigned to APC 8006 (CT and CTA with Contrast), for which we proposed a median cost of approximately $744 for the CY 2012 OPPS. We proposed to assign CPT codes 74176 to imaging composite APC 8005 and to assign CPT codes 74177 and 74178 to imaging composite APC 8006 because the predecessor codes for CPT codes 74176, 74177, and 74178 (identified in Table 20 of the proposed rule) continue to be reported when either abdominal CT or pelvis CT (but not both) is furnished, and we proposed to continue to assign them to imaging composite APCs 8005 and 8006. We stated that we believe that it would be inconsistent with our proposed imaging composite policy if we did not propose to assign CPT codes 74176, 74177, and 74178 to the applicable imaging composite APC for CY 2012. We refer readers to section II.A.2.e.(5) of the proposed rule and this final rule with comment period for the discussion of the calculation of our median costs for APCs 8005 and 8006 for CY 2012.

In summary, we proposed to establish new APCs 0331 and 0334 to which we would assign the abdominal and pelvis CT codes that were created by the AMA CPT Editorial Panel for CY 2011 and to use the simulation methodology we describe above to establish simulated median costs on which we would base the CY 2012 payment rates because we believe that to do so would result in relative payment weights for these new services that will more accurately reflect the resources required to furnish these services as defined by CPT than would be true of continued assignment of the codes to the single service APCs to which we made interim assignments for CY 2011. We noted that claims and cost data for these services will be available for the CY 2013 OPPS rulemaking, and we will reassess the payment policy for these codes based on the cost data that are used to establish the CY 2013 OPPS median cost and payment rates.

At its August 10–11, 2011 meeting, the APC Panel recommended that CMS adopt the proposal to create new APC 0331 (Combined Abdomen and Pelvis CT [computed tomography] without Contrast), for payment of CPT code 74176 (Computed tomography, abdomen and pelvis; without contrast material); and new APC 0334 (Combined Abdomen and Pelvis CT with Contrast), for payment of CPT code 74177 (Computed tomography, abdomen and pelvis; with contrast material(s)); and CPT code 74178 (Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by contrast material(s) and further sections in one or both body regions). We respond to the Panel's recommendation as part of the response to comments below.

Comment: Commenters supported the use of data for the predecessor codes for the services that were combined into CPT codes 74176, 74177, and 74178 to create simulated median costs for use in establishing payments for CY 2012. Commenters supported the creation of APC 0331, to which we proposed to assign CPT code 74176, and APC 0334, to which we proposed to assign CPT codes 74177 and 74178 for CY 2012. As described previously, commenters on the CY 2011 OPPS/ASC final rule with comment period also stated that the most appropriate approach to establishing payment for these new codes is to assign these procedures to APCs that recognize that each of the new codes reflects the reporting under a single code of two services that were previously reported under two separate codes and that, therefore, payments would be more accurate and better reflective of the relative cost of the services under the OPPS if we were to establish payment rates for the codes for CY 2012 using claims data that reflect the combined cost of the two predecessor codes.

Response: We continue to believe that it is appropriate to base payment for CPT codes 74176, 74177, and 74178 on simulated median costs established using the cost data for predecessor codes for CY 2012 for the reasons we stated in the proposed rule, as summarized in the discussion above. Therefore, the median costs for CPT codes 74176, 74177, and 74178 for CY 2012 are based on the cost data for the predecessor codes, and we are establishing new APCs 0331 and 0334 to which these codes are assigned, as we proposed. The final rule median cost for CPT code 74176, which is the only code in APC 0331, is approximately $406. The final median cost for CPT code 74177 is approximately $561 and the final median cost for CPT code 74178 is approximately $631. The final median cost for APC 0334 to which CPT codes 74177 and 74178 are assigned is approximately $581.

We have a large volume of services in the predecessor data on which to base the simulated median costs for APCs 0331 and 0334. Specifically, to calculate the medians for CPT code 71476, we used 222,193 claims; for CPT code 71477, we used 331,262 claims; and for CPT code 74178, we used 201,693 claims. Because these codes were created effective January 1, 2011, we will have claims data containing actual charges for use in calculating the median cost of these services for the CY 2013 OPPS. We expect to have a very robust set of claims data containing actual hospital charges to which we expect to apply our standard processes to calculate the median costs for these codes for CY 2013 because of the large volume of services that we found in the predecessor data that meet the definition of the new codes. At that time, we will decide whether it is necessary and appropriate to propose to retain APCs 0331 and 0334. However, we note that the extent to which hospitals establish charges in a manner that reflects that the new codes report both the abdominal and pelvis CT services will greatly affect the median

costs that are calculated, using our longstanding methodology, from the charge data present on claims for services in CY 2011.

Comment: One commenter on the CY 2012 proposed rule and several commenters on the CY 2011 final rule with comment period asked that CMS increase payment for the services described by CPT codes 74176, 74177, and 74178 for CY 2011 because they believe that CMS inappropriately reduced payment for these services as a result of the assignment of CPT code 74176 to APC 0332 and the assignment of CPT codes 74177 and 74178 to APC 0333 for CY 2011. Commenters on the CY 2011 final rule with comment period objected to the assignment of CPT code 74176 to APC 0332 and to the assignment of CPT codes 74177 and 741178 to APC 0333 on the basis that the payments for these single service APCs reduced the payment for the services which, when coded using multiple CPT codes in CY 2010, would have been paid as imaging composite APCs at much higher payment rates.

Response: The prospective payments that were established as a result of publication of the CY 2011 OPPS/ASC final rule with comment period are generally final payments, with the exception of any outlier payment or transitional outpatient payment to which the hospital may be entitled. We generally do not change payments that we implement as a result of the standard regulatory process during the year in which the payments are in effect unless required by legislation. We followed our longstanding policy when we made an interim assignment of CPT code 74176 to APC 0332 and when we made an interim assignment of CPT codes 74177 and 74178 to APC 0333 for CY 2011, based on our understanding of the hospital resources required to furnish these services. It is our longstanding practice to assign new CPT codes to interim APCs without having an opportunity to acquire comment from the public because the new codes are not announced to the public until after the opportunity for public comment has ended. This interim assignment remains in effect for the calendar year under this established process. The first opportunity to change the APC assignment for new codes is the final rule with comment period following the year the new codes are first recognized for OPPS payment.

After consideration of the public comments we received, for CY 2012, for the reasons we discussed previously in this section, we are creating new APC 0331, to which we are assigning CPT code 74176, and new APC 0334, to which we are assigning CPT codes 74177 and 74178. Using the claims data for the predecessor codes and the methodology we identify above and in the proposed rule, we calculated a simulated median cost of approximately $406 for APC 0331 and a simulated median cost of approximately $581 for APC 0334 for CY 2012. We will reassess whether there is a continued need for these APCs for the CY 2013 OPPS once we have actual charges for these services.

For the reasons we discuss previously in this section, we also are finalizing our proposal to assign CPT code 74176 to imaging composite APC 8005 where CPT code 74176 is reported with CT codes that describe CT services for regions of the body other than the abdomen and pelvis in which contrast is not used and to assign CPT codes 74177 and 74178 to APC 8006 when either of them is reported with CT codes that describe CT services for regions of the body other than abdomen and pelvis in which contrast is used. For CY 2012, APC 8005 has a median cost of approximately $432 and APC 8006 has a median cost of approximately $722.

g. Complex Interstitial Radiation Source Application (APC 0651)

APC 0651 (Complex Interstitial Radiation Source Application) consists of one service described by CPT code 77778 (Interstitial radiation source application; complex). Composite APC 8001 (Low Dose Rate Prostate Brachytherapy Composite) employs claims on which both CPT code 77778 and CPT code 55875 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) are found on the same date of service, as described in section II.A.2.e.(2) of this final rule with comment period. For the CY 2012 proposed rule, APC 0651 had a median cost of approximately $897, based on 96 claims. APC 0651 has a final CY 2012 median cost of approximately $835, based on 92 single claims.

Comment: Several commenters expressed concern about the low volume of single and ''pseudo'' single claims used for APC 0651 ratesetting. They pointed out that both CY 2011 and CY 2012 payment rates for APC 0651 are based on fewer than 100 claims, and that the proposed CY 2012 payment rate for APC 0651 of $866.08 is a 23.3 percent decrease from the final CY 2011 payment rate of $1,129.46. The commenters believed the 96 claims used to set the proposed CY 2012 rate for APC 0651 are inadequate, and recommended that CMS continue to explore additional methodologies to increase the number of multiple procedure claims used for brachytherapy ratesetting.

Response: While we agree that 96 single claims associated with CPT code 77778 is not optimal for APC 0651 ratesetting, we believe that a low volume of single claims for this code is not unexpected due to the clinical nature of the procedure. As we describe in section II.A.2.e.(2) of this final rule with comment period, the application of brachytherapy sources described by CPT code 77778 and the placement of needles or catheters into the prostate described by CPT code 55875 are generally provided in the same operative session in the same hospital on the same date of service to the Medicare beneficiary being treated with LDR brachytherapy for prostate cancer. For this reason, we are continuing to pay for these two procedures when performed together through composite APC 8001. However, as we indicate in that section, we understand that there are a few occasions when a physician places the needles or catheters outside the hospital and the patient is then transferred to a hospital for brachytherapy source application, in which case CPT code 77778 would be reported alone in the hospital outpatient setting. While we agree with the commenter that it would be preferable if we had more single bills on which to base the payment for APC 0651, we believe the variation in the median costs for CPT code 77778 between the CY 2011 final rule and the CY 2012 final rule appears to be normal variation that we would expect to see for low-volume services. We also found from examining the single bills for CPT code 77778 that they are from different hospitals from year to year, which also could result in fluctuations in the median costs. We will continue to evaluate additional refinements and improvements to our ratesetting methodologies to maximize our use of claims data generally and continue to study means by which we can use more claims data to establish the payment rate for APC 0651 in particular.

For CY 2012, the final median cost for APC 0651 is approximately $835, based on 92 single bills. We will continue to use this median cost to establish payment for APC 0651 for CY 2012, and are finalizing our policy for CY 2012 that CPT code 77778, when billed alone, will be paid at the APC 0651 payment rate.

h. Radioelement Applications (APC 0312)

APC 0312 consists of six radioelement application codes, one of which is unlisted CPT code 77799 (Unlisted procedure, clinical brachytherapy). For the CY 2012 proposed rule, APC 0312 had a median cost of approximately $338 based on 168 single claims. For CY 2011, APC 0312 had a final rule median cost of $351.17, based on 254 single claims.

Comment: One commenter stated that the number of APC 0312 single claims is sparse and shows large and random variations in yearly median costs. The commenter pointed to a decrease in single claims from the CY 2011 final rule to the CY 2012 proposed rule of 33 percent, and a decrease in the CY 2011 final payment rate to the CY 2012 proposed payment rate of 8.1 percent. The commenter recommended that CMS continue to explore additional methodologies to increase the number of multiple procedure claims used for brachytherapy ratesetting, such as for APC 0312.

Response: The CY 2012 final median cost of approximately $378 shows an increase of 7.8 percent from the CY 2011 final median of $351.17. We believe the variation in the median costs between the CY 2011 final rule and the CY 2012 final rule appears to be normal variation that we would expect to see for low-volume services. We agree with the commenter that it would be preferable if we had more single bills on which to base the payment for APC 0312, and we will continue to evaluate additional refinements and improvements to our ratesetting methodologies generally to maximize our use of claims data generally and continue to study means by which we can use more claims data to establish the payment rate for APC 0312 in particular. However, we note that 268, or approximately 36 percent, of the 736 total lines reported for services that are assigned to APC 0312 in the CY 2012 final rule data, were reported as CPT code 77799, which we do not use for setting the median cost for the APC because there is no definition of the service that was furnished. Therefore, some of the approximately 36 percent of the lines paid under APC 0312 might be used to establish the median cost for services in APC 0312 if they had been coded specifically, or in cases in which there is no existing code for the service, a new code were to be created to describe the services being furnished.

After consideration of the public comments we received, we are finalizing a CY 2012 median cost for APC 0312 of approximately $378, based on 183 single claims.

8. Respiratory Services

a. Pulmonary Rehabilitation (APC 0102)

Section 144(a)(1) of Public Law 110–275 (MIPPA) added section 1861(fff) to the Act to provide Medicare Part B coverage and payment for a comprehensive program of pulmonary rehabilitation services furnished to beneficiaries with chronic obstructive pulmonary disease, effective January 1, 2010. Accordingly, in the CY 2010 OPPS/ASC final rule with comment period, we established a policy to pay for pulmonary rehabilitation services furnished as a part of the comprehensive pulmonary rehabilitation program benefit (74 FR 60567). There was and continues to be no single CPT code that fully and accurately describes the comprehensive pulmonary rehabilitation benefit provided in section 1861(fff) of the Act. Moreover, at that time, there were no alphanumeric HCPCS codes that described the comprehensive pulmonary rehabilitation benefit in effect for CY 2008 (on which the CY 2010 OPPS was based) or CY 2009 (on which the CY 2011 OPPS was based). Therefore, for CY 2010, we created new HCPCS code G0424 (Pulmonary rehabilitation, including exercise (includes monitoring), one hour, per session, up to two sessions per day) and assigned the code to APC 0102 (Level II Pulmonary Treatment), which we also created for the CY 2010 OPPS. Because none of the pulmonary treatment codes for which there were charges for CY 2008 or CY 2009 accurately described the comprehensive pulmonary rehabilitation service for which MIPPA provided coverage, we did not assume that the charge reported on any one of the previously existing HCPCS codes under which pulmonary treatments were reported would represent the full charge for the comprehensive pulmonary rehabilitation service.

Instead, for the CY 2010 OPPS, which was based on claims for services in CY 2008, we calculated a median ''per session'' cost that we simulated from historical hospital claims data for pulmonary therapy services that were billed in combination with one another, much like we create composite APC median costs by summing the costs of multiple procedures that are typically provided on the same date. Our methodology for calculating the ''per session'' median cost that we used as the basis for the CY 2010 OPPS payment rate for HCPCS code G0424 and APC 0102 is discussed in detail in the CY 2010 OPPS final rule with comment period (74 FR 60567 through 60570).

Specifically, to simulate the ''per session'' median cost of new HCPCS code G0424 from claims data for existing services, we used only claims that contained at least one unit of HCPCS code G0239 (Therapeutic procedures to improve respiratory function or increase strength or endurance of respiratory muscles, two or more individuals (includes monitoring), the group code that is without limitation on time duration, and one unit of HCPCS code G0237 (Therapeutic procedures to increase strength or endurance of respiratory muscles, one on one, face to face, per 15 minutes (includes monitoring) or HCPCS code G0238 (Therapeutic procedures to improve respiratory function or increase strength or endurance of respiratory muscles, one on one, face to face, per 15 minutes (includes monitoring), the individual, face-to-face codes that report 15 minutes of service, on the same date of service. We reasoned that patients in a pulmonary rehabilitation program would typically receive individual and group services in each session of approximately 1 hour in duration. This was consistent with public comments that suggested that pulmonary rehabilitation is often provided in group sessions in the HOPD, although patients commonly require additional one-on-one care in order to fully participate in the program. We note that our use of ''per session'' claims reporting one unit of HCPCS code G0237 or G0238 and one unit of HCPCS code G0239 in this simulation methodology was also consistent with our overall finding of approximately 2.4 service units of the HCPCS G-codes per day on a single date of service, usually consisting of both individual and group services, for patients receiving pulmonary therapy services in the HOPD based upon CY 2008 claims. We concluded that the typical session of pulmonary rehabilitation would be 1 hour based on public comments that indicated that a session of pulmonary rehabilitation is typically 1 hour and based on our findings that the most commonly reported HCPCS code for pulmonary treatment is HCPCS code G0239, which has no time definition for this group service.

We included all costs of the related tests and assessment services (CPT codes 94620 (Pulmonary stress testing; simple (e.g., 6-minute walk test, prolonged exercise test for bronchospasm with pre- and post-spirometry and oximetry)); 94664 (Demonstration and/or evaluation of

patient utilization of an aerosol generator, nebulizer, metered dose inhaler or IPPB device); and 94667 (Manipulation chest wall, such as cupping, percussion and vibration to facilitate lung function; initial demonstration and/or evaluation), and all CPT codes for established patient clinic visits, on the same date of service as the HCPCS G-codes in the claims we used to simulate the median cost for HCPCS code G0424. After identifying these ''per session'' claims, which we believe to represent 1 hour of care, we summed the costs on them and calculated the median cost for the set of selected claims. In light of the cost and clinical similarities of pulmonary rehabilitation and the existing services described by HCPCS codes G0237, G0238, and G0239 and the CPT codes for related assessments and tests, and the significant number of ''per session'' hospital claims we found, we believed that the simulated median cost for HCPCS code G0424, constructed to include the costs of these services where furnished, was our best estimate of the expected hospital cost of a pulmonary rehabilitation session, given that we did not have hospital charges for the comprehensive pulmonary rehabilitation service provided by MIPPA for which we created HCPCS code G0424. We indicated in our discussion of the simulated median that we expected hospitals would establish charges for pulmonary rehabilitation that would reflect all of the services that are included in comprehensive benefit that would be reported by one unit of HCPCS code G0424 (76 FR 42240).

We used the resulting simulated median ''per session'' cost of approximately $50 as the basis for the payment for pulmonary rehabilitation service for CY 2010, the first year in which the comprehensive pulmonary rehabilitation benefit was covered. For CY 2011, which was based on claims for services furnished in CY 2009, we continued to assign HCPCS code G0424 to APC 0102 and to apply the simulation methodology that we used in CY 2010 to claims for services in CY 2009 to calculate a median ''per session'' cost simulated from historical hospital claims data for similar pulmonary therapy services for the CY 2011 OPPS. The CY 2011 OPPS final rule median cost of approximately $62 resulted in a national unadjusted payment rate for CY 2011 of approximately $63.

For the CY 2012 OPPS, however, we have a very robust set of claims for HCPCS code G0424 on which hospitals reported the charges for the comprehensive pulmonary rehabilitation service for which MIPPA provided the pulmonary rehabilitation benefit beginning on January 1, 2010. Specifically, the CY 2012 OPPS proposed rule data, based on CY 2010 claims, contained a total frequency of 393,056 lines of HCPCS code G0424, of which we were able to use 391,901 single procedure bills or almost 100 percent of the claims submitted for HCPCS code G0424. This is an extremely robust volume of single procedure bills containing charges for HCPCS code G0424 on which to base a median cost. In general, we have found that higher volumes of single bills both in absolute numbers and as a percentage of total frequency provide very stable estimates of hospital costs.

Therefore, in the CY 2012 OPPS/ASC proposed rule (76 FR 42239 and 42240), we proposed that the payment rate for HCPCS code G0424 and, therefore, for APC 102, would be based on the median cost for the service as derived from claims for services furnished in CY 2010 and the most current available cost report information, using our longstanding process for estimating the median cost of a service described by a HCPCS code. We refer readers to section II. of the proposed rule and this final rule with comment period for a description of our longstanding standard process for calculating the median costs on which the OPPS payment rates are based. Using our standard median calculation process for HCPCS code G0424 resulted in a proposed median cost of approximately $38 for HCPCS code G0424 and, therefore, for APC 0102. Given that the volume of claims in the CY 2012 OPPS proposed rule data was so robust for HCPCS code G0424, we believed that the proposed median cost we calculated for HCPCS code G0424 was a valid reflection of the relative cost of the comprehensive pulmonary rehabilitation service described by HCPCS code G0424 and that the proposed median cost for HCPCS code G0424 was an appropriate basis on which to establish the proposed national unadjusted payment rate for APC 0102.

We indicated in the proposed rule that we recognized that there is a significant difference between our simulated median cost for CY 2011 and the CY 2012 proposed rule median cost of approximately $38 that was derived from application of our standard median calculation process to hospital claims data for CY 2010. We believe that this difference arises because the median simulation methodology we used for CY 2010 and CY 2011 selected claims that contained multiple procedures and packaged the costs of numerous services into the ''per session'' cost for the simulated code where numerous services appeared on the same date of service. Our simulation methodology assumed that hospitals would include the charges for these additional services in their CY 2010 charges for HCPCS code G0424 because the services are included in the definition of comprehensive pulmonary rehabilitation.

In response to the CY 2012 OPPS proposed median cost of approximately $38 for HCPCS code G0424, we looked at our claims data in more depth. We found that 1,048 hospitals, approximately 25 percent of hospitals paid under the OPPS, reported HCPCS code G0424 and that the median line item median cost (exclusive of packaging) was approximately $38, virtually no different from the median cost per unit that we derived from the single bills. We also examined the charges that were submitted for HCPCS code G0424 in CY 2010 and the CCRs that were applied to the charges for HCPCS code G0424 to calculate the estimated median cost for the code for the CY 2012 proposed rule. We also looked at the revenue codes under which charges for HCPCS code G0424 were reported and the percentage of cost that was associated with packaged costs, such as oxygen, drugs, and medical supplies. We found that the median line item charge for HCPCS code G0424 in the CY 2012 proposed rule data was approximately $150 and that the median CCR was 0.29. We also found that the most frequently reported revenue code for HCPCS code G0424 was revenue code 410 (Respiratory therapy), approximately 108,000 single bills, and with revenue code 948 (Pulmonary Rehabilitation), approximately 81,000 single bills, being the second most commonly reported revenue code for HCPCS code G0424. We found that only 0.02 percent of the cost of HCPCS code G0424 was packaged cost (for example, oxygen, drugs, and supplies). In general, our detailed examination of total and line item charges for pulmonary rehabilitation, the CCRs used to reduce the charges to estimated costs on the single bills, the revenue codes reported, and the absence of packaging on the single bills supports the proposed median cost of approximately $38 per unit as a valid estimate of the relative cost of one unit of HCPCS code G0424.

In summary, our examination of the claims and cost data for HCPCS code G0424 caused us to believe that the proposed median cost that we calculated from claims data for HCPCS code G0424 was calculated correctly

according to our longstanding standard median cost calculation methodology. Therefore, we proposed to base the CY 2012 OPPS payment rate for HCPCS code G0424 and APC 0102 on the median cost that we derive from applying our standard median calculation methodology to the CY 2010 charges and cost data for HCPCS code G0424.

Comment: Commenters objected to the proposed CY 2012 payment because it proposed a significant reduction in payment from the payment that resulted from the simulated median cost for pulmonary rehabilitation for CY 2010 and CY 2011. They stated that such a reduction in payment would not cover the labor cost of the service and would result in hospitals ceasing to furnish the service and, therefore, would reduce access to care for beneficiaries. Commenters believed that hospitals do not understand the nature of HCPCS code G0424 as a unit of a comprehensive service. They believed that hospitals are very familiar with HCPCS code G0237, which is for 15 minutes of care for patients with chronic pulmonary diseases, and they believed that hospitals presumed that a single code for very similar services correlated to a different diagnosis would also be a 15 minute code and that they set the charge for HCPCS code G0424, which is for similar services but is limited to persons with chronic obstructive pulmonary disease (COPD), accordingly. Commenters stated that CMS data support that hospitals are not reporting charges associated with the corollary services that are part of HCPCS code G0424. They urged CMS to freeze the payment for pulmonary rehabilitation for CY 2012 at the CY 2011 rate and to shift from the use of a standard cost center to the use of a nonstandard cost center for determining the relative cost of pulmonary rehabilitation services because they believed that using a standard cost center does not adequately capture the cost of the services. The commenters believed that continuing the CY 2011 payment for CY 2012 is justified because there is strong historical data for HCPCS codes G0237 through G0239 and a weak data base for HCPCS code G0424 and that using 10 years of data for HCPCS codes G0237 through G0239 is wiser than using one year of artifact data for HCPCS code G0424 as the basis for the payment for HCPCS code G0424. They indicated that the proposed payment for pulmonary rehabilitation will reduce access to care and thereby result in CMS losing an important tool for reducing readmissions and decreasing length of stay in inpatient hospital settings. The commenters stated that HCPCS codes G0237 through G0239 are used to report individual pulmonary services while HCPCS code G0424 is generally recognized as a group code with a maximum ratio of one staff to four patients. However, they stated that this is not always the case and that HCPCS code G0424 is sometimes requires a one-to-one staff to patient ratio. Therefore, until such time as a more robust set of data is available, the commenters asked that CMS continue to base payment for HCPCS code G0424 on the data for HCPCS codes G0237 through G0239 using the simulated median methodology that was the basis for payments for HCPCS code G0424 for CY 2010 and 2011.

Response: After considering the comments and reexamining our claims data, we are establishing the CY 2012 median cost on which the CY 2012 payment for HCPCS code G0424 will be based on our claims and cost report data. The final rule median cost for APC 0102 to which HCPCS code G0424 is assigned is approximately $37. Our final rule data shows that hospitals billed a total frequency of 448,396 lines of pulmonary rehabilitation, of which we were able to use 446,456 or nearly 100 percent of the billed lines, for the calculation of the final median cost for HCPCS code G0424 for CY 2012. We disagree with commenters that these claims are artifact claims that should not be used.

For this final rule we expanded our data analysis to look not only at the charges and CCRs for HCPCS code G0424, but also to look at the charges and CCRs for HCPCS code G0237 through G0239, which the commenters indicated are similar services, and also to look at the cost centers that were used to reduce the charges to costs. We found that the median charge for one unit of HCPCS code G0424 is approximately $152 and the median charge for HCPCS code G0239, which is defined to include services to two or more persons, rather than one on one service, is approximately $120. Commenters stated that HCPCS code G0424 is generally, but not always, considered to be a group service with a staff to patient ratio of 1:4. Therefore, we view it as most similar to HCPCS code G0239, which is defined as a group service and which was the basis for the simulated median cost methodology on which we based the OPPS payments for CY 2010 and CY 2011. Therefore, it seems logical that hospitals charged more for the comprehensive pulmonary rehabilitation service of HCPCS code G0424 than for HCPCS code G0239 which is not a comprehensive service but which is a group service for which time is not limited. Hospital charges represent the hospital's statement of the dollar value of the service they furnish and we conclude that hospitals place a higher dollar value on HCPCS code G0424 than on G0239. We do not view HCPCS code G0237 or G0238, which have median charges of approximately $88 and $85, respectively, and which represent 15 minutes of care to be similar to HCPCS code G0424 because each of them is for one-on-one care, as opposed to the group nature of HCPCS codes G0239 and G0424. For that reason, when we simulated median costs for CY 2010 and CY 2011, we based the simulation on the presence of HCPCS code G0239 on the claim, with HCPCS code G0237 and/or HCPCS code G0238 being a secondary requirement.

We next looked at the revenue codes under which hospitals reported HCPCS code G0424 and G0239. We found that the most commonly reported revenue codes on the lines with the single bills for HCPCS code G0424 were 0410, Respiratory Services, with 108,154 single bills; 0948, Pulmonary Rehabilitation, with 84,126 single bills; 0460, Pulmonary Function, with 64,641 single bills; 0419, Other Respiratory Services, with 37,833 single bills, and 0940, Other Therapeutic, with 59,533 single bills. Therefore, of the 446,456 single bills used to set the median cost for APC 102, 345,738 bills (excluding the single bills reported as ''Other therapeutic''), or 77 percent, were reported under revenue codes that were specific to respiratory services of some nature (that is, revenue codes 0410, 0948, 0460, and 0419). The remaining single bills were reported under a variety of revenue codes. We next looked at the cost centers that were applied to the charges on the single bills, and we found that we used the respiratory therapy cost center, cost center 4900 on the hospital cost report CMS 2552–96, to reduce the charges on the line to costs on 63 percent of the single bills. When we looked at the CCRs used to reduce charges to cost for HCPCS codes G0424 and G0239, we found that both the HCPCS codes G0424 and G0239 have a CCR of 0.25, which is consistent with our finding that charges for both codes were usually reduced by the CCR for cost center 4900, Respiratory Therapy. We disagree with the commenters' request that we create a nonstandard cost center for pulmonary rehabilitation because we believe that it is not necessary and would not result in more accurate estimated median costs for pulmonary rehabilitation.

Stakeholders have repeatedly told us that respiratory therapists furnish most pulmonary rehabilitation. Therefore, we expect that the costs of pulmonary rehabilitation are captured in the standard cost center 4900 (Respiratory Therapy), which is used to convert charges to costs for pulmonary rehabilitation for approximately 63 percent of single bills used to establish the median cost for pulmonary rehabilitation. We note also that a nonstandard cost center, which commenters' requested, is not required to be used to report costs. However, a standard cost center, like cost center 4900, must be completed by a hospital if it has a cost account for those costs in its general ledger. Hence, the creation of a nonstandard cost center would not necessarily be used.

Everything we observe in the claims data for the 446,456 single bills used to report the CY 2010 charges from which we calculated the median cost for HCPCS code G0424 leads us to believe that the calculation of the median cost of approximately $37 for HCPCS code G0424 is appropriate, based on the charge that hospitals set for the service. The median cost was calculated using charges, the majority of which are reported under pulmonary specific revenue codes and using CCRs, and which mostly used the respiratory therapy cost center.

With regard to the comment that the payment that results from a median cost of approximately $37 would be insufficient to pay the labor cost for the service, we note that, given that HCPCS code G0424 is generally recognized to be a group service, generally with a ratio of 1 staff to 4 patients, the payment for an hour of service would usually be 3 to 4 times the payment for one unit of HCPCS code G0424.

We do not agree with the commenters that freezing the payment for HCPCS code G0424 at the rate that was based on the simulated median cost for CY 2011 would be appropriate, given the results of our analysis of the robust charge data and cost report data that hospitals submitted. Similarly, we see no basis for continuing to use the simulated methodology to calculate median costs for pulmonary rehabilitation because we now have an abundant number of single bills containing the actual charges that hospitals requested in payment for the service they are furnishing. With regard to the comment that hospitals established their charges based on misunderstanding of the nature of the service or based on charges for services that they wrongly viewed to be similar, we note that the median hospital charge for HCPCS code G0424 is higher than the median charge for HCPCS code G0239, the group respiratory service as we would expect given that HCPCS code G0424 is a comprehensive service. The charges that hospitals establish for services are the amount they seek to be paid for the service they furnish, and therefore, we view them as being a reflection of the monetary value the hospital places on the service. Under our longstanding methodology, we use hospital charges to calculate the median costs on which the OPPS payment is based.

Lastly, we do not agree with commenters that payment based on the median cost we derived from hospital's costs and charges for CY 2010 will necessarily result in reduced access to care for Medicare patients. We note that the respiratory therapy services reported under HCPCS code G0239, which commenters stated is for an hour of group respiratory therapy and is the most similar code to HCPCS code G0424, has a median cost of approximately $31, which compares reasonably to the median cost of approximately $37 which we found for HCPCS code G0424, a service of more complexity. We note that in CY 2010, when the payment rate for HCPCS code G0239 was $27.39, hospitals reported a total frequency of 146,616, which indicates no absence of access to care at a payment rate significantly less than the median cost for HCPCS code G0424 in CY 2012.

Comment: Commenters also stated that some CMS instructions to contractors were not issued until May 2010 and that some MACs did not permit billing of HCPCS code G0424 until October of 2010. Moreover, they stated that some MACs instructed hospitals to report HCPCS codes G0237 through G0239 for pulmonary rehabilitation for COPD patients contrary to CMS instructions. They added that, given these issues with implementation of billing and payment for HCPCS code G0424, it is understandable that hospitals struggled with developing charges for a one hour code for COPD patients when charges were already in place for very similar services for patients with other chronic pulmonary diseases.

Response: Hospitals are responsible for updating their billing systems to recognize changes to codes and payment for services, particularly with regard to the quarterly changes to HCPCS codes, including the addition of new codes. CMS posts all instructions regarding new codes on the CMS Web site, issues Medicare Learning Network (MLN) Matters articles on new codes and hosts Hospital Open Door Forum calls regularly to provide easy ways for hospitals to stay up to date on changes in Medicare payment policy. The instructions to MACs are available to the public via the Web site. If a hospital believes that a MAC is not in compliance with the instructions and cannot achieve satisfaction from discussing the issue with the MAC, the hospital should bring it to the attention of the CMS regional office staff for the area in which the hospital is located. We acknowledge that Change Request (CR) 6823 regarding coverage and implementation of pulmonary rehabilitation was issued by CMS on May 7, 2010, effective for services furnished on and after January 1, 2010. However, the **Federal Register** notice of the OPPS for CY 2010, which was posted to *http://www.cms.gov/HospitalOutpatientPPS/* on October 30, 2009, contained the coverage and payment policy for the pulmonary rehabilitation benefit, a discussion of how the services should be coded, including a full discussion of HCPCS code G0424 and an explanation of how the simulated median was created, including how CMS viewed HCPCS code G0424 to be similar to HCPCS codes G0237 through G0239 (74 FR 60569). Moreover, CMS hosted regular Hospital Open Door Forum calls between November 2009 and January 1, 2010 at which CMS staff was available to discuss any issue arising from the Medicare hospital OPPS. CMS expected that hospitals would use the detailed explanation of how we arrived at the simulated median that was articulated in the CY 2010 OPPS/ASC final rule with comment period that was posted on the CMS Web site as a basis for establishing charges for the services for HCPCS code G0424 for CY 2010, because CMS advised hospitals of how the simulated median was created. Therefore, notwithstanding the delay in the issuance of CR 6823, we believe that hospitals had access to all of the information that was necessary to report the new codes and to establish appropriate charges for HCPCS code G0424 beginning with the January 1, 2010 effective date.

Comment: Commenters asked that, for hospital cost reports filed January 1, 2012 and later, CMS require that pulmonary rehabilitation be reported in a nonstandard cost center rather than a standard cost center. They believed that the recommendations of RTI in its 2006 report, with regard to the creation of a new nonstandard cost center for cardiac rehabilitation, should also apply to pulmonary rehabilitation because the

authorizing legislation is almost identical and because they believed that this would result in more accurate charge data and cost reports for pulmonary rehabilitation.

Response: We do not agree that the accuracy of median calculation would be improved if CMS would create a nonstandard cost center for pulmonary rehabilitation. There is already a cost center in which hospitals can isolate the costs of respiratory services (which may include the cost of hospital staff other than respiratory therapists who furnish respiratory therapy): Cost center 4900, Respiratory Therapy, on the CMS form 2552–96 and cost center 6600, Respiratory Therapy, on the CMS form 2552–10. However, we believe that respiratory therapists provide the majority of pulmonary rehabilitation and that the costs of respiratory therapists are largely reported on the cost report under the respiratory therapy cost center. Therefore, we believe that most of the costs of pulmonary rehabilitation are already carried in the Respiratory Therapy cost center, based on our finding that the CCR for the Respiratory Therapy cost center (4900 in the CMS hospital cost report form 2552–96) is reported sufficiently often that it was used to reduce the charge for 279,803 of the 446,456 single bills, or 63 percent of the single bills, to cost. In view of the existence of the standard cost center for respiratory therapy on both the CMS form 2552–96 and the CMS form 2552–10 hospital cost reports, we have no reason to believe that creation of a nonstandard cost center would result in more specific and accurate cost data for HCPCS code G0424. In contrast, unlike respiratory therapy, which has long had a dedicated cost center, the costs of the staff who furnish cardiac rehabilitation were not predominantly carried in a single cost center before the creation of the cardiac rehabilitation cost center. For this reason, the creation of a cardiac rehabilitation cost center does not justify the creation of a pulmonary rehabilitation cost center.

Comment: One commenter asked that CMS reconsider the valuation of the cost of HCPCS code G0424 to appropriately account for the services delivered by physical therapists. The commenter asked that, alternatively, CMS create a separate HCPCS code that can be used to delineate those patients who require individualized physical therapy within the pulmonary rehabilitation program. The commenter stated that the need for the service that would be reported by the new code would be determined by conducting separate screening that has clear and distinct criteria that justify the need for the physical therapy services.

Response: Pulmonary rehabilitation is a comprehensive service in which it would be inappropriate to create a code for a particular type of professional who participates in providing the service. The charge a hospital establishes for HCPCS code G0424 is a charge for the comprehensive package of services that are encompassed in the pulmonary rehabilitation benefit and includes the charge for whatever portion of those services may be furnished by a physical therapist. We do not believe that it would be appropriate to create a new and separate code for the services furnished by a physical therapist as part of a comprehensive pulmonary rehabilitation service because those services are already included in the charge for HCPCS code G0424. Similarly no additional payment should be made for those services because payment for HCPCS code G0424 includes payment for the comprehensive package of services for which payment is claimed when a hospital reports HCPCS code G0424.

In summary, for CY 2010, we are establishing payment for APC 0102, for which HCPCS code G0424 is the only assigned code, based on the median cost of approximately $37 that we calculated using 446,456 single bills of 448,396 total frequency, or nearly 100 percent, of the billed lines for HCPCS code G0424 and the most recent hospital cost reports for the hospitals whose bills are being used. We are not establishing a special purpose cost center for pulmonary rehabilitation because the service is largely furnished by respiratory therapists for which there is standard cost center (4900, Respiratory Therapy), which is already used to reduce most charges for HCPCS code G0424 to costs. Therefore, we do not believe that creating a pulmonary rehabilitation cost center in addition to the standard respiratory therapy cost center is necessary to the calculation of the median cost of HCPCS code G0424.

b. Bronchial Thermoplasty (APC 0415)

We created two new HCPCS codes, C9730 (Bronchoscopic bronchial thermoplasty with imaging guidance (if performed), radiofrequency ablation of airway smooth muscle, 1 lobe) and C9731 (Bronchoscopic bronchial thermoplasty with imaging guidance (if performed), radiofrequency ablation of airway smooth muscle, 2 or more lobes), also known as bronchial thermoplasty, and assigned them to APC 0415 (Level II Endoscopy lower airway), effective July 1, 2011. Bronchial thermoplasty is indicated for the treatment of severe persistent asthma, and the bronchial thermoplasty system consists of a radiofrequency (RF) controller and a single use device with an electrode array that is delivered through the working channel of a bronchoscope. The bronchial thermoplasty services, technology, and estimated costs came to our attention via an application for the services to be placed into a New Technology APC. The APC 0415 median cost for the CY 2012 proposed rule is $2,094.64. AMA's CPT Editorial Panel has recently created two new Category III CPT codes to be effective January 1, 2012, specifically, CPT codes 0276T (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe) and 0277T (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes). At the August 2011 APC Panel meeting, the APC Panel heard from a presenter regarding APC placement for bronchial thermoplasty, but the Panel did not make any recommendations to CMS. We indicated at the August 2011 APC Panel meeting that we anticipate retiring HCPCS codes C9730 and C9731, and replacing them with CPT codes 0276T and 0277T, respectively, effective January 1, 2012. For CY 2012, we proposed maintaining assignment of bronchial thermoplasty services to APC 0415.

Comment: One commenter stated that the bronchial thermoplasty codes, HCPCS codes C9730 and C9731, should not be assigned to APC 0415 for CY 2012 because the resources are not covered by the CY 2012 proposed rule median cost for APC 0415 of $2,094.64. The commenter's estimated costs for the bronchial thermoplasty procedures range from approximately $4,130 to $5,087, which includes its estimated cost of $2,500 for the single use catheter, while the CY 2012 proposed rule median costs of service codes assigned to APC 0415 range from approximately $1,780 to $3,122. The commenter contended that no existing clinical APCs are appropriate both in terms of clinical characteristics and resource costs. On the other hand, the commenter requested that CMS consider an assignment of the bronchial thermoplasty codes to APC 0423 (Level II percutaneous abdominal and biliary procedures). The commenter argued that APC 0423 includes CPT code 32998 (Ablation therapy for reduction or eradication of one or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension,

percutaneous, radiofrequency, unilateral), a service that the commenter claimed is a better comparator for bronchial thermoplasty in terms of procedural costs as well as clinical similarity. The commenter stated that, clinically, the two procedures entail similar supplies and equipment and involve ablative techniques. However, the commenter stated that CPT code 32998 is performed percutaneously, while bronchial thermoplasty is performed through a bronchoscope. The commenter asserted that bronchial thermoplasty requires a disposable catheter costing $2,500, while CPT code 32998 requires a disposable probe costing approximately $1,375. Also, the commenter asserted that because the CY 2012 proposed median cost of CPT code 32998 is approximately $3,962 and the CY 2012 proposed median cost of APC 0423 is about $4,112, bronchial thermoplasty should be assigned to APC 0423 because of greater resource similarity as reflected in the higher median cost. The second option recommended by the commenter is to revise existing APC 0415 into APCs ''0415A'' and ''0415B'' and place the two bronchial thermoplasty codes into an APC 0415B with CPT codes 31626 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of fiducial markers, single or multiple), 31631 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of tracheal stent(s) (includes tracheal/bronchial dilation as required)), and 31636 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of bronchial stent(s) (includes tracheal/bronchial dilation as required), initial bronchus). The commenter's third, final and preferred recommendation was to assign bronchial thermoplasty codes to a New Technology APC.

Response: As stated above, effective January 1, 2012, newly created CPT codes 0276T and 0277T will be the codes used to report bronchial thermoplasty, and HCPCS codes C9730 and C9731 will be deleted effective that date. Regarding the commenter's recommended option to assign bronchial thermoplasty codes to APC 0423, we do not believe that the bronchial thermoplasty service is clinically similar to the procedures in APC 0423. APC 0423 consists of percutaneous procedures, while CPT codes 0276T and 0277T are bronchoscopic procedures, clinically similar to services in bronchoscopy APCs. We also do not agree that APC 0415 needs to be split into 2 APCs at this time. All of the bronchoscopy procedures in APC 0415 are clinically similar, and the final rule median costs for procedures within APC 0415 range from approximately $1,745 to approximately $3,300, with an overall median cost of approximately $2,048. We proposed to assign bronchial thermoplasty to APC 0415 because it is similar clinically to the bronchoscopy procedures in APC 0415, particularly CPT code 31641 (Bronchoscopy, with destruction of tumor or relief of stenosis by any method other than excision (e.g., laser therapy, cryotherapy)), and because the estimated resource costs are approximately similar to the upper end of the range of median costs for procedures assigned to APC 0415. We generally prefer to wait until median cost claims data are available before reassignment of a service to a new APC. We also note that, according to our usual practice, when adequate actual hospital reported cost data become available for these procedures, we reevaluate their APC assignments and may reassign them to another APC, as appropriate. Regarding the option to assign the service to a New Technology APC, we believe that APC 0415 is an appropriate clinical APC for bronchial thermoplasty procedures. Therefore, we are maintaining assignment of the bronchial thermoplasty services to APC 0415.

We are finalizing our proposal to maintain the assignment of bronchial thermoplasty procedures (CPT codes 0276T and 0277T beginning January 1, 2012) to APC 0415 for CY 2012, which has a final median cost of approximately $2,024.

c. Insertion of Bronchial Valve (APC 0415)

AMA's CPT Editorial Panel created CPT code 0250T (Airway sizing and insertion of bronchial valve(s), each lobe) effective January 1, 2011 to report insertion of a bronchial valve for treatment of prolonged air leaks of the lung. CPT code 0250T is an add-on code; therefore, hospitals must list the code in addition to the primary bronchoscopy procedure code. For 2011, we assigned CPT code 0250T to APC 0415 (Level II Endoscopy lower airway), with a payment rate of $1,971.77. We believe CPT code 0250T is similar to other services in APC 0415 in its clinical characteristics. For 2012, we proposed to maintain the assignment of CPT code 0250T to APC 0415, which had a proposed rule median cost of approximately $2,095, and a proposed payment rate of approximately $2,022. The CPT code 0250T procedure is performed with a bronchial valve intended to control prolonged air leaks of the lung following three specific surgical procedures: Lobectomy, segmentectomy, or lung volume reduction surgery (LVRS).

Comment: One commenter stated that APC 0415 does not adequately cover the resource costs of CPT code 0250T, and recommended that CMS create a new clinical APC that would accurately reflect the device and procedural costs associated with CPT code 0250T. The commenter claimed that the cost for the bronchial valve that is necessary to perform the CPT code 0250T procedure is $2,750, and that a total device cost based on the number of valves (2.4 mean, or median of 2.0 valves) is $6,600 based on the mean number of valves and $5,500 based on the median valves. The commenter asserted that it certified to the FDA that the current price of $2,750 complies with Humanitarian Device Exemption (HDE) regulations governing the price of the device. The commenter estimated that the CY 2012 total procedural cost for CPT code 0250T is $7,268.91 (based on the mean number of valves) or $6,168.91 (based on the median). The commenter asserted that the highest paying bronchoscopy in APC 0415 does not adequately pay for the cost of CPT code 0250T and requested that CMS create a new clinical APC for bronchial valve insertion and reassign CPT code 0250T to that APC for CY 2012.

Response: CPT code 0250T is a new code as of January 1, 2011, and therefore, we have no CY 2010 claims data for this service for CY 2012 ratesetting. The commenter apparently agrees that the bronchoscopy APC classification is the correct clinical APC type for the CPT code 0250T procedure, but that the estimated resource costs support a higher paying bronchoscopy APC. We generally wait until median cost claims data are available before reassignment to a new APC, particularly when there are no comparable clinical procedures that would allow us to easily estimate the cost of this new procedure. We again note that CPT code 0250T is an add-on code to a base bronchoscopy code.

After consideration of the public comments we received, we are maintaining our assignment of CPT code 0250T to APC 0415 for CY 2012, which has a final median cost of approximately $2,024, because it is clinically similar to the services in APC 0415. We will review this assignment for CY 2013, when we should have some claims data for CPT code 0250T to determine the cost of the procedure.

9. Other Services

a. Skin Repair (APCs 0133, 0134, and 0135)

For CY 2012, we proposed to reassign CPT code 15004 (Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet and/or multiple digits; first 100 sq cm or 1% of body area of infants and children) from APC 0135 (Level III Skin Repair) to APC 0134 (Level II Skin Repair). Similarly, we also proposed to reassign CPT code 15430 (Acellular xenograft implant; first 100 sq cm or less, or 1% of body area of infants and children) from APC 0135 (Level III Skin Repair) to APC 0134 (Level II Skin Repair). We reassigned CPT codes 15004 and 15430 from APC 0135 to APC 0134 to avoid a 2 times rule violation in APC 0135.

For CY 2012, the AMA's CPT Editorial Panel deleted 24 skin replacement and skin substitute-related CPT codes and replaced them with 8 new CPT codes in the Integumentary System section of the 2012 CPT code book to describe more accurately the services associated with skin replacement procedures. In particular, the CPT Editorial deleted 24 skin replacement and skin substitute-related CPT codes in the range between CPT code 15170 through 15431 and created 8 new CPT codes in the range between 15271 through 15278, which will be effective January 1, 2012.

Our standard process for dealing with new CPT codes is to assign the code to the APC that we believe contains services that are comparable with respect to clinical characteristics and resources required to furnish the service. The new CPT code is given a comment indicator of ''NI'' (New code, interim APC assignment; comments will be accepted on the interim APC assignment for the new code) to identify it as a new interim APC assignment for the new year and the APC assignment for the new codes is then open to public comment. In the case of the new the skin replacement and skin substitute-related CPT codes, we crosswalked the existing CY 2011 CPT codes to the new CY 2012 CPT codes that appropriately describes them. In assigning the new codes to their appropriate APCs, we took into consideration the size of the wound described in the code descriptor. Specifically, we assigned the new codes to their appropriate APCs based on the following factors:

- New codes whose long descriptors included the words ''each additional 25 sq cm'' were assigned to APC 0133;
- New codes whose long descriptors included the words ''first 25 sq cm or less'' or ''each additional 100 sq cm'' were assigned to APC 0134; and
- New codes whose long descriptors included the words ''first 100 sq cm'' were assigned to APC 0135

Table 29 below lists the CY 2011 APC assignments for the CY 2011 CPT codes that will be deleted on December 31, 2011, and crosswalked to the replacement codes, which are described by the new CY 2012 CPT codes that will be effective January 1, 2012. We note that because the eight new CPT codes will be effective January 1, 2012, they are flagged with comment indicator ''NI'' in Addendum B of this final rule, which will be published and made available only via the Internet on the CMS Web site at *http://www.cms.gov/*.

BILLING CODE 4120–01–P

TABLE 29.—CPT CODE CHANGES FOR THE SKIN REPLACEMENT AND SKIN SUBSTITUTE CODES EFFECTIVE JANUARY 1, 2012

CY 2011 CPT Code	CY 2011 Long Descriptor	CY 2011 APC	CY 2012 CPT Code	CY 2012 Long Descriptor	CY 2012 APC
15170	Acellular dermal replacement, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children	0135	**15273**	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children	0135
15171	Acellular dermal replacement, trunk, arms, legs; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof	0134	**15274**	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof	0134
15175	Acellular dermal replacement, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children	0135	**15277**	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children	0135
15176	Acellular dermal replacement, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof	0135	**15278**	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof	0134
15300	Allograft skin for temporary wound closure, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children	0135	**15273**	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children	0135

CY 2011 CPT Code	CY 2011 Long Descriptor	CY 2011 APC	CY 2012 CPT Code	CY 2012 Long Descriptor	CY 2012 APC
15301	Allograft skin for temporary wound closure, trunk, arms, legs; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof	0135	**15274**	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof	0134
15320	Allograft skin for temporary wound closure, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children	0135	**15277**	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children	0135
15321	Allograft skin for temporary wound closure, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof	0135	**15278**	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof	0134
15330	Acellular dermal allograft, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children	0135	**15273**	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children	0135
15331	Acellular dermal allograft, trunk, arms, legs; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof	0135	**15274**	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof	0134

CY 2011 CPT Code	CY 2011 Long Descriptor	CY 2011 APC	CY 2012 CPT Code	CY 2012 Long Descriptor	CY 2012 APC
15335	Acellular dermal allograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children	0135	**15277**	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children	0135
15336	Acellular dermal allograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof	0135	**15278**	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof	0134
15340	Tissue cultured allogeneic skin substitute; first 25 sq cm or less	0134	**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	0134
			15275	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; first 25 sq cm or less wound surface area	0134
15341	Tissue cultured allogeneic skin substitute; each additional 25 sq cm, or part thereof	0134	**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	0133
			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	0133

CY 2011 CPT Code	CY 2011 Long Descriptor	CY 2011 APC	CY 2012 CPT Code	CY 2012 Long Descriptor	CY 2012 APC
15360	Tissue cultured allogeneic dermal substitute, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children	0134	**15273**	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children	0135
15361	Tissue cultured allogeneic dermal substitute, trunk, arms, legs; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof	0134	**15274**	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof	0134
15365	Tissue cultured allogeneic dermal substitute, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children	0134	**15277**	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children	0135
15366	Tissue cultured allogeneic dermal substitute, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof	0134	**15278**	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof	0134
15400	Xenograft, skin (dermal), for temporary wound closure, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children	0135	**15273**	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children	0135

CY 2011 CPT Code	CY 2011 Long Descriptor	CY 2011 APC	CY 2012 CPT Code	CY 2012 Long Descriptor	CY 2012 APC
15401	Xenograft, skin (dermal), for temporary wound closure, trunk, arms, legs; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof	0135	**15274**	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof	0134
15420	Xenograft skin (dermal), for temporary wound closure, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children	0135	**15277**	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children	0135
15421	Xenograft skin (dermal), for temporary wound closure, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof	0135	**15278**	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof	0134
15430	Acellular xenograft implant; first 100 sq cm or less, or 1% of body area of infants and children	0135	**15273**	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children	0135
			15277	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children	0135

CY 2011 CPT Code	CY 2011 Long Descriptor	CY 2011 APC	CY 2012 CPT Code	CY 2012 Long Descriptor	CY 2012 APC
15431	Acellular xenograft implant; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof	0135	**15274**	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof	0134
			15278	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof	0134

BILLING CODE 4120–01–C

Comment: Some commenters requested CMS to continue to assign CPT code 15004 to APC 0135 because the procedure is clinically similar to CPT codes 15002, 15003, and 15005, which are in APC 0135.

Response: As we stated above, we reassigned CPT code 15004 from APC 0135 to APC 0134 to eliminate a 2 times rule violation in APC 0135. Based on our analysis, our claims data show a CPT median cost of approximately $278 for CPT code 15004 based on 1,529 single claims (out of 5,116 total claims). The median cost of approximately $278 for CPT code 15004 is closer to the median cost of approximately $227 for APC 0134 than to the median cost of approximately $345 for APC 0135. Moreover, the range of the median costs for the procedures with significant claims data that are assigned to APC 0134 is between $157 and $291, while the range for the procedures with significant claims data that are assigned to APC 0135 is between $284 and $642. The median cost of approximately $278 for CPT code 15004 is in the range of median costs for the procedures with significant claims data in APC 0134 but not in the range of median costs for the procedures with significant claims data in APC 0135. Further, we believe that CPT code 15004 is similar to the procedures in APC 0134 based on clinical homogeneity and resource costs. We remind hospitals that we have more than two levels of skin repair APCs. Specifically, we have five levels of skin repair APCs as follows:

- APC 0133 (Level I Skin Repair)
- APC 0134 (Level II Skin Repair)
- APC 0135 (Level III Skin Repair)
- APC 0136 (Level IV Skin Repair)
- APC 0137 (Level V Skin Repair)

Therefore, after consideration of the public comments that we received, we are finalizing our CY 2012 proposal, without modification, to reassign CPT code 15004 from APC 0135 to APC 0134, which has a final CY 2012 APC median cost of approximately $227.

Comment: Several commenters urged CMS not to finalize its proposal to assign CPT code 15430 to APC 0134 and requested that CMS continue to assign the code to APC 0135, which is the same APC that is assigned to its add-on CPT code 15431 (Acellular xenograft implant; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof). The commenters stated that APC 0135 is the appropriate APC assignment for CPT code 15430 based on its clinical homogeneity and resource costs to other procedures assigned in APC 0135. One commenter indicated that the proposed CPT median cost of approximately $300 is closer to the proposed payment rate of approximately $361 for APC 0135 than to the proposed payment rate of approximately $228 for APC 0134.

Response: Although we proposed to reassign CPT code 15430 from APC 0135 to APC 0134, the code will be deleted on December 31, 2011, and replaced with new CPT codes effective January 1, 2012. As listed in Table 29, the replacement codes for CPT code 15430 have been crosswalked to APC 0135 based on the code descriptor.

Comment: One commenter recommended that CMS provide proper notice and comment before deleting HCPCS codes from the system. The commenter indicated that, in the case of HCPCS code Q4109 (Tissuemend, per square centimeter), the public should be provided adequate notice before the code is deleted with an explanation for its deletion. This same commenter requested that CMS temporarily reassign HCPCS code Q4109 to status indicator ''K'' (Nonpass-Through Drugs and Nonimplantable Biologicals, Including Therapeutic Radiopharmaceuticals) for CY 2012.

Response: HCPCS code Q4109 was deleted on December 31, 2010. We are not considering a status indicator reassignment for this code because the HCPCS code is no longer active. This HCPCS code was assigned to status indicator ''D'' (Discontinued Codes) in Addendum B of the CY 2011 OPPS/ASC final rule with comment period. Every

year hundreds of new codes are created, revised, and deleted as part of the annual HCPCS cycle. In its role as the Level II Alphanumeric HCPCS code set maintainer, the CMS HCPCS Workgroup identifies redundancies across the HCPCS Level II national code set which reduces opportunities for duplicate billing. Because we are not aware of all the coding changes for the upcoming year when we publish our proposed rules, we do not address the coding changes in the proposed rule. Any interested party that disagrees with the coding actions for the Level II Alphanumeric HCPCS codes is welcome to submit a request to CMS to review the matter by submitting an application using CMS' standard procedures. The application will be considered as part of CMS' standard code review process, including an opportunity for public comment in reaction to a published preliminary HCPCS coding decision. The application can be downloaded from this CMS Web site: *https://www.cms.gov/MedHCPCSGenInfo/01a_Application_Form_and_Instructions.asp#TopOfPage.*

b. Nasal Sinus Endoscopy (APC 0075)

For CY 2012, we proposed to assign CPT codes 31295 (Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (e.g., balloon dilation), transnasal or via canine fossa), 31296 (Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (e.g., balloon dilation), and 31297 (Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (e.g., balloon dilation) to APC 0075 (Level V Endoscopy Upper Airway).

Comment: One commenter on the CY 2012 OPPS/ASC proposed rule objected to the assignment of CPT codes 31295, 31296, and 31297 to APC 0075 because the commenter believed that the payment rate for APC 0075 substantially underpays providers. Commenters on the CY 2011 OPPS/ASC final rule with comment period (75 FR 71800) relating to the interim APC assignments and/or status indicators of HCPCS codes identified with comment indicator ''NI'' in Addendum B to that final rule with comment period addressed the same issue. The commenters suggested that instead of assigning CPT codes 31295, 31296, and 31297 to APC 0075, CMS create a new device-dependent APC for these three CPT codes. Or, if CMS does not decide to create a new device-dependent APC, the commenters suggested that the three CPT codes should instead be assigned to one of four alternative APCs. The commenters believed that assigning these codes to APCs 0056 (Level II Foot Musculoskeletal Procedures), 0083 (Level I Endovascular Revascularization of the Lower Extremity), or 0114 (Thyroid/Lymphadenectomy Procedures) would be justified because the payment rates for these APCs more closely reflect the costs associated with CPT codes 31295, 31296, and 31297. Commenters also suggested that another option would be to assign these CPTs to the new technology APC 1525 (New Technology—Level XXV ($3500-$4000)) until more claims data are accumulated and an appropriate clinical APC can be assigned.

Response: We do not agree that CPT codes 31295, 31296, and 31297 should be assigned to a new device-dependent APC. When assigning procedures to an APC, we first consider the clinical and resource characteristics of a procedure and determine the most appropriate APC assignment. We believe that the most clinically appropriate APC is APC 0075, which includes other nasal and sinus endoscopy procedures. The APCs suggested by the commenters (APCs 0056, 0083, and 0114) are clinically unrelated to the procedures described by CPT codes 31295, 31296, and 31297. Regarding the resource costs of the procedures in question, the commenters asserted costs of approximately $4,000 for these procedures, which are currently assigned to the highest paying clinically appropriate APC (APC 0075), which is level 5 out of 5 levels of APCs for ''endoscopy upper airway.'' The highest median cost of all of the procedures assigned to APC 0075 is approximately $4,000. Therefore, even the non-claims data-based cost estimate for these procedures offered by the commenters is within the approximate range (although on the high end of the range) of median costs for procedures assigned to APC 0075. Therefore, we believe that, until we have claims data to better inform an APC assignment, the current APC assignment is the most appropriate. We have no further information at this time that indicates that a device-dependent APC, the assignment of status indicator ''S'' instead of status indicator ''T,'' or a new technology APC would be more appropriate at this time. Once OPPS claims data are available for these procedures, we will reevaluate their APC assignments, as we do for all procedures on an ongoing and annual basis.

c. Bioimpedance Spectroscopy (APC 0097)

CPT code 0239T (Bioimpedance spectroscopy (BIS), measuring 100 frequencies or greater, direct measurement of extracellular fluid differences between the limbs) was effective January 1, 2011. In accordance with our standard policy, we assessed the properties of the service as CPT code 0239T was defined by the AMA's CPT Editorial Board. We assigned it to the APC that we believed to have the most similar clinical characteristics and resource requirements. In the case of CPT code 0239T, we assigned bioimpedance spectroscopy to APC 0099 (Electrocardiogram/Cardiography). For CY 2012, we proposed to continue to assign CPT code 0239T, for which we had no claims data on which to calculate a median cost, to APC 0099 for CY 2012. We proposed a median cost of approximately $28 for APC 0099.

Comment: One commenter objected to the proposed assignment of CPT code 0239T to APC 0099 for CY 2012 on the basis that the proposed payment rate for APC 0099 would be inadequate to pay hospitals' costs and, therefore, would jeopardize beneficiary access to the service. The commenter stated that BIS is a method to aid surgeons and oncologists in the pre-surgical assessment and post-operative monitoring of unilateral lymphedema of the arm. The commenter also stated that BIS is an aid for therapists to assess and monitor the measurement of extra cellular fluid volume differences between the arms during the treatment phase for early stage lymphedema. The commenter stated that BIS is not a diagnostic test but rather an aid to the physician in the clinical assessment of the patient because the results require interpretation by the physician and review of previous results for clinical relevance.

The commenter asked that CMS reassign CPT code 0239T from APC 0099 to APC 0096 (Level II Noninvasive Physiologic Studies). The commenter stated that CPT code 239T is not similar to 93701 (Bioimpedance-derived physiologic cardiovascular analysis), which the commenter assumed was the CMS rationale for also placing 0239T into APC 0099. Instead the commenter indicated that CPT code 239T is more similar in resource time, for which the commenter stated that physician time is a proxy to CPT code 93924 (Noninvasive physiologic studies of lower extremity arteries, at rest and following treadmill stress testing, (i.e., bidirectional Doppler waveform or volume plethysmography recording and analysis at rest with ankle/brachial indices immediately after and at timed intervals following performance of a standardized protocol on a motorized treadmill plus recording of time of onset of claudication or other symptoms, maximal walking time, and time to

recovery) complete bilateral study). The commenter stated that the work description for CPT code 93924 of setting the patient up, taking diagnostic measurements, and analyzing and interpreting the records is similar to the work involved for CPT code 0239T and, therefore, CPT code 0239T should be assigned to APC 0096 rather than to APC 0099. The commenter also stated that the resource time for CPT code 0239T is similar to the resource time, using physician time as a proxy, for CPT code 99214 (Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed history; A detailed examination; Medical decision making of moderate complexity). The commenter believed that because CPT code 99214 is assigned to APC 0606, which has a median cost of approximately $99, CPT code 0239T should be assigned to an APC with a comparable payment rate. In addition, the commenter stated that the proposed payment for APC 0099 is not adequate to compensate hospitals for what the commenter indicated are the cost of the necessary machine (approximately $27,000) and supplies (approximately $50 per unit). The commenter stated that compensation under APC 0099 would not be adequate and without adequate compensation, hospitals would not provide the service.

Response: We have no CY 2010 claims data for the service reported by CPT code 239T because the CPT code is new for CY 2011. Therefore, under our longstanding policy, we assigned the new code to the APC that we believed to be most similar clinically and with regard to homogeneity of hospital resources. Specifically, we assigned HCPCS code 0239T to APC 0099 for CY 2011, and we proposed to continue that assignment for CY 2012. We disagree with the commenter that BIS is not a diagnostic service because the service is used for the diagnosis of a clinical condition. However, after examination of the information furnished by the commenter, we agree with the commenter that CPT code 0239T appears to be somewhat dissimilar in resource utilization to the services assigned to APC 0099. However, we do not agree with the commenters that CPT code 0239T should be assigned to APC 0096 because we do not believe that CPT code 0239T rises to the same level of complexity as codes that are assigned to APC 0096. For example, we believe that CPT code 93924, to which the commenters compared CPT code 239T, reports a service that is more complex clinically and more costly to hospitals than the service reported by CPT code 0239T. Similarly, we believe that there is neither clinical similarity nor similarity of hospital resources between the services reported by CPT code 0239T, which is used to diagnose lymphedema and CPT code 99214, which is an established patient outpatient visit.

Although we do not believe that CPT code 0239T should be assigned to APC 0096, we believe that CPT code 0239T is sufficiently more complex than the services that are assigned to APC 0099 that it would be more appropriately placed in APC 0097, based on its clinical homogeneity and resource similarity to other procedures in APC 0097. For example, we believe that CPT code 0239T is more similar to CPT code 93922 (Limited bilateral noninvasive physiologic studies of upper or lower extremity arteries, (eg, for lower extremity: ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus bidirectional, Doppler waveform recording and analysis at 1–2 levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus volume plethysmography at 1–2 levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries with transcutaneous oxygen tension measurements at 1–2 levels)), which is assigned to APC 0097, both clinically and in resource requirements, than to CPT code 93924. Therefore, we are reassigning CPT code 0239T from APC 0099 to APC 0097, which has a final median cost of approximately $65 for CY 2012. We will reassess the APC placement for CPT code 0239T when we have claims data for services furnished on and after January 1, 2011, the effective date for CPT code 0239T.

d. Autologous Blood Salvage (APC 0345)

For CY 2012, we proposed to assign CPT code 86891 (Autologous blood or component, collection processing and storage; intra- or postoperative salvage) to APC 0345 (Level I Transfusion Laboratory Procedures).

Comment: One commenter objected to the assignment of CPT code 86891 to APC 0345 because the commenter believed that the payment rate for APC 0345 underpays providers. The commenter stated that the reason for the inappropriately low payment is that CPT 86891 would never appear on a single procedure claim. The commenter suggested that this service should be further analyzed and a more appropriate payment level established based upon analysis using external data. The commenter further stated that the current way in which the groupings and payment levels for services under APCs are calculated does not appropriately address the autologous blood salvage service performed at hospitals.

Response: The calculated median cost for CPT code 86891 based on 2010 claims data for this final rule with comment period is approximately $21 based on 124 single procedure claims out of 332 total claims. The calculated median cost of approximately $21 for CPT code 86891 is within the range of the median costs of the other procedures assigned to APC 0345, and there is no violation of the 2 times rule. Therefore, assignment of CPT code 86891 to APC 0345 satisfies the APC assignment requirements of clinical and resource homogeneity. We do not agree that additional analysis of external data is necessary. We set the payment rates for APCs using our standard OPPS methodology based on relative costs from hospital outpatient claims and the most recent cost report data that are available. We have no reason to believe that our claims and cost report data, as reported by hospitals, do not accurately reflect hospitals' costs of the services assigned to APC 0345, including the service described by CPT code 86891. Furthermore, as the service described by CPT code 86891 is a transfusion laboratory procedure, this service is appropriately assigned to APC 0345, which is titled ''Level I Transfusion Laboratory Procedures'' and includes other transfusion laboratory procedures. Therefore, we are finalizing our proposal to assign CPT code 86891 to APC 0345 for CY 2012, which has a final rule median cost of approximately $15 for CY 2012.

IV. OPPS Payment for Devices

A. Pass-Through Payments for Devices

1. Expiration of Transitional Pass-Through Payments for Certain Devices

a. Background

Section 1833(t)(6)(B)(iii) of the Act requires that, under the OPPS, a category of devices be eligible for transitional pass-through payments for at least 2, but not more than 3, years. This pass-through payment eligibility period begins with the first date on which transitional pass-through payments may be made for any medical device that is described by the category. We may establish a new device category for pass-through payment in any quarter. Under our established policy, we base the pass-through status expiration date for a device category on

the date on which pass-through payment is effective for the category. The date on which a pass-through category is in effect is the first date on which pass-through payment may be made for any medical device that is described by such category. We propose and finalize the dates for expiration of pass-through status for device categories as part of the OPPS annual update.

We also have an established policy to package the costs of the devices that are no longer eligible for pass-through payments into the costs of the procedures with which the devices are reported in the claims data used to set the payment rates (67 FR 66763). Brachytherapy sources, which are now separately paid in accordance with section 1833(t)(2)(H) of the Act, are an exception to this established policy.

There currently are three new device categories eligible for pass-through payment. These device categories are described by HCPCS code C1749 (Endoscope, retrograde imaging/illumination colonoscope device (implantable)), which we announced in the October 2010 OPPS Update (Transmittal 2050, Change Request 7117, dated September 17, 2010); and HCPCS codes C1830 (Powered bone marrow biopsy needle), and C1840 (Lens, intraocular (telescopic)), which were made effective for pass-through payment October 1, 2011, and announced in Transmittal 2296, Change Request 7545, dated September 2, 2011. There are no categories for which we proposed expiration of pass-through status in CY 2011. If we create new device categories for pass-through payment status during the remainder of CY 2011, we will propose future expiration dates in accordance with the statutory requirement that they be eligible for pass-through payments for at least 2, but not more than 3, years from the date on which pass-through payment for any medical device described by the category may first be made.

b. CY 2012 Policy

As stated above, section 1833(t)(6)(B)(iii) of the Act requires that, under the OPPS, a category of devices be eligible for transitional pass-through payments for at least 2, but not more than 3 years. Device pass-through category C1749 was established for pass-through payments on October 1, 2010, and will have been eligible for pass-through payments for more than 2 years but less than 3 years as of the end of CY 2012. Therefore, in the CY 2012 OPPS/ASC proposed rule (76 FR 42242), we proposed an expiration date for pass-through payment for device category C1749 of December 31, 2012. Therefore, under our proposal, beginning January 1, 2013, device category C1749 will no longer be eligible for pass-through payments. We will propose expiration dates for pass-through payment for device categories C1830 and C1840 in a future rulemaking.

Comment: Two commenters indicated that there was only one currently approved device for pass-through payment, noting that in the CY 2012 OPPS/ASC proposed rule, we stated that there was only one device category eligible for pass-through payment for CY 2012. These commenters opined that there has been a decrease in the number of categories eligible for pass-through payment over the past several years, and encouraged CMS to approve additional device categories for technologies that meet the criteria for pass-through payments. One commenter recommended that CMS reevaluate the criteria and approval process for device category pass-through eligibility. The commenter also recommended that CMS annually publish a list of all pass-through applications filed with CMS, along with CMS' determinations and rationale for the resulting decisions.

Response: As indicated, we currently have three device categories eligible for pass-through payment, rather than one category as stated in the CY 2012 proposed rule, and we believe this shows that we have a robust device pass-through evaluation and approval process. The number of device pass-through categories eligible for payment will always vary, and we believe that the number of active device pass-through categories eligible for pass-through payment at any time is a function of the quality of applications under consideration, that is, whether they fully meet the device pass-through criteria, rather than a function of our criteria and approval process, which we believe to be appropriate. As we stated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71922), we will take the recommendation to publish a list of all pass-through applications filed with us under advisement as we consider our device pass-through criteria and process in the future.

After consideration of the public comments we received, we are finalizing our proposal of an expiration date for pass-through payment for device category C1749 of December 31, 2012. Therefore, beginning January 1, 2013, device category C1749 will no longer be eligible for pass-through payments. We remind the public that as of January 1, 2013, device category C1749 will still be active for the billing and reporting of devices and their charges along with the HCPCS codes of the procedures with which they are used. When billing for procedures utilizing devices that have active device codes, hospitals are required to report the codes for the devices on their claims for the procedure.

2. Provisions for Reducing Transitional Pass-Through Payments to Offset Costs Packaged Into APC Groups

a. Background

We have an established policy to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of the associated devices that are eligible for pass-through payments (66 FR 59904). We deduct from the pass-through payments for identified device categories eligible for pass-through payments an amount that reflects the portion of the APC payment amount that we determine is associated with the cost of the device, defined as the device APC offset amount, as required by section 1833(t)(6)(D)(ii) of the Act. We have consistently employed an established methodology to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of an associated device eligible for pass-through payment, using claims data from the period used for the most recent recalibration of the APC rates (72 FR 66751 through 66752). We establish and update the applicable device APC offset amounts for eligible pass-through device categories through the transmittals that implement the quarterly OPPS updates.

We publish a list of all procedural APCs with the CY 2011 portions (both percentages and dollar amounts) of the APC payment amounts that we determine are associated with the cost of devices, on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS/01_overview.asp.* The dollar amounts are used as the device APC offset amounts. In addition, in accordance with our established practice, the device APC offset amounts in a related APC are used in order to evaluate whether the cost of a device in an application for a new device category for pass-through payment is not insignificant in relation to the APC payment amount for the service related to the category of devices, as specified in our regulations at § 419.66(d).

As of CY 2009, the costs of implantable biologicals without pass-through status are packaged into the payment for the procedures in which they are inserted or implanted because implantable biologicals without pass-through status are not separately paid

(73 FR 68633 through 68636). For CY 2010, we finalized a new policy to specify that the pass-through evaluation process and pass-through payment methodology for implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice; also referred to as ''implantable biologicals'') and that are newly approved for pass-through status beginning on or after January 1, 2010, be the device pass-through process and payment methodology only. As a result, for CY 2010, we included implantable biologicals in our calculation of the device APC offset amounts (74 FR 60476). We calculated and set the device APC offset amount for a newly established device pass-through category, which could include a newly eligible implantable biological, beginning in CY 2010 using the same methodology we have historically used to calculate and set device APC offset amounts for device categories eligible for pass-through payment (72 FR 66751 through 66752), with one modification. Because implantable biologicals are considered devices rather than drugs for purposes of pass-through evaluation and payment under our established policy, the device APC offset amounts include the costs of implantable biologicals. For CY 2010, we also finalized a policy to utilize the revised device APC offset amounts to evaluate whether the cost of an implantable biological in an application for a new device category for pass-through payment is not insignificant in relation to the APC payment amount for the service related to the category of devices. Further, for CY 2010, we no longer used the ''policy-packaged'' drug APC offset amounts for evaluating the cost significance of implantable biological pass-through applications under review and for setting the APC offset amounts that would apply to pass-through payment for those implantable biologicals, effective for new pass-through status determinations beginning in CY 2010 (74 FR 60463).

For CY 2011, we continued our policy that the pass-through evaluation process and pass-through payment methodology for implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) and that are newly approved for pass-through status beginning on or after January 1, 2010, be the device pass-through process and payment methodology only.

b. CY 2012 Policy

In the CY 2012 OPPS/ASC proposed rule (76 FR 42243), we proposed to continue our policy, for CY 2012, that the pass-through evaluation process and pass-through payment methodology for implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) and that are newly approved for pass-through status beginning on or after January 1, 2010, be the device pass-through process and payment methodology only. The rationale for this policy is provided in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60471 through 60477). We also proposed to continue our established policies for calculating and setting the device APC offset amounts for each device category eligible for pass-through payment. In addition, we proposed to continue to review each new device category on a case-by-case basis to determine whether device costs associated with the new category are already packaged into the existing APC structure. If device costs packaged into the existing APC structure are associated with the new category, we proposed to deduct the device APC offset amount from the pass-through payment for the device category. As stated earlier, these device APC offset amounts also would be used in order to evaluate whether the cost of a device in an application for a new device category for pass-through payment is not insignificant in relation to the APC payment amount for the service related to the category of devices (§ 419.66(d)).

For CY 2012, we also proposed to continue our policy established in CY 2010 to include implantable biologicals in our calculation of the device APC offset amounts. In addition, we proposed to continue to calculate and set any device APC offset amount for a new device pass-through category that includes a newly eligible implantable biological beginning in CY 2012 using the same methodology we have historically used to calculate and set device APC offset amounts for device categories eligible for pass-through payment, and to include the costs of implantable biologicals in the calculation of the device APC offset amounts, as we first finalized and implemented for CY 2010.

In addition, we proposed to update, on the CMS Web site at *http://www.cms.gov/HospitalOutpatientPPS*, the list of all procedural APCs with the final CY 2012 portions of the APC payment amounts that we determine are associated with the cost of devices so that this information is available for use by the public in developing potential CY 2012 device pass-through payment applications and by CMS in reviewing those applications.

In summary, for CY 2012, consistent with the policy established for CY 2010, we proposed to continue the following policies related to pass-through payment for devices: (1) Treating implantable biologicals, that are surgically inserted or implanted (through a surgical incision or a natural orifice) and that are newly approved for pass-through status on or after January 1, 2010, as devices for purposes of the OPPS pass-through evaluation process and payment methodology; (2) including implantable biologicals in calculating the device APC offset amounts; (3) using the device APC offset amounts to evaluate whether the cost of a device (defined to include implantable biologicals) in an application for a new device category for pass-through payment is not insignificant in relation to the APC payment amount for the service related to the category of devices; and (4) reducing device pass-through payments based on device costs already included in the associated procedural APCs, when we determine that device costs associated with the new category are already packaged into the existing APC structure.

Comment: Several commenters recommended that all biological therapies, including implantable biologicals that are approved by the FDA under biological license applications (BLAs), be treated as drugs for pass-through payment status for CY 2012. The commenters claimed that Congress intended that all biologicals approved by the FDA under a BLA be paid under the current SCOD payment system, including according to the drug pass-through provisions. Another commenter requested that CMS clarify its policy to state that the device pass-through criteria apply only to biologicals with an FDA approved indication or indications that are only surgically implanted. This commenter believed that the current regulation is unclear regarding how CMS would evaluate pass-through eligibility of a biological that has indications in which the biological is surgically implanted for one indication and nonimplantable for another indication. The commenter recommended that CMS revise the regulations text at 42 CFR 419.64(a)(4) so that if refers to ''a biological that is not always surgically implanted into the body.''

Response: As stated in the CY 2010 OPPS/ASC final rule with comment period and reiterated in the CY 2011 OPPS/ASC final rule with comment period, we evaluate implantable biologicals that function as, and are substitutes for, implantable devices for OPPS payment purposes. This is done

regardless of their FDA approval route, the intent of which is to ensure their safety and effectiveness through appropriate scientific review (74 FR 60476; 75 FR 71924).

We do not agree with the commenters who asserted that Congress intended biologicals approved under BLAs to be paid under the statutory provisions that apply to SCODs, including the pass-through provisions. Moreover, as we stated in the CY 2010 and CY 2011 OPPS/ASC final rules with comment period, Congress did not specify in the statute that we must pay for implantable biologicals as biologicals rather than devices, if these products that function as medical devices also meet our criteria for payment as devices (74 FR 60476; 75 FR 71924). We continue to believe that implantable biologicals are devices for the purposes of OPPS payment, and therefore that it is appropriate for us to treat implantable biologicals as implantable devices and not as nonimplantable biologicals.

We appreciate the commenter's request that we clarify our meaning of the regulation text at 42 CFR 419.64(a)(4)(iii), which states that a biological for pass-through status purposes must meet the following condition (among others): ''biological that is not surgically implanted or inserted into the body.'' By this regulatory language, we mean to exclude from consideration for drug and biological pass-through status any biological that has an indication such that it may function as a surgically implanted or inserted biological, even if there are also other indications in which the biological is not surgically implanted or inserted.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue the policy to specify that the pass-through evaluation process and pass-through payment methodology for implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) and that are newly approved for pass-through status on or after January 1, 2010, be the device pass-through process and payment methodology only. We also are finalizing our other proposals, without modification, to continue the following policies regarding device offsets: (1) Including implantable biologicals in calculating the device APC offset amounts; (2) using the device APC offset amounts to evaluate whether the cost of a device (defined to include implantable biologicals) in an application for a new device category for pass-through payment is not insignificant in relation to the APC payment amount for the service related to the category of devices; and (3) reducing device pass-through payments based on device costs already included in the associated procedural APCs, when we determine that device costs associated with the new category are already packaged into the existing APC structure.

B. Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices

1. Background

In recent years, there have been several field actions on and recalls of medical devices as a result of implantable device failures. In many of these cases, the manufacturers have offered devices without cost to the hospital or with credit for the device being replaced if the patient required a more expensive device. In order to ensure that payment rates for procedures involving devices reflect only the full costs of those devices, our standard ratesetting methodology for device-dependent APCs uses only claims that contain the correct device code for the procedure, do not contain token charges, do not contain the ''FB'' modifier signifying that the device was furnished without cost or with a full credit, and do not contain the ''FC'' modifier signifying that the device was furnished with partial credit. As discussed in section II.A.2.d.(1) of this final rule with comment period, as we proposed, we are continuing to use our standard ratesetting methodology for device-dependent APCs for CY 2012.

To ensure equitable payment when the hospital receives a device without cost or with full credit, in CY 2007, we implemented a policy to reduce the payment for specified device-dependent APCs by the estimated portion of the APC payment attributable to device costs (that is, the device offset) when the hospital receives a specified device at no cost or with full credit (71 FR 68071 through 68077). Hospitals are instructed to report no cost/full credit cases using the ''FB'' modifier on the line with the procedure code in which the no cost/full credit device is used. In cases in which the device is furnished without cost or with full credit, the hospital is instructed to report a token device charge of less than $1.01. In cases in which the device being inserted is an upgrade (either of the same type of device or to a different type of device) with a full credit for the device being replaced, the hospital is instructed to report as the device charge the difference between its usual charge for the device being implanted and its usual charge for the device for which it received full credit. In CY 2008, we expanded this payment adjustment policy to include cases in which hospitals receive partial credit of 50 percent or more of the cost of a specified device. Hospitals are instructed to append the ''FC'' modifier to the procedure code that reports the service provided to furnish the device when they receive a partial credit of 50 percent or more of the cost of the new device.

We reduce the OPPS payment for the implantation procedure by 100 percent of the device offset for no cost/full credit cases when both a specified device code is present on the claim and the procedure code maps to a specified APC. Payment for the implantation procedure is reduced by 50 percent of the device offset for partial credit cases when both a specified device code is present on the claim and the procedure code maps to a specified APC. Beneficiary copayment is based on the reduced payment amount when either the ''FB'' or the ''FC'' modifier is billed and the procedure and device codes appear on the lists of procedures and devices to which this policy applies. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for more background information on the ''FB'' and ''FC'' payment adjustment policies (72 FR 66743 through 66749).

2. APCs and Devices Subject to the Adjustment Policy

In the CY 2012 OPPS/ASC proposed rule (76 FR 42244 through 42245), we proposed for CY 2012 to continue the existing policy of reducing OPPS payment for specified APCs by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device. Because the APC payments for the related services are specifically constructed to ensure that the full cost of the device is included in the payment, we stated in the CY 2012 OPPS/ASC proposed rule (76 FR 42244) that we continue to believe it is appropriate to reduce the APC payment in cases in which the hospital receives a device without cost, with full credit, or with partial credit, in order to provide equitable payment in these cases. (We refer readers to section II.A.2.d.(1) of this final rule with comment period for a description of our standard ratesetting methodology for device-dependent APCs.) Moreover, the payment for these devices comprises a

large part of the APC payment on which the beneficiary copayment is based, and we continue to believe it is equitable that the beneficiary cost sharing reflects the reduced costs in these cases.

In the CY 2012 OPPS/ASC proposed rule (76 FR 42244), we also proposed to continue using the three criteria established in the CY 2007 OPPS/ASC final rule with comment period for determining the APCs to which this policy applies (71 FR 68072 through 68077). Specifically: (1) All procedures assigned to the selected APCs must involve implantable devices that would be reported if device insertion procedures were performed; (2) the required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedure (at least temporarily); and (3) the device offset amount must be significant, which, for purposes of this policy, is defined as exceeding 40 percent of the APC cost. We also proposed to continue to restrict the devices to which the APC payment adjustment would apply to a specific set of costly devices to ensure that the adjustment would not be triggered by the implantation of an inexpensive device whose cost would not constitute a significant proportion of the total payment rate for an APC. We stated in the CY 2012 OPPS/ASC proposed rule (76 FR 42244) that we continue to believe these criteria are appropriate because free devices and device credits are likely to be associated with particular cases only when the device must be reported on the claim and is of a type that is implanted and remains in the body when the beneficiary leaves the hospital. We believe that the reduction in payment is appropriate only when the cost of the device is a significant part of the total cost of the APC into which the device cost is packaged, and that the 40-percent threshold is a reasonable definition of a significant cost.

As indicated in the CY 2012 OPPS/ASC proposed rule (76 FR 42244 through 42245), we examined the offset amounts calculated from the CY 2012 proposed rule data and the clinical characteristics of APCs to determine whether the APCs to which the no cost/full credit and partial credit device adjustment policy applied in CY 2011 continue to meet the criteria for CY 2012, and to determine whether other APCs to which the policy did not apply in CY 2011 would meet the criteria for CY 2012. Based on the CY 2010 claims data available for the proposed rule, we did not propose any changes to the APCs and devices to which this policy applies. However, as discussed in section II.A.2.e.(6) of the proposed rule, we proposed to delete APC 0418 (Insertion of Left Ventricular Pacing Electrode) for CY 2012 and, therefore, proposed to remove this APC from the list of APCs to which the no cost/full credit and partial credit device adjustment policy would apply in CY 2012.

Table 24 of the CY 2012 OPPS/ASC proposed rule (76 FR 42245) listed the proposed APCs to which the payment adjustment policy for no cost/full credit and partial credit devices would apply in CY 2012 and displayed the proposed payment adjustment percentages for both no cost/full credit and partial credit circumstances. We proposed that the no cost/full credit adjustment for each APC to which this policy would continue to apply would be the device offset percentage for the APC (the estimated percentage of the APC cost that is attributable to the device costs that are already packaged into the APC). We also proposed that the partial credit device adjustment for each APC would continue to be 50 percent of the no cost/full credit adjustment for the APC. Table 25 of the CY 2012 OPPS/ASC proposed rule (76 FR 42245) listed the proposed devices to which the payment adjustment policy for no cost/full credit and partial credit devices would apply in CY 2012. We stated in the CY 2012 proposed rule (76 FR 42244) that we would update the lists of APCs and devices to which the no cost/full credit and partial credit device adjustment policy would apply for CY 2012, consistent with the three criteria discussed earlier in this section, based on the final CY 2010 claims data available for the CY 2012 OPPS/ASC final rule with comment period.

Comment: One commenter asserted that the proposed full offset amount of 60 percent and proposed partial offset amount of 30 percent for APC 0425 is not supported by real world cost data. The commenter suggested that, based on its data on resource costs for the devices used in the procedures assigned to APC 0425, the full offset amount for this APC should be no greater than 40 percent. The commenter argued that a 60-percent offset would result in significant financial hardship to certain facilities and possibly lead to diminishing patient access to critical devices.

Response: We do not agree with the commenter that the CY 2012 proposed device offset percentage for APC 0425 is inaccurate. As we described in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71926), the device cost is estimated from the device HCPCS codes present on hospital claims and charges in the lines for four specific revenue codes: 275 (Medical/Surgical Supplies: Pacemaker); 276 (Medical/Surgical Supplies: Intraocular lens); 278 (Medical/Surgical Supplies: Other implants); and 624 (Medical/Surgical Supplies: FDA investigational devices). The commenter did not provide the ''real world cost data'' upon which it based its assertion that the full offset amount for APC 0425 should be no greater than 40 percent. Therefore, we do not know why there would be a discrepancy between that estimate and our estimated device offset percentage of approximately 60 percent stated in the proposed rule that was based on actual hospital cost as calculated from hospital claims as described above. We have no reason to believe that this device offset percentage does not accurately reflect the percent of cost attributable to devices in APC 0425. Therefore, we do not agree that it is necessary to limit the device offset percentage for no cost/full credit cases for APC 0425 to 40 percent, as the commenter suggested.

Comment: One commenter asked for clarification of CMS' policy for instances when a device upgrade occurs and the original device is refunded at full cost and the upgraded device is charged at full cost. According to the commenter, the new device is often more expensive than the original device, thus yielding additional device acquisition costs. The commenter believes that the ''FC'' modifier should be used in this situation.

Response: As stated in the Medicare Claims Processing Manual (Pub. 100–04, Chapter 4, Section 61.3.2), when a hospital replaces a device with a more expensive device and receives a credit in the amount that the device being replaced would otherwise cost, the hospital must append modifier ''–FB'' to the procedure code (not on the device code) that reports the service provided to replace the device. The hospital must charge the difference between its usual charge for the device being implanted and its usual charge for the device for which it received credit. This charge should be billed in the covered charge field. As we stated in the CY 2009 OPPS final rule with comment period (73 FR 68630), we do not agree that we need to modify the no cost/full credit and partial credit device adjustment policy to account for the cost of more expensive replacement devices when manufacturers provide device upgrades. We continue to believe that making the full APC payment would result in significant overpayment because, as described above, we use only those claims that reflect the full costs of devices in ratesetting for device-

dependent APCs. In cases where a hospital incurs a cost for a device upgrade, the difference between the cost of the replacement device and the full credit the hospital receives for the device being replaced would likely be much less than the full cost of the device that is included in the device-dependent APC payment rate. To provide the full APC payment in these cases would favor a device upgrade, rather than replacement with a comparable device, in warranty or recall cases where the surgical procedure to replace the device is only medically necessary because of the original defective device, for which the manufacturer bears responsibility. Moreover, we also are concerned that a new policy to apply a smaller APC payment percentage reduction in an upgrade case, if we were eventually able to estimate such a percentage from sufficient claims data, could also favor device upgrades, rather than replacement with a comparable device in those situations for which the upgrade is only being provided because the old model failed (and for which the manufacturer provides a full credit) but is no longer available for use in the replacement procedure. We recognize that, in some cases, the estimated device cost and, therefore, the amount of the payment reduction will be more or less than the cost a hospital would otherwise incur for a no cost/full credit device. However, because averaging is inherent in a prospective payment system, we do not believe this is inappropriate. Therefore, we continue to believe that the full device offset reduction should be made when hospitals receive full credit for the cost of a replaced device against the cost of a more expensive replacement device.

After consideration of the public comments we received, we are finalizing our CY 2012 proposals, without modification, to continue the established no cost/full credit and partial credit adjustment policies.

Table 30 below lists the APCs to which the payment adjustment policy for no cost/full credit and partial credit devices will apply in CY 2012 and displays the final payment adjustment percentages for both no cost/full credit and partial credit circumstances. Table 31 below lists the devices to which no cost/full credit and partial credit device adjustment policy will apply for CY 2012, consistent with the three selection criteria discussed earlier in this section, based on the final CY 2010 claims data available for this final rule with comment period. For CY 2012, OPPS payments for implantation procedures to which the ''FB'' modifier is appended are reduced by 100 percent of the device offset for no cost/full credit cases when both a device code listed in Table 31 below, is present on the claim, and the procedure code maps to an APC listed in Table 30 below. OPPS payments for implantation procedures to which the ''FC'' modifier is appended are reduced by 50 percent of the device offset when both a device code listed in Table 31 is present on the claim and the procedure code maps to an APC listed in Table 30. Beneficiary copayment is based on the reduced amount when either the ''FB'' modifier or the ''FC'' modifier is billed and the procedure and device codes appear on the lists of procedures and devices to which this policy applies.

We note that, as discussed in section II.A.2.e.(6) of this final rule with comment period, we are finalizing our proposal to delete APC 0418 for CY 2012 and, therefore, will remove this APC from the list of APCs to which the no cost/full credit and partial credit device adjustment policy will apply in CY 2012.

BILLING CODE 4120–01–P

TABLE 30.—APCs TO WHICH THE NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WILL APPLY IN CY 2012

CY 2012 APC	CY 2012 APC Title	CY 2012 Device Offset Percentage for No Cost/ Full Credit Case	CY 2012 Device Offset Percentage for Partial Credit Case
0039	Level I Implantation of Neurostimulator Generator	86%	43%
0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes	55%	28%
0061	Level II Implantation/Revision/Replacement of Neurostimulator Electrodes	64%	32%
0089	Insertion/Replacement of Permanent Pacemaker and Electrodes	71%	36%
0090	Insertion/Replacement of Pacemaker Pulse Generator	73%	37%
0106	Insertion/Replacement of Pacemaker Leads and/or Electrodes	41%	21%
0107	Insertion of Cardioverter-Defibrillator	89%	45%
0108	Insertion/Replacement/Repair of AICD Leads, Generator, and Pacing Electrodes	87%	43%
0227	Implantation of Drug Infusion Device	81%	41%
0259	Level VII ENT Procedures	84%	42%
0315	Level II Implantation of Neurostimulator Generator	88%	44%
0318	Implantation of Cranial	86%	43%

CY 2012 APC	CY 2012 APC Title	CY 2012 Device Offset Percentage for No Cost/ Full Credit Case	CY 2012 Device Offset Percentage for Partial Credit Case
	Neurostimulator Pulse Generator and Electrode		
0385	Level I Prosthetic Urological Procedures	61%	31%
0386	Level II Prosthetic Urological Procedures	71%	35%
0425	Level II Arthroplasty or Implantation with Prosthesis	61%	31%
0648	Level IV Breast Surgery	46%	23%
0654	Insertion/Replacement of a permanent dual chamber pacemaker	75%	37%
0655	Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing Electrode	74%	37%
0680	Insertion of Patient Activated Event Recorders	73%	36%

TABLE 31.—DEVICES TO WHICH THE NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WILL APPLY IN CY 2012

CY 2012 Device HCPCS Code	CY 2012 Short Descriptor
C1721	AICD, dual chamber
C1722	AICD, single chamber
C1728	Cath, brachytx seed adm
C1764	Event recorder, cardiac
C1767	Generator, neurostim, imp
C1771	Rep dev, urinary, w/sling
C1772	Infusion pump, programmable

CY 2012 Device HCPCS Code	CY 2012 Short Descriptor
C1776	Joint device (implantable)
C1777	Lead, AICD, endo single coil
C1778	Lead, neurostimulator
C1779	Lead, pmkr, transvenous VDD
C1785	Pmkr, dual, rate-resp
C1786	Pmkr, single, rate-resp
C1789	Prosthesis, breast, imp
C1813	Prosthesis, penile, inflatab
C1815	Pros, urinary sph, imp
C1820	Generator, neuro rechg bat sys
C1881	Dialysis access system
C1882	AICD, other than sing/dual
C1891	Infusion pump, non-prog, perm
C1895	Lead, AICD, endo dual coil
C1896	Lead, AICD, non sing/dual
C1897	Lead, neurostim, test kit
C1898	Lead, pmkr, other than trans
C1899	Lead, pmkr/AICD combination
C1900	Lead coronary venous
C2619	Pmkr, dual, non rate-resp
C2620	Pmkr, single, non rate-resp
C2621	Pmkr, other than sing/dual
C2622	Prosthesis, penile, non-inf
C2626	Infusion pump, non-prog, temp
C2631	Rep dev, urinary, w/o sling
L8600	Implant breast silicone/eq
L8614	Cochlear device/system
L8680	Implt neurostim elctr each
L8685	Implt nrostm pls gen sng rec
L8686	Implt nrostm pls gen sng non
L8687	Implt nrostm pls gen dua rec
L8688	Implt nrostm pls gen dua non
L8690	Aud osseo dev, int/ext comp

BILLING CODE 4120–01–C

V. OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

A. OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals

1. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or ''transitional pass-through payments'' for certain drugs and biologicals (also referred to as biologics). As enacted by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act (BBRA) of 1999 (Pub. L. 106–113), this provision requires the Secretary to make additional payments to hospitals for current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act (Pub. L. 107–186); current drugs and biologicals and brachytherapy sources used for the treatment of cancer; and current radiopharmaceutical drugs and biologicals. For those drugs and biologicals referred to as ''current,'' the transitional pass-through payment began on the first date the hospital OPPS was implemented.

Transitional pass-through payments also are provided for certain ''new'' drugs and biologicals that were not being paid for as an HOPD service as of December 31, 1996, and whose cost is ''not insignificant'' in relation to the OPPS payments for the procedures or services associated with the new drug or biological. For pass-through payment purposes, radiopharmaceuticals are included as ''drugs.'' Under the statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the product's first payment as a hospital outpatient service under Medicare Part B. Proposed CY 2012 pass-through drugs and biologicals and their designated APCs were assigned status indicator ''G'' in Addenda A and B to the proposed rule, which are referenced in section XVII. of the proposed rule and this final rule with comment period and available via the Internet.

Section 1833(t)(6)(D)(i) of the Act specifies that the pass-through payment amount, in the case of a drug or biological, is the amount by which the amount determined under section 1842(o) of the Act for the drug or biological exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological. If the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, the pass-through payment amount is determined by the Secretary to be equal to the average price for the drug or biological for all competitive acquisition areas and the year established under such section as calculated and adjusted by the Secretary.

As we noted in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68633), the Part B drug CAP program was postponed beginning in CY 2009 (Medicare Learning Network (MLN) Matters Special Edition 0833, available via the Web site: *http://www.cms.gov*). As of publication of this final rule with comment period, the postponement of the Part B drug CAP program remains in effect, and there is no effective CAP program rate for pass-through drugs and biologicals as of January 1, 2009. Consistent with what we indicated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71928), if the program is reinstituted during CY 2012 and Part B drug CAP rates become available, we would again use the Part B drug CAP rate for pass-through drugs and biologicals if they are a part of the Part B drug CAP program. Otherwise, we would continue to use the rate that would be paid in the physician's office setting for all drugs and biologicals with pass-through status.

This methodology for determining the pass-through payment amount is set forth in regulations at 42 CFR 419.64, which specify that the pass-through payment equals the amount determined under section 1842(o) of the Act minus the portion of the APC payment that CMS determines is associated with the drug or biological. Section 1847A of the Act establishes the average sales price (ASP) methodology, which is used 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, as applied under the OPPS, uses several sources of data as a basis for payment, including the ASP, the wholesale acquisition cost (WAC), and the average wholesale price (AWP). In this final rule with comment period, the term ''ASP methodology'' and ''ASP-based'' are inclusive of all data sources and methodologies described therein. Additional information on the ASP methodology can be found on the CMS Web site at: *http://www.cms.gov/McrPartBDrugAvgSalesPrice*.

For CYs 2005, 2006, and 2007, we estimated the OPPS pass-through payment amount for drugs and biologicals to be zero based on our interpretation that the ''otherwise applicable Medicare OPD fee schedule'' amount was equivalent to the amount to be paid for pass-through drugs and biologicals under section 1842(o) of the Act (or section 1847B of the Act, if the drug or biological is covered under a competitive acquisition contract). We concluded for those years that the resulting difference between these two rates would be zero. For CYs 2008 and 2009, we estimated the OPPS pass-through payment amount for drugs and biologicals to be $6.6 million and $23.3 million, respectively. For CY 2010, we estimated the OPPS pass-through payment estimate for drugs and biologicals to be $35.5 million. For CY 2011, we estimated the OPPS pass-through payment for drugs and biologicals to be $15.5 million. Our OPPS pass-through payment estimate for drugs and biologicals in CY 2012 is $19 million, which is discussed in section VI.B. of this final rule with comment period.

The pass-through application and review process for drugs and biologicals is explained on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS/04_passthrough_payment.asp*.

2. Drugs and Biologicals With Expiring Pass-Through Status in CY 2011

In the CY 2012 OPPS/ASC proposed rule (76 FR 42246 through 42247), we proposed that the pass-through status of 19 drugs and biologicals would expire on December 31, 2011, as listed in Table 26 of the proposed rule (76 FR 42246 through 42247). All of these drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2011. These drugs and biologicals were approved for pass-through status on or before January 1, 2010. With the exception of those groups of drugs and biologicals that are always packaged when they do not have pass-through status, specifically diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals, our standard methodology for providing payment for drugs and biologicals with expiring pass-through status in an upcoming calendar year is to determine the product's estimated per day cost and compare it with the OPPS drug packaging threshold for that calendar year (which is $75), as discussed further in section V.B.2. of this final rule with comment period. If the drug's or biological's estimated per day cost is less than or equal to the applicable OPPS drug packaging threshold, we would package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPPS drug packaging threshold, we would provide

separate payment at the applicable relative ASP-based payment amount (which is ASP+4 percent for CY 2012, as discussed further in section V.B.3. of this final rule with comment period). Section V.B.2.d. of this final rule with comment period discusses the packaging of all nonpass-through contrast agents, diagnostic radiopharmaceuticals, and implantable biologicals.

Comment: A number of commenters requested that CMS continue pass-through payments for a third year for certain drugs that, as of December 31, 2011, will have received pass-through payments for at least 2 years and no more than 3 years and which CMS proposed to remove from pass-through status in Table 26 of the CY 2012 OPPS/ASC proposed rule (76 CR 42246). Several commenters stated that the volume for products for which CMS proposed to expire pass-through status had been low for some portion of the pass-through period, and asserted that a third year of pass-through would permit CMS to collect more accurate and complete cost data on the products. Other commenters stated that the costs associated with certain drugs for which CMS proposed to expire pass-through status are high, so packaging the product in an APC is ''not appropriate.'' Several commenters urged CMS to adopt a 3-year pass-through period for all eligible products. One commenter requested that CMS grant an additional year of pass-through payments for the product described by HCPCS code C9248 (Injection, clevidipine butyrate, 1 mg) that was removed from the pass-through list on December 31, 2010, because the product had been subject to a 10-month long voluntary manufacturer's recall during its pass-through period.

Response: As described in section V.A.1 of this final rule with comment period, section 1833(t)(6)(C)(i)(II) of the Act permits CMS to make pass-through payments for a period of at least 2 years, but not more than 3 years, after the product's first payment as a hospital outpatient service under Medicare Part B. We believe this period of payment facilitates dissemination of these new products into clinical practice and for the collection of hospital claims data reflective of their costs for future OPPS ratesetting. Our longstanding practice has been to provide pass-through payment for a period of 2 to 3 years, with expiration of pass-through status proposed and finalized through the annual rulemaking process. Each year, when proposing to expire the pass-through status of certain drugs and biologicals, we examine our claims data for these products. We observe that hospitals typically have incorporated these products into their chargemasters based on the utilization and costs observed in our claims data. Under the existing pass-through policy, which has been generally supported by commenters, we begin pass-through payment on a quarterly basis that depends on when applications are submitted to us for consideration and, because we expire pass-through status only on an annual basis, there is no way to ensure that all pass-through drugs and biologicals receive pass-through payment for a full 3 years, while also providing pass-through payment for no more than 3 years as the statute requires. Further, based on our review of available data, we are confident that the period of time for which the products listed in Table 26 of the CY 2012 OPPS proposed rule (76 CR 42246) received pass-through payments is adequate for CMS to collect sufficient data to make a packaging determination and/or an APC assignment in CY 2012. We further note that, consistent with the Act, each of these products has received pass-through status for at least 2 years, but not more than 3 years. As noted in section V.A.1. of this final rule with comment period, when a product's pass-through status expires, it is either packaged by CMS into an APC if it is either a relatively low-cost product that does not exceed the packaging threshold or is ''policy packaged'', or, if it is a relatively high-cost product, it is paid separately on the basis of the product's ASP (we refer readers to section V.B.3. of this final rule with comment period for more details regarding our payment policy for separately payable drugs). Because our policies for drugs with expiring pass-through status recognize products' relative costliness and establish either separate or bundled payment as appropriate, based on such costliness, we disagree with commenters that certain relatively high cost products currently receiving pass-through payment would not be adequately paid if taken off pass-through, and as a result should continue with such status.

Regarding the request for a third year of pass-through status for the product described by HCPCS code C9248 (Injection, clevidipine butyrate, 1 mg) which was subject to a 10-month recall during its pass-through period and for which pass-through status expired on December 31, 2010, we note that because CMS expires pass through status on an annual basis, if CMS were to extend the pass-through period for the product through CY 2012, as requested by the commenters, this would result in the pass-through period being in excess of 3 years; this result is not permitted under the statute.

After consideration of the public comments we received, we are finalizing, without modification, our proposal to expire the pass-through status of the 19 drugs and biologicals listed in Table 32 below. Table 32 lists the drugs and biologicals for which pass-through status will expire on December 31, 2011, the status indicator, and the assigned APC for CY 2012.

BILLING CODE 4120–01–P

TABLE 32.—DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH STATUS WILL EXPIRE DECEMBER 31, 2011

CY 2012 HCPCS Code	CY 2012 Long Descriptor	CY 2012 SI	CY 2012 APC
A9582	Iodine I-123 iobenguane, diagnostic, per study dose, up to 15 millicuries	N	N/A
A9583	Injection, gadofosveset trisodium, 1 ml	N	N/A
C9250	Human plasma fibrin sealant, vapor-heated, solvent-detergent (Artiss), 2ml	K	9250
C9360	Dermal substitute, native, non-denatured collagen, neonatal bovine origin (SurgiMend Collagen Matrix), per 0.5 square centimeters	K	9360
C9361	Collagen matrix nerve wrap (NeuroMend Collagen Nerve Wrap), per 0.5 centimeter length	N	N/A
C9362	Porous purified collagen matrix bone void filler (Integra Mozaik Osteoconductive Scaffold Strip), per 0.5 cc	N	N/A
C9363	Skin substitute, Integra Meshed Bilayer Wound Matrix, per square centimeter	K	9363
C9364	Porcine implant, Permacol, per square centimeter	N	N/A
J0598	Injection, C-1 esterase inhibitor (human), Cinryze, 10 units	K	9251
J0641	Injection, levoleucovorin calcium, 0.5 mg	K	1236
J0718	Injection, certolizumab pegol, 1 mg	K	9249
J1680	Injection, human fibrinogen concentrate, 100 mg	K	1290
J2426	Injection, paliperidone palmitate, 1 mg	K	9255
J2562	Injection, plerixafor, 1 mg	K	9252
J7312	Injection, dexamethasone intravitreal implant, 0.1 mg	K	9256

CY 2012 HCPCS Code	CY 2012 Long Descriptor	CY 2012 SI	CY 2012 APC
J8705	Topotecan, oral, 0.25 mg	K	1238
J9155	Injection, degarelix, 1 mg	K	1296
J9328	Injection, temozolomide, 1 mg	K	9253
Q0138	Injection, Ferumoxytol, for treatment of iron deficiency anemia, 1 mg	K	1297

BILLING CODE 4120–01–C

3. Drugs, Biologicals, and Radiopharmaceuticals With New or Continuing Pass-Through Status in CY 2012

In the CY 2012 OPPS/ASC proposed rule (76 FR 42247 through 42249), we proposed to continue pass-through status in CY 2012 for 33 drugs and biologicals. None of these drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2011. These drugs and biologicals, which were approved for pass-through status between April 1, 2010 and July 1, 2011, were listed in Table 27 of the proposed rule (76 FR 42248 through 42249). The APCs and HCPCS codes for these drugs and biologicals were assigned status indicator ''G'' in Addenda A and B, which are referenced in section XVII. of the proposed rule and this final rule with comment period and available via the Internet.

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a CAP under section 1847B of the Act, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and the year established under such section as calculated and adjusted by the Secretary) and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. Payment for drugs and biologicals with pass-through status under the OPPS is currently made at the physician's office payment rate of ASP+6 percent. We believe it is consistent with the statute to continue to provide payment for drugs and biologicals with pass-through status at a rate of ASP+6 percent in CY 2012, the amount that drugs and biologicals receive under section 1842(o) of the Act. Thus, for CY 2012, we proposed to pay for pass-through drugs and biologicals at ASP+6 percent, equivalent to the rate these drugs and biologicals would receive in the physician's office setting in CY 2012. Therefore, the difference between ASP+6 percent and ASP+4 percent that we proposed to pay for nonpass-through separately payable drugs under the CY 2012 OPPS would be the CY 2012 pass-through payment amount for these drugs and biologicals. In the case of pass-through contrast agents and diagnostic radiopharmaceuticals, the difference between ASP+6 percent and the ''policy-packaged'' drug APC offset amount for the associated clinical APC in which the drug or biological is utilized would be the CY 2012 pass-through payment amount for these policy-packaged products.

We note that we proposed to expire pass-through status for the remaining three implantable biologicals approved on or before January 1, 2010, under pass-through status as a drug or biological. Therefore, as described in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60476) and in this final rule with comment period, implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) will be evaluated under the device pass-through process and paid according to the device payment methodology. Payment for nonpass-through implantable biologicals would continue to be packaged into the payment for the associated procedure as described in section V.B.2.d. of this final rule with comment period.

In addition, we proposed to continue to update pass-through payment rates on a quarterly basis on the CMS Web site during CY 2012 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 42722 and 42723). If the Part B drug CAP is reinstated during CY 2012, and a drug or biological that has been granted pass-through status for CY 2012 becomes covered under the Part B drug CAP, we proposed to provide pass-though payment at the Part B drug CAP rate and to make the adjustments to the payment rates for these drugs and biologicals on a quarterly basis, as appropriate.

As is our standard methodology, we annually review new permanent HCPCS codes and delete temporary HCPCS C-codes if an alternate permanent HCPCS code is available for purposes of OPPS billing and payment. We specifically review drugs with pass-through status for CY 2012 that will change from C-code to permanent J-code for CY 2012. For our CY 2012 review, we have determined that HCPCS code J1557 (Injection, immune globulin (Gammaplex), intravenous, non-lyophilized (e.g. liquid), 500 mg) describes the product reported under HCPCS code C9270 (Injection, immune globulin (Gammaplex), intravenous, non-lyophilized (e.g. liquid), 500 mg); HCPCS code J0894 (Injection, denosumab, 1 mg) describes the product reported under HCPCS code C9272 (Injection, denosumab, 1 mg); HCPCS code J0840 (Crotalidae Polyvalent Immune Fab (Ovine), 1 vial) describes the product reported under HCPCS code C9274 (Crotalidae Polyvalent Immune Fab (Ovine), 1 vial); HCPCS code J9043 (Injection, cabazitaxel, 1 mg) describes the product reported under HCPCS code C9276 (Injection, cabazitaxel, 1 mg); HCPCS code J0221 (Injection, alglucosidase alfa (Lumizyme), 1 mg) describes the product reported under HCPCS code C9277 (Injection, alglucosidase alfa (Lumizyme), 1 mg); HCPCS code J9179 (Injection, eribulin

mesylate, 1 mg) describes the product reported under HCPCS code C9270 (Injection, eribulin mesylate, 1 mg); HCPCS code J2507 (Injection, pegloticase, 1 mg) describes the product reported under HCPCS code C9281 (Injection, pegloticase, 1 mg); HCPCS code J0712 (Injection, ceftaroline fosamil, 10 mg) describes the product reported under HCPCS code C9282 (Injection, ceftaroline fosamil, 10 mg); HCPCS code J0131 (Injection, acetaminophen, 10 mg) describes the product reported under HCPCS code C9283 (Injection, acetaminophen, 10 mg); and, HCPCS code J9228 (Injection, ipilimumab, 1 mg) describes the product reported under HCPCS code C9284 (Injection, ipilimumab, 1 mg).

In CY 2012, as is consistent with our CY 2011 policy for diagnostic and therapeutic radiopharmaceuticals, we proposed to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through status based on the ASP methodology. As stated above, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through status during CY 2012, we proposed to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which is ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we proposed to provide pass-through payment at WAC+6 percent, the equivalent payment provided to pass-through drugs and biologicals without ASP information. If WAC information is also not available, we proposed to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

Comment: Many commenters supported CMS' proposal to continue providing pass-through payments for drugs, biological, and radiopharmaceuticals. One commenter stated that it viewed the provision of pass-through payments as a ''temporary solution,'' and asserted that the global marketplace for Molybdenum and other medical isotopes could make historical payment data an inadequate indicator of costs. One commenter recommended that CMS require manufacturers to submit ASP data for all therapeutic radiopharmaceuticals currently paid under the OPPS.

Response: We appreciate the commenters' support for our pass-through payment policy. Although we acknowledge that pass-through payments are, by statute, ''temporary'' (section 1833(t)(6)(C)(i)(II) of the Act permits CMS to make pass-through payments only for a period of at least 2 years, but not more than 3 years), we disagree with the commenter's assertion that historical payment data are an inadequate indicator of costs. We permit radiopharmaceutical manufacturers to voluntarily submit ASP data to us for therapeutic radiopharmaceuticals, and for diagnostic radiopharmaceuticals with pass-through status. These data are updated regularly, are as current as possible (the most recently available ASP data used for this final rule with comment period are from October 2011), and are an important component of payment. Therefore, we believe that CMS' use of recent ASP data, together with the most recently available cost and claims data, are adequately responsive to changes in global prices for Molybdenum and other medical isotopes.

We do not believe, however, that requiring manufacturers to submit ASP data for all therapeutic radiopharmaceuticals currently paid under the OPPS is appropriate. As we stated in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524 through 60525), the challenges involved in reporting ASP for a radiopharmaceutical are significant, given the variety of manufacturing processes in some cases. Therefore, due to the fact that the added administrative burden of direct reporting outweighs the expected benefits, and given the relative accuracy of hospital claims data regarding such drugs, payment based on mean unit cost from historical hospital claims data offers the best proxy for average hospital acquisition cost and associated handling costs for a radiopharmaceutical in the absence of ASP. If ASP information is unavailable for a therapeutic radiopharmaceutical, meaning that a manufacturer is not willing or not able to submit ASP information, we will provide payment based on the mean unit cost of the product that is applicable to payment rates for the year the nonpass-through therapeutic radiopharmaceutical is administered.

Comment: Several commenters supported CMS' proposal to provide payment at ASP+6 percent for drugs, biologicals, contrast agents, and radiopharmaceuticals that are granted pass-through status. One commenter approved of the proposal to use the ASP methodology that would provide payment based on WAC if ASP information is not available, and payment at 95 percent of AWP if WAC information is not available. Some commenters requested that CMS provide an additional payment for radiopharmaceuticals that are granted pass-through status.

Response: As discussed above, the statutorily mandated pass-through payment for pass-through drugs and biologicals for CY 2012 generally equals the amount determined under section 1842(o) of the Act minus the portion of the otherwise applicable APC payment that CMS determines is associated with the drug or biological. Therefore, the pass-through payment is determined by subtracting the otherwise applicable payment amount under the OPPS (determined to be ASP+4 percent for CY 2012) from the amount determined under section 1842(o) of the Act (ASP+6 percent).

Regarding the comments that CMS should provide an additional payment for radiopharmaceuticals that are granted pass-through status, we note that for CY 2012, consistent with our CY 2011 payment policy for diagnostic and therapeutic radiopharmaceuticals, we proposed to provide payment for both diagnostic and therapeutic radiopharmaceuticals with pass-through status based on the ASP methodology. As stated above, the ASP methodology, as applied under the OPPS, uses several sources of data as a basis for payment, including the ASP, WAC if ASP is unavailable, and 95 percent of the radiopharmaceutical's most recent AWP if ASP and WAC are unavailable. For purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through status during CY 2012, we proposed to follow the standard ASP methodology to determine its pass-through payment rate under the OPPS. We have routinely provided a single payment for drugs, biologicals, and radiopharmaceuticals under the OPPS to account for the acquisition and pharmacy overhead costs, including compounding costs. We continue to believe that a single payment is appropriate for diagnostic radiopharmaceuticals with pass-through status in CY 2012, and that the payment rate of ASP+6 percent (or payment based on the ASP methodology) is appropriate to provide payment for both the radiopharmaceutical's acquisition cost and any associated nuclear medicine handling and compounding costs. We refer readers to section V.B.3. of this final rule with comment period for further discussion of payment for therapeutic radiopharmaceuticals based on ASP information submitted by manufacturers and the CMS Web site at:

http://www.cms.gov/HospitalOutpatientPPS/.

After consideration of the comments we received, we are finalizing our proposal to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through status based on the ASP methodology. If a diagnostic or therapeutic radiopharmaceutical receives pass-through status during CY 2012, we will follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which is ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we will provide pass-through payment at WAC+6 percent, the equivalent payment provided to pass-through drugs and biologicals without ASP information. If WAC information is also not available, we will provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

As discussed in more detail in section V.B.2.d. of this final rule with comment period, over the last 4 years, we implemented a policy whereby payment for all nonpass-through diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals is packaged into payment for the associated procedure. In the CY 2012 OPPS/ASC proposed rule (76 FR 42247 through 42248), we proposed to continue the packaging of these items, regardless of their per day cost. As stated earlier, pass-through payment is the difference between the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a CAP under section 1847B of the Act, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and the year established under such section as calculated and adjusted by the Secretary) and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. Because payment for a drug that is either a diagnostic radiopharmaceutical or a contrast agent (identified as a ''policy-packaged'' drug, first described in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68639)) would otherwise be packaged if the product did not have pass-through status, we believe the otherwise applicable OPPS payment amount would be equal to the ''policy-packaged'' drug APC offset amount for the associated clinical APC in which the drug or biological is utilized. The calculation of the ''policy-packaged'' drug APC offset amounts is described in more detail in section IV.A.2. of this final rule with comment period. It follows that the copayment for the nonpass-through payment portion (the otherwise applicable fee schedule amount that we would also offset from payment for the drug or biological if a payment offset applies) of the total OPPS payment for those drugs and biologicals would, therefore, be accounted for in the copayment for the associated clinical APC in which the drug or biological is used.

According to section 1833(t)(8)(E) of the Act, the amount of copayment associated with pass-through items is equal to the amount of copayment that would be applicable if the pass-through adjustment was not applied. Therefore, as we did in CY 2011, we proposed to continue to set the associated copayment amount for pass-through diagnostic radiopharmaceuticals and contrast agents that would otherwise be packaged if the item did not have pass-through status to zero for CY 2012. The separate OPPS payment to a hospital for the pass-through diagnostic radiopharmaceutical or contrast agent, after taking into account any applicable payment offset for the item due to the device or ''policy-packaged'' APC offset policy, is the item's pass-through payment, which is not subject to a copayment according to the statute. Therefore, we proposed to not publish a copayment amount for these items in Addenda A and B to the proposed rule (which are referenced in section XVII. of the proposed rule and this final rule with comment period and available via the Internet on the CMS Web site).

Comment: Several commenters supported the CY 2012 proposal to continue to set the associated copayment amounts for pass-through diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals that would otherwise be packaged if the product did not have pass-through status to zero. The commenters noted that this policy is consistent with statutory requirements and provides cost-saving benefits to beneficiaries.

Response: We appreciate the commenters' support of our proposal. As discussed in the CY 2012 OPPS/ASC proposed rule (76 FR 42248), we believe that, for drugs and biologicals that are ''policy–packaged,'' the copayment for the nonpass-through payment portion of the total OPPS payment for this subset of drugs and biologicals is accounted for in the copayment for the associated clinical APC in which the drug or biological is used. According to section 1833(t)(8)(E) of the Act, the amount of copayment associated with pass-through items is equal to the amount of copayment that would be applicable if the pass-through adjustment was not applied. Therefore, we believe that the copayment amount should be zero for drugs and biologicals that are ''policy-packaged,'' including diagnostic radiopharmaceuticals.

After consideration of the public comments we received, we are finalizing our proposal to continue to set the associated copayment amount for pass-through diagnostic radiopharmaceuticals and contrast agents that would otherwise be packaged if the item did not have pass-through status to zero for CY 2012.

The 33 drugs and biologicals that we proposed to continue on pass-through status for CY 2012 or that have been granted pass-through status as of July 2011 were displayed in Table 27 of the proposed rule (76 FR 42248 through 42249). We note that, for CY 2010 and the first two quarters of CY 2011, HCPCS code J1572 (Injection, immune globulin, (flebogamma/flebogamma dif), intravenous, non-lyophilized (e.g. liquid), 500 mg) was assigned a status indicator of ''K,'' meaning that this product was paid separately as a nonpass-through separately payable drug. Beginning on July 1, 2011, HCPCS code J1572 is assigned a status indicator of ''G'' and will be given pass-through status for at least 2, but not more than 3 years. The payment rate reflecting a pass-through payment amount of ASP+6 percent was not included in Addenda A and B of the proposed rule because these Addenda solely reflect codes and prices effective as of the second quarter of CY 2011, or April 2011. The 38 drugs and biologicals that we are continuing on pass-through status for CY 2012 or that have been granted pass-through status as of January 2012 are displayed in Table 33.

BILLING CODE 4120–01–P

TABLE 33.—DRUGS AND BIOLOGICALS WITH PASS-THROUGH STATUS IN CY 2012

CY 2011 HCPCS Code	CY 2012 HCPCS Code	CY 2012 Long Descriptor	Final CY 2012 SI	Final CY 2012 APC
C9406**	A9584	Iodine I-123 ioflupane, diagnostic, per study dose, up to 5 millicuries	G	9406
C9275	C9275	Injection, hexaminolevulinate hydrochloride, 100 mg, per study dose	G	9275
C9279	C9279	Injection, ibuprofen, 100 mg	G	9279
C9285**	C9285	Lidocaine 70 mg/tetracaine 70 mg, per patch	G	9285
C9286	C9286	Injection, belatacept, 1 mg	G	9286
N/A	C9287	Injection, brentuximab vedotin, 1 mg	G	9287
N/A	C9366	EpiFix, per square centimeter	G	9366
C9367	C9367	Skin substitute, Endoform Dermal Template, per square centimeter	G	9367
C9283**	J0131	Injection, acetaminophen, 10 mg	G	9283
C9277	J0221	Injection, alglucosidase alfa (Lumizyme), 1 mg	G	1413
Q2044**	J0490	Injection, belimumab, 10 mg	G	1353
J0597	J0597	Injection, C-1 Esterase inhibitor (human), Berinert, 10 units	G	9269
J0638	J0638	Injection, canakinumab, 1 mg	G	1311
C9282	J0712	Injection, ceftaroline fosamil, 10 mg	G	9282
J0775	J0775	Injection, collagenase clostridium histolyticum, 0.01 mg	G	1340
C9274	J0840	Crotalidae polyvalent immune fab (ovine), 1 vial	G	9274
C9272	J0897	Injection, denosumab, 1 mg	G	9272
J1290	J1290	Injection, ecallantide, 1 mg	G	9263
C9270	J1557	Injection, immune globulin (Gammaplex), intravenous, non-lyophilized (e.g. liquid), 500 mg	G	9270
J1572***	J1572	Injection, immune globulin, (Flebogamma/Flebogamma Dif), intravenous, non-lyophilized (e.g. liquid), 500 mg	G	0947
C9281	J2507	Injection, pegloticase, 1 mg	G	9281

CY 2011 HCPCS Code	CY 2012 HCPCS Code	CY 2012 Long Descriptor	Final CY 2012 SI	Final CY 2012 APC
J3095	J3095	Injection, telavancin, 10 mg	G	9258
J3262	J3262	Injection, tocilizumab, 1 mg	G	9624
J3357	J3357	Injection, ustekinumab, 1 mg	G	9261
J3385	J3385	Injection, velaglucerase alfa, 100 units	G	9271
N/A	J7180	Injection, factor xiii (antihemophilic factor, human), 1 i.u.	G	1416
Q2041**	J7183	Injection, von willebrand factor complex (human), Wilate, 1 i.u. vwf:rco	G	1352
J7335	J7335	Capsaicin 8% patch, per 10 square centimeters	G	9268
J8562	J8562	Fludarabine phosphate, oral, 10 mg	G	1339
C9276	J9043	Injection, cabazitaxel, 1 mg	G	9276
C9280	J9179	Injection, eribulin mesylate, 1 mg	G	1426
C9284**	J9228	Injection, ipilimumab, 1 mg	G	9284
J9302	J9302	Injection, ofatumumab, 10 mg	G	9260
J9307	J9307	Injection, pralatrexate, 1 mg	G	9259
J9315	J9315	Injection, romidepsin, 1 mg	G	9625
Q2040****	J0588	Injection, incobotulinumtoxin A, 1 unit	G	9278
Q2043*	Q2043*	Sipuleucel-T, minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF, including leukapheresis and all other preparatory procedures, per infusion	G	9273
C9365**	Q4124	Oasis Ultra Tri-Layer Matrix, per square centimeter	G	9365

*HCPCS code C9273 was deleted June 30, 2011, and replaced with HCPCS code Q2043 effective July 1, 2011.

**These HCPCS codes were effective July 1, 2011, and are included in the Addenda to this final rule with comment period.

***HCPCS code J1572 has a status indicator of "G," effective July 1, 2011.

**** HCPCS code C9278 was deleted March 31, 2011, and replaced with HCPCS code Q2040 effective April 1, 2011.

BILLING CODE 4120–01–C

4. Provisions for Reducing Transitional Pass-Through Payments for Diagnostic Radiopharmaceuticals and Contrast Agents To Offset Costs Packaged Into APC Groups

a. Background

Prior to CY 2008, diagnostic radiopharmaceuticals and contrast agents were paid separately under the OPPS if their mean per day costs were greater than the applicable year's drug packaging threshold. In CY 2008 (72 FR 66768), we began a policy of packaging payment for all nonpass-through diagnostic radiopharmaceuticals and contrast agents as ancillary and supportive items and services into their

associated nuclear medicine procedures. Therefore, beginning in CY 2008, nonpass-through diagnostic radiopharmaceuticals and contrast agents were not subject to the annual OPPS drug packaging threshold to determine their packaged or separately payable payment status, and instead all nonpass-through diagnostic radiopharmaceuticals and contrast agents were packaged as a matter of policy. For CY 2012, we proposed to continue to package payment for all nonpass-through diagnostic radiopharmaceuticals and contrast agents, as discussed in section V.B.2.d. of this final rule with comment period.

b. Payment Offset Policy for Diagnostic Radiopharmaceuticals

As previously noted, radiopharmaceuticals are considered to be drugs for OPPS pass-through payment purposes. As described above, section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under section 1842(o) of the Act (or the Part B drug CAP rate) and the otherwise applicable OPD fee schedule amount. There is currently one radiopharmaceutical with pass-through status under the OPPS, HCPCS code A9584 (Iodine I–123 ioflupane, diagnostic, per study dose, up to 5 millicuries). This product, which is presently referred to using HCPCS code A9584, was granted pass-through status using HCPCS code C9406 beginning July 1, 2011, and we proposed that it continue receiving pass-through status in CY 2012. We currently apply the established radiopharmaceutical payment offset policy to pass-through payment for this product. As described earlier in section V.A.3. of this final rule with comment period, we proposed that new pass-through diagnostic radiopharmaceuticals would be paid at ASP+6 percent, while those without ASP information would be paid at WAC+6 percent or, if WAC is not available, payment would be based on 95 percent of the product's most recently published AWP.

Because a payment offset is necessary in order to provide an appropriate transitional pass-through payment, we deduct from the pass-through payment for radiopharmaceuticals an amount reflecting the portion of the APC payment associated with predecessor radiopharmaceuticals in order to ensure no duplicate radiopharmaceutical payment is made. In CY 2009, we established a policy to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of predecessor diagnostic radiopharmaceuticals when considering a new diagnostic radiopharmaceutical for pass-through payment (73 FR 68638 through 68641). Specifically, we use the ''policy-packaged'' drug offset fraction for APCs containing nuclear medicine procedures, calculated as 1 minus (the cost from single procedure claims in the APC after removing the cost for ''policy-packaged'' drugs divided by the cost from single procedure claims in the APC).

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60480 through 60484), we finalized a policy to redefine ''policy-packaged'' drugs as only nonpass-through diagnostic radiopharmaceuticals and contrast agents, as a result of the policy discussed in sections V.A.4. and V.B.2.d. of the CY 2010 OPPS/ASC final rule with comment period (74 FR 60471 through 60477 and 60495 through 60499, respectively) that treats nonpass-through implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) and implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) with newly approved pass-through status beginning in CY 2010 or later as devices, rather than drugs. To determine the actual APC offset amount for pass-through diagnostic radiopharmaceuticals that takes into consideration the otherwise applicable OPPS payment amount, we multiply the ''policy-packaged'' drug offset fraction by the APC payment amount for the nuclear medicine procedure with which the pass-through diagnostic radiopharmaceutical is used and, accordingly, reduce the separate OPPS payment for the pass-through diagnostic radiopharmaceutical by this amount.

Beginning in CY 2011 and as discussed in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71934 through 71936), we finalized a policy to require hospitals to append modifier ''FB'' to specified nuclear medicine procedures when the diagnostic radiopharmaceutical is received at no cost/full credit. These instructions are contained within the I/OCE CMS specifications on the CMS Web site at *http://www.cms.gov/OutpatientCodeEdit/02_OCEQtrReleaseSpecs.asp#TopOfPage.* For CY 2012 and future years, we proposed to continue to require hospitals to append modifier ''FB'' to specified nuclear medicine procedures when the diagnostic radiopharmaceutical is received at no cost/full credit. In addition, we proposed to continue to require that when a hospital bills with an ''FB'' modifier with the nuclear medicine scan, the payment amount for procedures in the APCs listed in Table 28 of the proposed rule (76 FR 42250) would be reduced by the full ''policy-packaged'' offset amount appropriate for diagnostic radiopharmaceuticals. Finally, we also proposed to continue to require hospitals to report a token charge of less than $1.01 in cases in which the diagnostic radiopharmaceutical is furnished without cost or with full credit.

Comment: Several commenters supported CMS for continuing to require that hospitals append modifier ''FB'' to specified nuclear medicine procedures when the diagnostic pharmaceutical is received at no cost/full credit.

Response: We appreciate the commenters' support for this proposed policy.

Comment: One commenter recommended that CMS extend modifier ''FB'' to all procedures involving nuclear medicine in which all diagnostic radiopharmaceuticals are received at no cost or full credit. Further, the commenter recommended that CMS consider adopting this policy for all contrast-enhanced procedures in which the contrast agent is provided at no cost/full credit. The commenter stated that CMS could then publish a list of appropriate APCs to which contrast-enhanced procedures are assigned in a calendar year, and hospitals would then be required to list the ''FB'' modifier with the appropriate APC for the contrast-enhanced procedure; payment, according to the commenter, could then be reduced by a policy-packaged offset amount for contrast agents. As in our policy for reporting of diagnostic radiopharmaceuticals in nuclear medicine procedures, the commenter suggested that CMS also require hospitals report a token charge of less than $1.01 in cases in which the contrast agent is furnished without cost or with full credit. The commenter asserted that requiring hospitals to report modifier ''FB'' for contrast agents received at no cost/full credit would lead to more accurate payment and would lead to greater consistency between drugs.

Response: In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71934 through 71936), we discussed our proposed and finalized policy requiring that hospitals append modifier ''FB'' to specified nuclear medicine procedures when the diagnostic pharmaceutical is received at no cost/full credit. The policy, which was finalized in the CY

2011 final rule with comment period and implemented in CY 2011, was prompted by questions from hospitals inquiring how to properly bill for diagnostic radiopharmaceuticals obtained free of charge, typically in cases when the radiopharmaceutical had been provided to the hospital as a free sample. Although we have not received similar billing questions from hospitals regarding contrast agents, and have no indications about how widespread the practice of a manufacturer is of providing ''sample'' contrast agents at no cost to a hospital, we agree with the commenter that requiring modifier ''FB'' in such circumstances would lead to more consistency between drugs and, potentially, to more accurate payment. As is the case with diagnostic radiopharmaceuticals, CMS also annually posts a proposed and final list of APCs to which a contrast offset may be applicable. We could foresee this list being a possible element of a future policy establishing a modifier ''FB'' reporting policy, policy-packaged offset amount, and token charge reporting requirement.

However, we note that contrast agents are different in some regards from diagnostic radiopharmaceuticals. Contrast agents are, in general, substantially less costly than diagnostic radiopharmaceuticals and are subject to a higher level of competition from generic competitors; this combination of lower price and higher potential for generic substitution may lead to fewer instances of manufacturers providing hospitals with free samples. Furthermore, many radiopharmaceuticals have a very limited shelf life, often requiring procurement for a specific patient or very narrow window. Contrast agents, on the other hand, have longer shelf lives, making it much more likely that ''wastage'' from a large vial could be used to reduce or eliminate the costs for a subsequent patient. Splitting single dose vials can be acceptable in certain situations and may create ''free'' contrast agent for a patient that does not economically justify an ''FB'' adjustment by the hospital. These complexities may reduce the utility of the ''FB'' modifier for contrast agents.

Regardless of the differences and similarities between diagnostic radiopharmaceutical products, and notwithstanding any possible policy merits of treating these two types of products similarly with regards to modifier ''FB,'' in the CY 2012 OPPS/ASC proposed rule, we did not propose to extend the modifier ''FB'' policy to contrast agents. However, we are interested in receiving comments from hospitals, manufacturers and other interested parties regarding the possible application of modifier ''FB'' to contrast agents when the product is received at no cost/full credit to the hospital, the establishment of a policy-packaged offset amount for contrast agents, and possible reporting of a token charge of less than $1.01 in cases in which the contrast agent is furnished without cost/full credit. Although we are not accepting the commenter's recommendation that CMS extend the modifier ''FB'' policy to contrast agents received at no cost/full credit to a hospital because it was not proposed by CMS in CY 2012, we anticipate considering these modifications for future rulemaking.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue requiring hospitals to append modifier ''FB'' to specified nuclear medicine procedures when the diagnostic radiopharmaceutical is received at no cost/full credit in CY 2012. In addition, we will continue to reduce the payment amount for procedures in the APCs listed in Table 34 in this final rule with comment period by the full ''policy-packaged'' offset amount appropriate for diagnostic radiopharmaceuticals. Finally, we also will continue to require hospitals to report a token charge of less than $1.01 in cases in which the diagnostic radiopharmaceutical is furnished without cost or with full credit.

For CY 2011, we finalized a policy to apply the diagnostic radiopharmaceutical offset policy to payment for pass-through diagnostic radiopharmaceuticals, as described above. For CY 2012, we proposed to continue to apply the diagnostic radiopharmaceutical offset policy to payment for pass-through diagnostic radiopharmaceuticals.

Comment: One commenter requested that CMS post all data used to calculate the offset amounts and stated that, without these amounts, the public cannot make comments on the accuracy and appropriateness of CMS' calculation of radiopharmaceutical costs packaged into the nuclear medicine APC or the corresponding offset amounts for pass-through radiopharmaceuticals.

Response: The exact data used to calculate all of the proposed and final payment rates, including the associated offset amounts, for the CY 2012 OPPS are available for purchase under a CMS data use agreement through the CMS Web site at: *http://www.cms.gov/hospitalOutpatientPPS*. This Web site includes information about purchasing the ''OPPS Limited Data Set,'' which now includes the additional variables previously available only in the OPPS Identifiable Data Set, including ICD–9–CMS diagnosis codes and revenue code payment amounts. We typically have not posted the offset amounts by APC until publication of the final rule because we assign services to APCs based on our estimate of their full resource cost, including, but not limited to, packaged diagnostic radiopharmaceuticals. The offset amount is the portion of each APC payment rate that could reasonably be attributed to the cost of predecessor diagnostic radiopharmaceuticals when considering a new diagnostic radiopharmaceutical for pass-through payment and has no bearing on APC assignment.

After consideration of the public comments we received, we are finalizing our proposal to continue applying the diagnostic radiopharmaceutical offset policy to payment for pass-through diagnostic radiopharmaceuticals, as described in the CY 2012 OPPS/ASC proposed rule (76 FR 42249 through 42250).

Table 34 below displays the APCs to which nuclear medicine procedures will be assigned in CY 2012 and for which we expect that an APC offset could be applicable in the case of diagnostic radiopharmaceuticals with pass-through status.

TABLE 34.--APCs TO WHICH NUCLEAR MEDICINE PROCEDURES WILL BE ASSIGNED FOR CY 2012

CY 2012 APC	CY 2012 APC Title
0308	Positron Emission Tomography (PET) Imaging
0377	Level II Cardiac Imaging.
0378	Level II Pulmonary Imaging.
0389	Level I Non-imaging Nuclear Medicine.
0390	Level I Endocrine Imaging.
0391	Level II Endocrine Imaging.
0392	Level II Non-imaging Nuclear Medicine.
0393	Hematologic Processing & Studies.
0394	Hepatobiliary Imaging.
0395	GI Tract Imaging.
0396	Bone Imaging.
0397	Vascular Imaging.
0398	Level I Cardiac Imaging.
0400	Hematopoietic Imaging.
0401	Level I Pulmonary Imaging.
0402	Level II Nervous System Imaging.
0403	Level I Nervous System Imaging.
0404	Renal and Genitourinary Studies.
0406	Level I Tumor/Infection Imaging.
0408	Level III Tumor/Infection Imaging.
0414	Level II Tumor/Infection Imaging.

c. Payment Offset Policy for Contrast Agents

Section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under section 1842(o) of the Act (or the Part B drug CAP rate) and the otherwise applicable OPD fee schedule amount. There is currently one contrast agent with pass-through status under the OPPS: HCPCS code C9275 (Injection, hexaminolevulinate hydrochloride, 100 mg, per study dose). HCPCS code C9275 was granted pass-through status beginning January 1, 2011, and was proposed to continue with pass-through status in CY 2012. As described in section V.A.3 of the proposed rule, we proposed that new pass-through contrast agents would be paid at ASP+6 percent, while those without ASP information would be paid at WAC+6 percent or, if WAC is not available, payment would be based on 95 percent of the product's most recently published AWP.

We believe that a payment offset is necessary in order to provide an appropriate transitional pass-through payment for contrast agents because all of these items are packaged when they do not have pass-through status. In accordance with our standard offset methodology, in the CY 2012 OPPS/ASC proposed rule (76 FR 42250 through 42251), we proposed for CY 2012 to deduct from the payment for pass-through contrast agents an amount that reflects the portion of the APC payment associated with predecessor contrast agents, in order to ensure no duplicate contrast agent payment is made.

In CY 2010, we established a policy to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of predecessor contrast agents when considering new contrast agents for pass-through payment (74 FR 60482 through 60484). For CY 2012, as we did in CY 2011, we proposed to continue to apply this same policy to contrast agents. Specifically, we proposed to utilize the ''policy-packaged'' drug offset fraction for clinical APCs calculated as 1 minus (the cost from single procedure claims in the APC after removing the cost for ''policy-packaged'' drugs divided by the cost from single procedure claims in the APC). In CY 2010, we finalized a policy

to redefine ''policy-packaged'' drugs as only nonpass-through diagnostic radiopharmaceuticals and contrast agents (74 FR 60495 through 60499). To determine the actual APC offset amount for pass-through contrast agents that takes into consideration the otherwise applicable OPPS payment amount, we proposed to multiply the ''policy-packaged'' drug offset fraction by the APC payment amount for the procedure with which the pass-through contrast agent is used and, accordingly, reduce the separate OPPS payment for the pass-through contrast agent by this amount. We proposed to continue to apply this methodology for CY 2012 to recognize that when a contrast agent with pass-through status is billed with any procedural APC listed in Table 29 of the proposed rule, a specific offset based on the procedural APC would be applied to payments for the contrast agent to ensure that duplicate payment is not made for the contrast agent.

We did not receive any public comments on our proposal to deduct, from the payment for pass-through contrast agents, an amount that reflects the portion of the APC payment associated with predecessor contrast agents in order to ensure no duplicate contrast agent payment is made. We are finalizing, as proposed, our policy to deduct from the payment for pass-through contrast agents an amount that reflects the portion of the APC payment for pass-through contrast agents, as described in the CY 2012 OPPS/ASC proposed rule (76 FR 42250 through 42251). We also are finalizing the proposed CY 2012 pass-through contrast agent offset policy to specify the procedural APCs to which offsets for pass through contrast agents would apply. In addition, as we proposed, for this final rule with comment period, procedural APCs for which we expect a contrast agent offset could be applicable in the case of a pass-through contrast agent have been identified as any procedural APC with a ''policy-packaged'' drug amount greater than $20 that is not a nuclear medicine APC identified in Table 34 above, and these APCs are displayed in Table 35 below. The methodology used to determine a threshold cost for application of a contrast agent offset policy is described in detail in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60483 through 60484). We are finalizing this methodology for CY 2012 to continue to recognize that, when a contrast agent with pass-through status is billed with any procedural APC listed in Table 35, a specific offset based on the procedural APC would be applied to payment for the contrast agent to ensure that duplicate payment is not made for the contrast agent.

As we proposed, for this final rule with comment period, we will continue to post annually on the CMS Web site at *http://www.cms.gov/HospitalOutpatientPPS* a file that contains the APC offset amounts that will be used for that year for purposes of both evaluating cost significance for candidate pass-through device categories and drugs and biologicals, including contrast agents, and establishing any appropriate APC offset amounts. Specifically, the file will continue to provide the amounts and percentages of APC payment associated with packaged implantable devices, ''policy-packaged'' drugs, and ''threshold-packaged'' drugs and biologicals for every OPPS clinical APC.

Procedural APCs for which we expect a contrast offset could be applicable in the case of a pass-through contrast agent have been identified as any procedural APC with a ''policy-packaged'' drug amount greater than $20 that is not a nuclear medicine APC identified in Table 34 above and these APCs are displayed in Table 35 below. The methodology used to determine a proposed threshold cost for application of a contrast agent offset policy is described in detail in the CY 2010 OPPS/ASC final rule with comment period (70 FR 60483 through 60484). For CY 2012, we proposed to continue to recognize that when a contrast agent with pass-through status is billed with any procedural APC listed in Table 29 of the proposed rule (76 FR 42251), a specific offset based on the procedural APC would be applied to payment for the contrast agent to ensure that duplicate payment is not made for the contrast agent.

We did not receive any public comments regarding this proposal and, therefore, are adopting it for CY 2012 without modification.

TABLE 35.--APCs TO WHICH A CONTRAST AGENT OFFSET MAY BE APPLICABLE FOR CY 2012

CY 2012 APC	CY 2012 APC Title
0080	Diagnostic Cardiac Catheterization.
0082	Coronary or Non-Coronary Atherectomy.
0083	Coronary Angioplasty, Valvuloplasty, and Level I Endovascular Revascularization
0093	Vascular Reconstruction/Fistula Repair without Device.
0104	Transcathether Placement of Intracoronary Stents.
0128	Echocardiogram with Contrast.
0152	Level I Percutaneous Abdominal and Biliary Procedures.
0229	Level II Endovascular Revascularization of the Lower Extremity
0278	Diagnostic Urography.
0279	Level II Angiography and Venography.
0280	Level III Angiography and Venography.
0283	Computed Tomography with Contrast.
0284	Magnetic Resonance Imaging and Magnetic Resonance Angiography with Contrast.
0333	Computed Tomography without Contrast followed by Contrast.
0334	Combined Abdomen and Pelvis CT with Contrast
0337	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast followed by Contrast.
0375	Ancillary Outpatient Services When Patient Expires.
0383	Cardiac Computed Tomographic Imaging.
0388	Discography.
0442	Dosimetric Drug Administration.
0653	Vascular Reconstruction/Fistula Repair with Device.
0656	Transcatheter Placement of Intracoronary Drug-Eluting Stents.
0662	CT Angiography.
0668	Level I Angiography and Venography.
8006	CT and CTA with Contrast Composite.
8008	MRI and MRA with Contrast Composite.

B. OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status

1. Background

Under the CY 2011 OPPS, we currently pay for drugs, biologicals, and radiopharmaceuticals that do not have pass-through status in one of two ways: as a packaged payment included in the payment for the associated service or as a separate payment (individual APCs). We explained in the April 7, 2000 OPPS final rule with comment period (65 FR 18450) that we generally package the cost of drugs and radiopharmaceuticals into the APC payment rate for the procedure or treatment with which the products are usually furnished. Hospitals do not receive separate payment for packaged items and supplies, and hospitals may not bill beneficiaries separately for any packaged items and supplies whose costs are recognized and paid within the national OPPS payment rate for the associated procedure or service.

(Transmittal A–01–133, issued on November 20, 2001, explains in greater detail the rules regarding separate payment for packaged services.)

Packaging costs into a single aggregate payment for a service, procedure, or episode-of-care is a fundamental principle that distinguishes a prospective payment system from a fee schedule. In general, packaging the costs of items and services into the payment for the primary procedure or service with which they are associated encourages hospital efficiencies and also enables hospitals to manage their resources with maximum flexibility.

Section 1833(t)(16)(B) of the Act set the threshold for establishing separate APCs for drugs and biologicals at $50 per administration for CYs 2005 and 2006. Therefore, for CYs 2005 and 2006, we paid separately for drugs, biologicals, and radiopharmaceuticals whose per day cost exceeded $50 and packaged the costs of drugs, biologicals, and radiopharmaceuticals whose per day cost was equal to or less than $50 into the procedures with which they were billed. For CY 2007, the packaging threshold for drugs, biologicals, and radiopharmaceuticals that were not new and did not have pass-through status was established at $55. For CYs 2008 and 2009, the packaging threshold for drugs, biologicals, and radiopharmaceuticals that were not new and did not have pass-through status was established at $60. For CY 2010, the packaging threshold for drugs, biologicals, and radiopharmaceuticals that were not new and did not have pass-through status was established at $65. For CY 2011, the packaging threshold for drugs, biologicals, and radiopharmaceuticals that were not new and did not have pass-through status was established at $70. The methodology used to establish the $55 threshold for CY 2007, the $60 threshold for CYs 2008 and 2009, the $65 threshold for CY 2010, the $70 threshold for CY 2011, and our proposed approach for CY 2012 are discussed in more detail in section V.B.2.b. of this final rule with comment period.

2. Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

a. Background

As indicated in section V.B.1. of this final rule with comment period, in accordance with section 1833(t)(16)(B) of the Act, the threshold for establishing separate APCs for payment of drugs and biologicals was set to $50 per administration during CYs 2005 and 2006. In CY 2007, we used the four quarter moving average Producer Price Index (PPI) levels for Pharmaceutical Preparations (Prescription) to trend the $50 threshold forward from the third quarter of CY 2005 (when the Pub. L. 108–173 mandated threshold became effective) to the third quarter of CY 2007. We then rounded the resulting dollar amount to the nearest $5 increment in order to determine the CY 2007 threshold amount of $55. Using the same methodology as that used in CY 2007 (which is discussed in more detail in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 through 68086)), we set the packaging threshold for establishing separate APCs for drugs and biologicals at $60 for CYs 2008 and 2009. For CY 2010, we set the packaging threshold at $65; and for CY 2011, we set the packaging threshold at $70.

Following the CY 2007 methodology, in the CY 2012 OPPS/ASC proposed rule, we used the most recently available four quarter moving average PPI levels to trend the $50 threshold forward from the third quarter of CY 2005 to the third quarter of CY 2012 and rounded the resulting dollar amount ($77.63) to the nearest $5 increment, which yielded a figure of $80, which we proposed as the packaging threshold for CY 2012. In performing this calculation, we used the most recent forecast of the quarterly index levels for the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics (BLS) series code WPUSI07003) from CMS' Office of the Actuary (OACT). (We note that we did not propose a change to the PPI that is used to calculate the threshold for CY 2012; rather, this change in terminology reflects a change to the BLS naming convention for this series.) We refer below to this series generally as the PPI for Prescription Drugs.

We chose this PPI as it reflects price changes associated with the average mix of all pharmaceuticals in the overall economy. In addition, we chose this price series because it is publicly available and regularly published, improving public access and transparency. Forecasts of the PPI for Prescription Drugs are developed by IHS Global Insight, Inc., a nationally recognized economic and financial forecasting firm. As actual inflation for past quarters replaced forecasted amounts, the PPI estimates for prior quarters have been revised (compared with those used in the CY 2007 OPPS/ASC final rule with comment period) and have been incorporated into our calculation. Based on the calculations described above, we proposed a packaging threshold for CY 2012 of $80. (For a more detailed discussion of the OPPS drug packaging threshold and the use of the PPI for Prescription Drugs, we refer readers to the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 through 68086).)

b. Cost Threshold for Packaging of Payment for HCPCS Codes That Describe Certain Drugs, Nonimplantable Biologicals, and Therapeutic Radiopharmaceuticals (''Threshold-Packaged Drugs'')

In the CY 2012 OPPS/ASC proposed rule (76 FR 42252 through 42253), we calculated on a HCPCS code-specific basis the per day cost of all drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals (collectively called ''threshold-packaged'' drugs) that had a HCPCS code in CY 2010 and were paid (via packaged or separate payment) under the OPPS in order to determine their proposed CY 2012 packaging status. We used data from CY 2010 claims processed before January 1, 2011 for this calculation. However, we did not perform this calculation for those drugs and biologicals with multiple HCPCS codes that include different dosages as described in section V.B.2.c. of this final rule with comment period or for diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals that we proposed to continue to package in CY 2012, as discussed in section V.B.2.d. of this final rule with comment period.

In order to calculate the per day costs for drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals to determine their proposed packaging status in CY 2012, we used the methodology that was described in detail in the CY 2006 OPPS proposed rule (70 FR 42723 through 42724) and finalized in the CY 2006 OPPS final rule with comment period (70 FR 68636 through 70 FR 68638). For each drug and nonimplantable biological HCPCS code, we used an estimated payment rate of ASP+4 percent (which is the payment rate we proposed for separately payable drugs and nonimplantable biologicals for CY 2012, as discussed in more detail in section V.B.3.b. of the proposed rule and this final rule with comment period) to calculate the CY 2012 proposed rule per day costs. We used the manufacturer submitted ASP data from the fourth quarter of CY 2010 (data that were used for payment purposes in the physician's office setting, effective April 1, 2011) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2012 we proposed to use payment rates based on the ASP data from the fourth quarter of CY 2010 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to the proposed rule (which were referenced in section XVII. of the proposed rule and available via the Internet) because these are the most recent data available for use at the time of development of the proposed rule. These data were also the basis for drug payments in the physician's office setting, effective April 1, 2011. For items that did not have an ASP-based payment rate, such as some therapeutic radiopharmaceuticals, we used their mean unit cost derived from the CY 2010 hospital claims data to determine their per day cost. We proposed to package items with a per day cost less than or equal to $80 and identified items with a per day cost greater than $80 as separately payable. Consistent with our past practice, we crosswalked historical OPPS claims data from the CY 2010 HCPCS codes that were reported to the CY 2011 HCPCS codes that we displayed in Addendum B of the proposed rule (which was referenced in section XVII. of the proposed rule and available via the Internet) for payment in CY 2012.

Comment: The majority of commenters objected to the proposed increase in the OPPS packaging threshold to $80 for CY 2012. Many stated that the $10 increase in the threshold from CY 2011 was larger than expected because recent increases in the packaging threshold have occurred in $5 increments. Several commenters recommended that CMS consider either eliminating the drug packaging threshold and providing separate payment for all drugs with HCPCS codes or freezing the packaging threshold at $70 for CY 2012. One commenter, in particular, suggested that CMS freeze the packaging threshold at $70 for at least 3 years. Many commenters objected to the use of a packaging threshold under the OPPS when one is not used for physician's office payment. These commenters expressed concern that the packaging threshold may impede beneficiary access to lower cost packaged drugs in the HOPD setting. A few commenters suggested that CMS limit increases in the packaging threshold amount to the market basket update for the year. One commenter also recommended that CMS not round up the threshold amount to the nearest $5 increment and, instead, defer increases in the threshold until changes in prices exceed $5.

Some commenters believed that eliminating the packaging threshold and paying separately for all drugs in the HOPD setting would allow a more accurate calculation of the separately payable payment amount for drugs (otherwise referred to as the ASP+X calculation).

Response: As discussed in detail in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66757 through 66758), the CY 2009 OPPS/ASC final rule with comment period (73 FR 68643), the CY 2010 OPPS/ASC final rule with comment period (74 FR 60485 through 60487), and the CY 2011 final rule with comment period (75 FR 71940 through 71943), we continue to believe that unpackaging payment for all drugs, biologicals and radiopharmaceuticals is inconsistent with the concept of a prospective payment system and that such a change could create an additional reporting burden for hospitals. The OPPS and the MPFS that applies to physician's services are fundamentally different payment systems with essential differences in their payment policies and structures. Specifically, the OPPS is a prospective payment system based on the concept of payment for groups of services that share clinical and resource characteristics. Payment is made under the OPPS according to prospectively established payment rates that are related to the relative costs of hospital resources for services. When physician's services are furnished in an office setting, they are paid under the MPFS, which is a fee schedule based on the realative value of each component. Under the MPFS, separate payment is made for each service provided in the physician's office; when individual drugs are furnished in the physician's office, they are generally paid under the ASP methodology. In contrast, the OPPS includes various drugs within a prospective payment system, where payment for certain drugs is packaged into the associated procedure payment for the APC group. Given the fundamental differences in the way payment is made in an HOPD and a physician's office setting, differences in payment are to be expected.

In general, we do not believe that our packaging methodology under the OPPS results in limited beneficiary access to drugs because packaging is a fundamental component of a prospective payment system that accounts for the cost of certain items and services in larger payment bundles, recognizing that some clinical cases may be more costly and others less costly, but that, on average, OPPS payment is appropriate for the services provided. The growing utilization associated with packaged drugs and biologicals in our claims data suggests Medicare beneficiaries have sufficient access to these items.

We note that, in CYs 2005 and 2006, the statutorily mandated drug packaging threshold was set at $50, and we continue to believe that it is appropriate to continue a modest drug packaging threshold for the CY 2012 OPPS for the reasons set forth below. As stated in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68086), we believe that packaging certain items is a fundamental component of a prospective payment system, that packaging these items does not lead to beneficiary access issues and does not create a problematic site of service differential, that the packaging threshold is reasonable based on the initial establishment in law of a $50 threshold for the CY 2005 OPPS, that updating the $50 threshold is consistent with industry and government practices, and that the PPI for Prescription Drugs is an appropriate mechanism to gauge Part B drug inflation. Therefore, because of our continued belief that packaging is a fundamental component of a prospective payment system that continues to provide important flexibility and efficiency in the delivery of high quality hospital outpatient services, we are not adopting the commenters' recommendations to pay separately for all drugs, biologicals, and radiopharmaceuticals for CY 2012 or to eliminate or to freeze the packaging threshold at $70.

We disagree with the commenters who suggested that CMS should limit increases in the outpatient drug packaging threshold amount to the market basket update for the year. As stated above, we continue to believe that updating the $50 threshold is consistent with industry and government practices and that the PPI for Prescription Drugs is an appropriate mechanism to gauge Part B drug inflation. As we stated in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085), we believe that the PPI for Prescription Drugs reflects price changes at the wholesale or manufacturer stage. Because OPPS payment rates for drugs and biologicals are generally based on the ASP data that are reported by their manufacturers, we believe that the PPI for Prescription Drugs is an appropriate price index to use to update the packaging threshold for CY 2007 and beyond.

In contrast, the market basket update contains numerous price proxies, including, but not limited to, proxies for wages and salaries, utilities, and

nonlabor-related expenses, that are not related to price increases for prescription drugs. Therefore, we believe that the market basket as a whole is not an appropriate mechanism for determining the outpatient drug packaging threshold amount. Within the calculation of the market basket update, we use the PPI for Prescription Drugs specifically to measure the price growth for prescription drugs, but price changes for prescription drugs are only one component of price changes for the numerous items and services hospitals purchase. Additionally, we disagree with the commenters' suggestion that we not round up the packaging threshold to the nearest $5 increment and, instead, defer any increases in the threshold until changes in prices exceed $5. We note that we equally round up or round down to the nearest $5 increment, and we continue to believe that rounding to the nearest $5 increment more accurately updates the 2005 statutorily mandated drug packaging threshold.

Finally, we believe that our continued application of the methodology initially adopted in CY 2007 to update the drug packaging threshold does not inhibit our ability to pay accurately for drugs and biologicals. We have made several refinements to the ASP+X drug payment methodology under the OPPS for nonpass-through drugs and biologicals over the past several years to improve its accuracy. During that time, we have continued to implement our established methodology for annually updating the drug packaging threshold. For CY 2010, we finalized an overhead adjustment methodology for determining payment for separately payable drugs without pass-through status while we have continued to consistently apply the methodology described above to update the drug packaging threshold.

Since publication of the CY 2012 OPPS/ASC proposed rule, consistent with our policy of updating the packaging threshold with more recently available data for the final rule, we have again followed the CY 2007 methodology for CY 2012 and used updated four quarter moving average PPI index levels provided by the CMS Office of the Actuary to trend the $50 threshold forward from the third quarter of CY 2005 to the third quarter of CY 2012. We then rounded the resulting dollar updated dollar amount ($77.44) to the nearest $5 increment, which yielded a figure of $75. We note that this calculation, by using the most recent forecast of the quarterly PPI index levels, resulted in a decrease in the trended dollar amount from $77.63 in the CY 2012 proposed rule to $77.44 for this final rule with comment period. Because it is our policy to round the dollar amount to the nearest $5 increment, the slight decrease in the trended dollar amount has resulted in a reduced packaging threshold, from $80 in the proposed rule, to a final CY 2012 packaging threshold of $75. Therefore, after consideration of the public comments we received, and consistent with our established methodology for establishing the packaging threshold using the most recent PPI forecast data, we are adopting a CY 2012 packaging threshold of $75.

Our policy during previous cycles of the OPPS has been to use updated ASP and claims data to make final determinations of the packaging status of HCPCS codes for drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals for the final rule with comment period. We note that it is also our policy to make an annual packaging determination for a HCPCS code only when we develop the OPPS/ASC final rule with comment period for the update year. Only HCPCS codes that are identified as separately payable in the final rule with comment period are subject to quarterly updates. For our calculation of per day costs of HCPCS codes for drugs and nonimplantable biologicals in this CY 2012 OPPS/ASC final rule with comment period, we proposed to use ASP data from the first quarter of CY 2011, which is the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective July 1, 2011, along with updated hospital claims data from CY 2010. We note that we also proposed to use these data for budget neutrality estimates and impact analyses for this CY 2012 OPPS/ASC final rule with comment period.

Payment rates for HCPCS codes for separately payable drugs and nonimplantable biologicals included in Addenda A and B to this final rule with comment period are based on ASP data from the second quarter of CY 2011. These data are the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective October 1, 2011. These physician's office payment rates will then be updated in the January 2012 OPPS update, based on the most recent ASP data to be used for physician's office and OPPS payment as of January 1, 2012. For items that do not currently have an ASP-based payment rate as proposed, we recalculate their mean unit cost from all of the CY 2010 claims data and updated cost report information available for this CY 2012 final rule with comment period to determine their final per day cost.

Consequently, the packaging status of some HCPCS codes for drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals in this CY 2012 OPPS/ASC final rule with comment period may be different from the same drug HCPCS code's packaging status determined based on the data used for the proposed rule. Under such circumstances, we proposed to continue to follow the established policies initially adopted for the CY 2005 OPPS (69 FR 65780) in order to more equitably pay for those drugs whose median cost fluctuates relative to the proposed CY 2012 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2011. Specifically, consistent with our historical practice, we applied the following policies to these HCPCS codes for drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals whose relationship to the $75 drug packaging threshold changes based on the updated drug packaging threshold and on the final updated data:

- HCPCS codes for drugs and nonimplantable biologicals that were paid separately in CY 2011 and that were proposed for separate payment in CY 2012, and that then have per day costs equal to or less than $75, based on the updated ASPs and hospital claims data used for this CY 2012 final rule with comment period, will continue to receive separate payment in CY 2012.
- HCPCS codes for drugs and nonimplantable biologicals that were packaged in CY 2011 and that are proposed for separate payment in CY 2012, and that then have per day costs equal to or less than $75, based on the updated ASPs and hospital claims data used for this CY 2012 final rule with comment period, will remain packaged in CY 2012.
- HCPCS codes for drugs and nonimplantable biologicals for which we proposed packaged payment in CY 2012 but then have per day costs greater than $75, based on the updated ASPs and hospital claims data used for this CY 2012 final rule with comment period, will receive separate payment in CY 2012.

We did not receive any public comments on our proposal to apply the established policies initially adopted for the CY 2005 OPPS (69 FR 65780) in order to more equitably pay for those drugs whose median cost fluctuates relative to the CY 2012 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2011. Therefore, we are

finalizing our proposal, without modification, for CY 2012.

We note that HCPCS codes J2513 (Pentastarch 10% solution), J3310 (Perphenazine injection), and J9351 (Topotecan) were paid separately for CY 2011 and were proposed for separate payment in CY 2012 and had final per day costs of less than the $75 drug packaging threshold, based on updated ASPs and the CY 2010 hospital claims data available for this CY 2012 final rule with comment period. Therefore, HCPCS codes J2513, J3310, and J9351 will continue to be paid separately in CY 2012 according to the established methodology set forth above.

In addition, we proposed to provide separate payment for HCPCS code J2597 (Inj desmopressin acetate) in CY 2012, which was packaged in CY 2011. Using updated ASPs and the CY 2010 hospital claims data available for this final rule with comment period, HCPCS code J2597 now has a per day cost of less than $75. In accordance with our established policy for such cases, for CY 2012, we are packaging payment for HCPCS code J2597.

We also proposed to package HCPCS codes 90378 (Rsv ig, im, 50mg), J0364 (Apomorphine hydrochloride), J1324 (Enfuvirtide injection), J1642 (Inj heparin sodium per 10 u), J1644 (Inj heparin sodium per 1000u), J1756 (Iron sucrose injection), J2700 (Oxacillin sodium injeciton), J3030 (Sumatriptan succinate/6 MG), J9070 (Cyclophosphamide 100 MG inj), J9185 (Fludarabine phosphate inj), J9206 (Irinotecan injection), J9390 (Vinorelbine tartrate inj), and Q4103 (Oasis burn matrix) . Using updated ASPs and the CY 2010 hospital claims data available for this final rule with comment period, HCPCS codes 90378, J0364, J1324, J1642, J1644, J1756, J2700, J3030, J9070, J9185, J9206, J9390, and Q4103 now have per day costs greater than $75. In accordance with our established policy for such cases, for CY 2012 we will pay for HCPCS codes 90378, J0364, J1324, J1642, J1644, J1756, J2700, J3030, J9070, J9185, J9206, J9390, and Q4103 separately.

Finally, because we did not have claims data for HCPCS code J9213 (Interferon alfa-2a inj) in the CY 2012 OPPS/ASC proposed rule, we had proposed a status indicator of ''E'' for this product in CY 2012. However, since publication of the proposed rule, we have received claims data and, because the per day cost for this product of approximately $70 is less than the final $75 CY 2012 packaging threshold, the product is packaged and has a CY 2012 status indicator of ''N.''

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60485 through 60489), we implemented a policy to treat oral and injectable forms of 5–HT3 antiemetics comparably to all other threshold packaged drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals under our standard packaging methodology of packaging drugs with a per day cost less than $65. In the CY 2012 OPPS/ASC proposed rule (76 FR 42252), we proposed for CY 2012 to continue our policy of not exempting these 5–HT3 antiemetic products from our standard packaging methodology. For CY 2012, we proposed to package payment for all of the 5–HT3 antiemetics except palonosetron hydrochloride, which for CY 2012 has an estimated per day cost, from the CY 2010 claims data, above the proposed CY 2012 drug packaging threshold. Our rationale for this policy is outlined in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60487 through 60488).

Comment: Several commenters suggested that CMS reinstate its policy of separate payment for 5–HT3 antiemetics, which are a class of drugs often used as part of an anti-cancer treatment regimen to treat nausea.

Response: We continue to believe that use of these antiemetics is an integral part of an anti-cancer treatment regimen and that OPPS claims data demonstrate their increasingly common hospital outpatient utilization. As we stated in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60488), we no longer believe that a specific exemption to our standard drug payment methodology is necessary to ensure access to the most appropriate antiemetic products for Medicare beneficiaries. We continue to believe that our analysis conducted in the CY 2010 OPPS/ASC proposed rule on 5–HT3 antiemetics (74 FR 35320), along with the historical stability in prescribing patterns for these products and the availability of generic alternatives for several of these products, allow us to continue our policy of specifically not exempting these products from the OPPS drug packaging threshold.

Comment: One commenter recommended that CMS not package any drugs used in anti-cancer regimens.

Response: We disagree with the commenter for the reasons mentioned above. We believe that packaging certain items, including items used in anti-cancer regimens, is a fundamental component of a prospective payment system, and is an essential feature that distinguishes a prospective payment system from a fee schedule. We do not believe that packaging drugs used in an anti-cancer regimen or in outpatient treatment of other significant diseases leads to beneficiary access issues. This finding is confirmed by our analysis of hospital claims data in which we have found that beneficiaries appear to have adequate access to cancer treatments, as is signified by ongoing volume growth in cancer-related APCs and stability in prescribing products for anti-cancer drugs such as 5–HT3 antiemetics, for which CMS has continued to observe volume growth, even after we ended our multiyear exemption from the packaging threshold for these products. In summary, after consideration of the public comments we received, we are finalizing our proposal to continue our policy of not exempting 5–HT3 antiemetics from the drug packaging threshold for CY 2012. In addition, we are not providing any exceptions to the standard drug packaging methodology for any class of drugs, including anti-cancer therapies, for CY 2012. However, we note that the 5–HT3 antiemetic product described by HCPCS code J2469 (palonosetron hydrocholride) has a CY 2012 estimated per day cost, from the CY 2010 claims data, above the CY 2012 drug packaging threshold and, therefore, will receive separate payment in CY 2012.

c. Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological But Different Dosages

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66776), we began recognizing, for OPPS payment purposes, multiple HCPCS codes reporting different dosages for the same covered Part B drugs or biologicals in order to reduce hospitals' administrative burden by permitting them to report all HCPCS codes for drugs and biologicals. In general, prior to CY 2008, the OPPS recognized for payment only the HCPCS code that described the lowest dosage of a drug or biological. We extended this recognition to multiple HCPCS codes for several other drugs under the CY 2009 OPPS (73 FR 68665). During CYs 2008 and 2009, we applied a policy that assigned the status indicator of the previously recognized HCPCS code to the associated newly recognized code(s), reflecting the packaged or separately payable status of the new code(s). In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66775), we explained that once claims data were available for these previously unrecognized HCPCS codes, we would determine the packaging status and resulting status indicator for each HCPCS code according to the general, established HCPCS code-specific

methodology for determining a code's packaging status for a given update year. However, we also stated that we planned to closely follow our claims data to ensure that our annual packaging determinations for the different HCPCS codes describing the same drug or biological did not create inappropriate payment incentives for hospitals to report certain HCPCS codes instead of others.

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60490 through 60491), we finalized a policy to make a single packaging determination for a drug, rather than an individual HCPCS code, when a drug has multiple HCPCS codes describing different dosages. We analyzed CY 2008 claims data for the HCPCS codes describing different dosages of the same drug or biological that were newly recognized in CY 2008 and found that our claims data would result in several different packaging determinations for different codes describing the same drug or biological. Furthermore, we found that our claims data included few units and days for a number of newly recognized HCPCS codes, resulting in our concern that these data reflected claims from only a small number of hospitals, even though the drug or biological itself may be reported by many other hospitals under the most common HCPCS code. Based on these findings from our first available claims data for the newly recognized HCPCS codes, we believed that adopting our standard HCPCS code-specific packaging determinations for these codes could lead to payment incentives for hospitals to report certain HCPCS codes instead of others, particularly because we do not currently require hospitals to report all drug and biological HCPCS codes under the OPPS in consideration of our previous policy that generally recognized only the lowest dosage HCPCS code for a drug or biological for OPPS payment.

For CY 2012, we continue to believe that adopting the standard HCPCS code-specific packaging determinations for these codes could lead to payment incentives for hospitals to report certain HCPCS codes for drugs instead of others. Making packaging determinations on a drug-specific basis eliminates these incentives and allows hospitals flexibility in choosing to report all HCPCS codes for different dosages of the same drug or only the lowest dosage HCPCS code. Therefore, in the CY 2012 OPPS/ASC proposed rule (76 FR 42253 through 42255), we proposed to continue our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages in CY 2012.

For CY 2012, in order to propose a packaging determination that is consistent across all HCPCS codes that describe different dosages of the same drug or biological, we aggregated both our CY 2010 claims data and our pricing information at ASP+4 percent across all of the HCPCS codes that describe each distinct drug or biological in order to determine the mean units per day of the drug or biological in terms of the HCPCS code with the lowest dosage descriptor. All HCPCS codes listed in Table 30 of the proposed rule (76 FR 42254 through 42255) had ASP pricing information available for the CY 2012 OPPS/ASC proposed rule. Therefore, we multiplied the weighted average ASP+4 percent per unit payment amount across all dosage levels of a specific drug or biological by the estimated units per day for all HCPCS codes that describe each drug or biological from our claims data to determine the estimated per day cost of each drug or biological at less than or equal to $80 (whereupon all HCPCS codes for the same drug or biological would be packaged) or greater than $80 (whereupon all HCPCS codes for the same drug or biological would be separately payable).

Although we did not receive any public comments regarding this methodology, as noted in section V.B.2.b. of this final rule with comment period, the final CY 2012 drug packaging threshold is $75, and not $80 as had been proposed in the CY 2012 OPPS proposed rule. Therefore, in preparation for the CY 2012 final rule with comment period, we again aggregated both our CY 2010 claims data and our pricing information at ASP+4 percent across all of the HCPCS codes that describe each distinct drug or biological in order to determine the mean units per day of the drug or biological in terms of the HCPCS code with the lowest dosage descriptor for those drugs listed in Table 30 of the proposed rule (76 FR 42254 through 42255). We then multiplied the weighted average ASP+4 percent per unit payment amount across all dosage levels of a specific drug or biological by the estimated units per day for all HCPCS codes that describe each drug or biological from our claims data to determine the estimated per day cost of each drug or biological at less than or equal to $75 (whereupon all HCPCS codes for the same drug or biological would be packaged) or greater than $75 (whereupon all HCPCS codes for the same drug or biological would be separately payable). In repeating this analysis, we found that two products for which we had proposed a CY 2012 status indicator of ''N,'' HCPCS J1642 (Injection, heparin sodium (heparin lock flush), per 10 units) and J1644 (Injection, heparin sodium, per 1000 units) had a recalculated per day cost in excess of the $75 packaging threshold. Therefore, HCPCS J1642 and J1644 are assigned status indicator ''K'' and will be separately payable in CY 2012.

With the exception of the changed status indicators for HCPCS J1642 and J1644, we are adopting as final the proposed packaging status of each drug and biological HCPCS code to which the aforementioned methodology applies. The products affected are displayed in Table 36 below.

BILLING CODE 4120–01–P

TABLE 36.--HCPCS CODES TO WHICH THE CY 2012 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY APPLIES

CY 2012 HCPCS Code	CY 2012 Long Descriptor	CY 2012 SI
C9257	Injection, bevacizumab, 0.25 mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1020	Injection, methylprednisolone acetate, 20 mg	N
J1030	Injection, methylprednisolone acetate, 40 mg	N
J1040	Injection, methylprednisolone acetate, 80 mg	N
J1070	Injection, testosterone cypionate, up to 100 mg	N
J1080	Injection, testosterone cypionate, 1 cc, 200 mg	N
J1440	Injection, filgrastim (g-csf), 300 mcg	K
J1441	Injection, filgrastim (g-csf), 480 mcg	K
J1460	Injection, gamma globulin, intramuscular, 1 cc	K
J1560	Injection, gamma globulin, intramuscular over 10 cc	K
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	K
J1644	Injection, heparin sodium, per 1000 units	K
J1850	Injection, kanamycin sulfate, up to 75 mg	N
J1840	Injection, kanamycin sulfate, up to 500 mg	N
J2270	Injection, morphine sulfate, up to 10 mg	N
J2271	Injection, morphine sulfate, 100mg	N
J2788	Injection, rho d immune globulin, human, minidose, 50 micrograms (250 i.u.)	K
J2790	Injection, rho d immune globulin, human, full dose, 300 micrograms (1500 i.u.)	K
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg	N
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg	N
J3120	Injection, testosterone enanthate, up to 100 mg	N
J3130	Injection, testosterone enanthate, up to 200 mg	N
J3471	Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)	N

CY 2012 HCPCS Code	CY 2012 Long Descriptor	CY 2012 SI
J3472	Injection, hyaluronidase, ovine, preservative free, per 1000 usp units	N
J7050	Infusion, normal saline solution , 250 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml=1 unit)	N
J7030	Infusion, normal saline solution , 1000 cc	N
J7515	Cyclosporine, oral, 25 mg	N
J7502	Cyclosporine, oral, 100 mg	N
J8520	Capecitabine, oral, 150 mg	K
J8521	Capecitabine, oral, 500 mg	K
J9250	Methotrexate sodium, 5 mg	N
J9260	Methotrexate sodium, 50 mg	N
Q0164	Prochlorperazine maleate, 5 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen	N
Q0165	Prochlorperazine maleate, 10 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen	N
Q0167	Dronabinol, 2.5 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen	N
Q0168	Dronabinol, 5 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen	N
Q0169	Promethazine hydrochloride, 12.5 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV antiemetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen	N

CY 2012 HCPCS Code	CY 2012 Long Descriptor	CY 2012 SI
Q0170	Promethazine hydrochloride, 25 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV antiemetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen	N
Q0171	Chlorpromazine hydrochloride, 10 mg, oral, FDA approved prescription antiemetic, for use as a complete therapeutic substitute for an IV antiemetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen	N
Q0172	Chlorpromazine hydrochloride, 25 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen	N
Q0175	Perphenazine, 4 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen	N
Q0176	Perphenazine, 8 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen	N
Q0177	Hydroxyzine pamoate, 25 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen	N
Q0178	Hydroxyzine pamoate, 50 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen	N

BILLING CODE 4120–01–C

d. Packaging of Payment for Diagnostic Radiopharmaceuticals, Contrast Agents, and Implantable Biologicals (''Policy-Packaged'' Drugs and Devices)

Prior to CY 2008, the methodology of calculating a product's estimated per day cost and comparing it to the annual OPPS drug packaging threshold was used to determine the packaging status of drugs, biologicals, and radiopharmaceuticals under the OPPS (except for our CYs 2005 through 2009 exemption for 5–HT3 antiemetics). However, as established in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66766 through 66768), we began packaging payment for all diagnostic radiopharmaceuticals and contrast agents into the payment for the associated procedure, regardless of their per day costs. In addition, in CY 2009, we adopted a policy that packaged the payment for nonpass-through

implantable biologicals into payment for the associated surgical procedure on the claim (73 FR 68633 through 68636). We refer to diagnostic radiopharmaceuticals and contrast agents collectively as ''policy-packaged'' drugs and implantable biologicals as devices because, in CY 2010, we began to treat implantable biologicals as devices for all OPPS payment purposes.

According to our regulations at § 419.2(b), as a prospective payment system, the OPPS establishes a national payment rate that includes operating and capital-related costs that are directly related and integral to performing a procedure or furnishing a service on an outpatient basis including, but not limited to, implantable prosthetics, implantable durable medical equipment, and medical and surgical supplies. Packaging costs into a single aggregate payment for a service, encounter, or episode-of-care is a fundamental principle that distinguishes a prospective payment system from a fee schedule. In general, packaging the costs of items and services into the payment for the primary procedure or service with which they are associated encourages hospital efficiencies and also enables hospitals to manage their resources with maximum flexibility.

Prior to CY 2008, we noted that the proportion of drugs, biologicals, and radiopharmaceuticals that were separately paid under the OPPS had increased in recent years, a pattern that we also observed for procedural services under the OPPS. Our final CY 2008 policy that packaged payment for all nonpass-through diagnostic radiopharmaceuticals and contrast agents, regardless of their per day costs, contributed significantly to expanding the size of the OPPS payment bundles and is consistent with the principles of a prospective payment system.

As discussed in more detail in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68645 through 68649), we presented several reasons supporting our initial policy to package payment of diagnostic radiopharmaceuticals and contrast agents into their associated procedures on a claim. Specifically, we stated that we believed packaging was appropriate because: (1) The statutorily required OPPS drug packaging threshold has expired; (2) we believe that diagnostic radiopharmaceuticals and contrast agents function effectively as supplies that enable the provision of an independent service; and (3) section 1833(t)(14)(A)(iii) of the Act requires that payment for specified covered outpatient drugs (SCODs) be set prospectively based on a measure of average hospital acquisition cost.

For these reasons, we believe it is appropriate to continue to treat diagnostic radiopharmaceuticals and contrast agents differently from SCODs for CY 2012. Therefore, in the CY 2012 OPPS/ASC proposed rule (76 FR 42255 through 42256), we proposed to continue packaging payment for all contrast agents and diagnostic radiopharmaceuticals, collectively referred to as ''policy-packaged'' drugs, regardless of their per day costs, for CY 2012. We also proposed to continue to package the payment for diagnostic radiopharmaceuticals into the payment for the associated nuclear medicine procedure and to package the payment for contrast agents into the payment of the associated echocardiography imaging procedure, regardless of whether the agent met the OPPS drug packaging threshold. We refer readers to the CY 2010 OPPS/ASC final rule with comment period for a detailed discussion of nuclear medicine and echocardiography services (74 FR 35269 through 35277).

Comment: Several commenters objected to CMS' proposal to package payment for all diagnostic radiopharmaceuticals and contrast agents in CY 2012. A number of commenters stated that diagnostic radiopharmaceuticals and contrast agents with per day costs over the proposed OPPS drug packaging threshold are defined as SCODs and, therefore, should be assigned separate APC payments. In particular, the commenters questioned CMS' authority to classify groups of drugs, such as diagnostic radiopharmaceuticals and contrast agents, and implement packaging and payment policies that do not reflect their status as SCODs. Several comments disagreed with CMS' labeling of radiopharmaceuticals as supplies and stated instead that they should be treated as other SCODs. The commenters recommended that diagnostic radiopharmaceuticals should be subject to the same per day cost drug packaging threshold that applies to other drugs, in order to determine whether their payment would be packaged or made separately.

Response: As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66766), the CY 2009 OPPS/ASC final rule with comment period (73 FR 68645), the CY 2010 OPPS/ASC final rule with comment period (74 FR 60497), and the CY 2011 final rule with comment period (75 FR 71949), we continue to believe that diagnostic radiopharmaceuticals and contrast agents are different from other drugs and biologicals for several reasons. We note that the statutorily required OPPS drug packaging threshold has expired, and we continue to believe that diagnostic radiopharmaceuticals and contrast agents function effectively as supplies that enable the provision of an independent service and are always ancillary and supportive to an independent service, rather than themselves serving as the therapeutic modality. We packaged their payment in CYs 2008, 2009, 2010, and 2011 as ancillary and supportive services in order to provide incentives for greater efficiency and to provide hospitals with additional flexibility in managing their resources. In order for payment to be packaged, it is not necessary that all products be interchangeable in every case, and we recognized that, in some cases, hospitals may utilize higher cost products and, in some cases, lower cost products, taking into consideration the clinical needs of the patient and efficiency incentives. While we recognize this variability from case to case, on average under a prospective payment system, we expect payment to pay appropriately for the services furnished. In the past, we have classified different groups of drugs for specific payment purposes, as evidenced by our CY 2005 through CY 2009 policy regarding 5–HT3 antiemetics and their exemption from the drug packaging threshold. We note that we treat diagnostic radiopharmaceuticals and contrast agents as ''policy-packaged'' drugs because our policy is to package payment for all of the products in the category.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68634), we also began packaging the payment for all nonpass-through implantable biologicals into payment for the associated surgical procedure because we consider these products to always be ancillary and supportive to independent services, similar to implantable nonbiological devices that are always packaged. Therefore, we currently package payment for nonpass-through implantable biologicals, also known as devices that are surgically inserted or implanted (through a surgical incision or a natural orifice) into the body. As we stated in the CY 2012 OPPS/ASC proposed rule (76 FR 42256), we continue to believe that payment should be packaged for nonpass-through implantable biologicals for CY 2012.

Although our final CY 2009 policy (which we are continuing for CY 2012 as discussed below) packages payment for all diagnostic radiopharmaceuticals,

contrast agents, and nonpass-through implantable biologicals into the payment for their associated procedures, we are continuing to provide payment for these items in CY 2012 based on a proxy for average acquisition cost, as we did in CY 2009. We continue to believe that the line-item estimated cost for a diagnostic radiopharmaceutical, contrast agent, or nonpass-through implantable biological in our claims data is a reasonable approximation of average acquisition and preparation and handling costs for diagnostic radiopharmaceuticals, contrast agents, and nonpass-through implantable biologicals, respectively. As we discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68645), we believe that hospitals have adapted to the CY 2006 coding changes for radiopharmaceuticals and responded to our instructions to include charges for radiopharmaceutical handling in their charges for the radiopharmaceutical products. Further, because the standard OPPS packaging methodology packages the total estimated cost of each radiopharmaceutical, contrast agent, or nonimplantable biological on each claim (including the full range of costs observed on the claims) with the cost of associated procedures for ratesetting, this packaging approach is consistent with considering the average cost for radiopharmaceuticals, contrast agents, or nonpass-through implantable biologicals, rather than the median cost. In addition, as we noted in the CY 2009 OPPS/ASC final rule with comment period (72 FR 68646), these drugs, biologicals, or radiopharmaceuticals for which we have not established a separate APC and therefore, for which payment would be packaged rather than separately provided under the OPPS, are considered to not be SCODs. Similarly, drugs and biologicals with per day costs of less than $75 in CY 2012 that are packaged and for which a separate APC has not been established also are not SCODs. This reading is consistent with our final payment policy whereby we package payment for diagnostic radiopharmaceuticals, contrast agents, and nonpass-through implantable biologicals and provide payment for these products through payment for their associated procedures.

Comment: Several commenters disagreed with the proposal to distinguish between diagnostic and therapeutic radiopharmaceuticals for payment purposes under the OPPS. The commenters noted that CMS' identification of HCPCS code A9544 (Iodine I-131 tositumomab, diagnostic, per study dose) as a diagnostic radiopharmaceutical is inappropriate because this radiopharmaceutical functions as a dosimetric radiopharmaceutical and not as a diagnostic radiopharmaceutical. A few commenters explained that this particular radiopharmaceutical product is used as part of a therapeutic regimen and, therefore, should be considered therapeutic for OPPS payment purposes.

Response: As discussed above and in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66641), the CY 2009 OPPS/ASC final rule with comment period (73 FR 68645), the CY 2010 OPPS/ASC final rule with comment period (74 FR 60498), and the CY 2011 OPPS/ASC final rule with comment period (75 FR 71949), we classified each radiopharmaceutical into one of the two groups according to whether its long descriptor contained the term ''diagnostic'' or ''therapeutic''. HCPCS code A9544 contains the term ''diagnostic'' in its long code descriptor. Therefore, according to our established methodology, we continue to classify it as diagnostic for the purposes of CY 2012 OPPS payment. While we understand that this item is provided in conjunction with additional supplies, imaging tests, and therapeutic radiopharmaceuticals for patients already diagnosed with cancer, we continue to believe that the purpose of administering the product described by HCPCS code A9544 is diagnostic in nature. As we first stated in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66641), we continue to believe that the product described by HCPCS code A9544 is a diagnostic radiopharmaceutical. While it is not used to necessarily diagnose a general disease state, it is used to determine whether future therapeutic services would be beneficial to the patient and to determine how to proceed with therapy. We note that this is no different than the use of a lab test to guide therapy; the fact that the diagnostic test, a service which provides information, is used to guide therapy does not make it a therapeutic service, one which intended to improve a patient's clinical condition. While a group of associated services may be considered a therapeutic regimen by some commenters, HCPCS code A9544 is provided in conjunction with a series of nuclear medicine imaging scans. Many nuclear medicine studies using diagnostic radiopharmaceuticals are provided to patients who already have an established diagnosis. We continue to consider HCPCS code A9544 to be diagnostic because this item is provided for the purpose of conducting a diagnostic imaging procedure and is used to identify the proposed dose of the therapeutic agent to be provided at a later time.

Comment: Some commenters recommended using the ASP methodology to make payment for nonpass-through diagnostic radiopharmaceuticals, noting that it would be inconsistent for CMS to treat diagnostic radiopharmaceuticals as ''drugs'' for pass-through payment purposes and provide payment for diagnostic radiopharmaceuticals that have pass-through status based on the ASP methodology, and, then, after the diagnostic radiopharmaceutical's pass-through payment status expires, package the costs included in historical hospital claims data, rather than use the ASP methodology to pay for the product and treat the drug as a supply. A few commenters suggested that diagnostic radiopharmaceuticals could be paid separately as therapeutic radiopharmaceuticals are paid, which would allow manufacturers to voluntarily submit ASP data, and then default to the mean unit cost when ASP data are unavailable. One commenter asserted that CMS, by paying separately for diagnostic radiopharmaceuticals, could reduce Medicare program expenditures through reduced outlier payments, decreased variability in packaged costs, and more accurate payments for nuclear medicine procedures. The commenter stated that this would occur at ''only a modest cost'' to the OPPS.

Response: As we stated above, the statutorily required OPPS drug packaging threshold has expired, and we continue to believe that diagnostic radiopharmaceuticals and contrast agents are always ancillary and supportive to an independent service, rather than services themselves as the therapeutic modality. We disagree with commenters who suggest that nonpass-through diagnostic radiopharmaceuticals should be paid under the ASP methodology, that nonpass-through diagnostic radiopharmaceuticals should be paid as pass-through drugs and biologicals, or that nonpass-through diagnostic radiopharmaceuticals should be paid similarly to therapeutic radiopharmaceuticals. We continue to believe that nonpass-through diagnostic radiopharmaceuticals and contrast agents function effectively as supplies that enable the provision of an independent service. As we noted in the CY 2009 OPPS/ASC final rule with comment period (72 FR 68646) and restate above, drugs biologicals, or

radiopharmaceuticals for which we have not established a separate APC will receive packaged payment under the OPPS, and are considered to not be SCODs. We are continuing to provide payment for these items in CY 2012 based on a proxy for average acquisition cost. We continue to believe that the line-item estimated cost for a diagnostic radiopharmaceutical, contrast agent, or nonpass-through implantable biological in our claims data is a reasonable approximation of average acquisition and preparation and handling costs for diagnostic radiopharmaceuticals, contrast agents and nonpass-through implantable biologicals, respectively.

Further, as we have stated above, we believe that packaging costs into a single aggregate payment for a service, encounter, or episode-of-care is a fundamental principle that distinguishes a prospective payment system from a fee schedule. Our policy of packaging payment for diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals into the payment for the primary procedure or service with which they are associated encourages hospital efficiencies and also enables hospitals to manage their resources with maximum flexibility. Paying separately for diagnostic radiopharmaceuticals, contrast agents, or implantable biologicals, when each of these items is ancillary and supportive to an independent service, is contrary to this principle of a prospective payment system. Moreover, we note that SCODs, the payment methodology for which the commenters suggest that CMS adopt for diagnostic radiopharmaceuticals and contrast agents, receive OPPS payments based on the ASP+X methodology, which has consistently resulted in payment rates for SCODs that are equal to some amount greater than 100 percent of average sales price for these products; in CY 2012, as discussed in section V.B.3.b. of this final rule with comment period, SCODs will receive payment equal to 104 percent of ASP (ASP+4). We do not agree that payment for diagnostic radiopharmaceuticals and contrast agents, were it equal to the SCOD reimbursement amount calculated using the ASP+X methodology (or ASP+4 in CY 2012), could reduce outlier payments or APC variability to an extent sufficient enough to offset higher payment rates for these products under the ASP+X methodology. Finally, we do not agree with the commenter's assertion that separate payment for diagnostic radiopharmaceuticals would result in more accurate payment for these products. When CMS discussed possible ASP-based payment for diagnostic radiopharmaceuticals in the proposed and final rules for OPPS in CY 2006 (70 FR 68653 through 68657), numerous public commenters advised CMS that radiopharmaceuticals are formulated, distributed, compounded, and administered in unique distribution channels that preclude the determination of ASP relevant to a radiopharmaceutical HCPCS code. Further, commenters advised CMS that the manufacturer has no way to calculate the ASP of the end product patient dose and, consequently, could not supply CMS with accurate ASP data. In the intervening period between the CY 2006 final rule with comment period and the present, diagnostic radiopharmaceutical use has become more widespread, and their formulation more complex. Moreover, we believe that the phenomena described by commenters (including radiopharmaceutical manufacturers) in the comment period preceding the CY 2006 OPPS final rule, including the many preparatory and compounding steps between manufacturer and the patient's bedside, remain an impediment to manufacturers' calculations of accurate ASP, and thus accurate payment, for these products. Therefore, we do not believe that diagnostic radiopharmaceuticals should be paid separately under the OPPS such that manufacturers voluntarily can submit ASP data and then default to mean unit cost when ASP data are unavailable. We believe they are appropriately packaged into a single aggregate payment for the accompanying service provided.

Comment: A few commenters recommended that CMS provide separate payment for all diagnostic radiopharmaceuticals with a median per day cost greater than $200. The commenters believed that this recommendation is most consistent with the APC Panel's recommendation to CMS at the Panel's September 2007 meeting (described below). One commenter recommended that if CMS does not adopt the recommended $200 packaging threshold for diagnostic radiopharmaceuticals, that CMS adopt alternate packaging criteria providing separate payment when the cost of the product is greater than the total APC payment or when the coefficient of variation of the radiopharmaceutical exceeds a certain threshold.

Response: As we stated in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60499), at the September 2007 APC Panel meeting, the APC Panel recommended that CMS package radiopharmaceuticals with a median per day cost of less than $200 but pay separately for radiopharmaceuticals with a median per day cost of $200 or more. In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66638), we did not accept the APC Panel's recommendation, citing an inability to determine an empirical basis for paying separately for radiopharmaceuticals with a median per day cost in excess of $200. Instead, as proposed, for CY 2008, we finalized the packaging of payment for all diagnostic radiopharmaceuticals. Consistent with the CY 2012 OPPS/ASC proposed rule, for this final rule with comment period, we continue to believe that diagnostic radiopharmaceuticals are ancillary and supportive to the nuclear medicine procedures in which they are used and that their costs should be packaged into the primary procedures with which they are associated. We do not believe it would be appropriate to set a cost threshold for packaging diagnostic radiopharmaceuticals because, regardless of their per day cost, they are always supportive of an independent procedure that is the basis for administration of the diagnostic radiopharmaceutical. We also do not believe that it is appropriate to consider alternate packaging criteria for nonpass-through diagnostic radiopharmaceuticals. We continue to believe that, regardless of their per-day cost, these items are always supportive of an independent procedure that is the basis for administration of the diagnostic radiopharmaceutical. Therefore, our policy of packaging costs for these products into an associated APC continues to be the approach best suited for use in a prospective payment system.

Further, we note that the OPPS, as a prospective payment system, already includes the costs associated with diagnostic radiopharmaceuticals into the APCs for which the product is ancillary or supportive. We believe that the cost associated with a given product at a given point in time is immaterial because the OPPS, as a prospective payment system with payments based on average costs associated with a covered procedure, already takes into account both higher and lower input costs associated with that procedure. We also note that the OPPS, like many of Medicare's prospective payment systems, has policies in place to provide hospitals with additional outlier payments for certain high-cost cases whose costs exceed certain thresholds. This system of outliers already provides hospitals (or, in the case of partial hospitalization services, community

mental health centers) with additional reimbursement to offset costs that are high relative to the prospective payment amount, regardless of whether the costs are associated with radiopharmaceuticals or another relatively high-cost element in the patient's course of care.

Comment: Several commenters requested that CMS provide the public with data detailing how the full costs of diagnostic radiopharmaceuticals and contrast agents are reflected in procedural APC payments.

Response: The exact data used to calculate all of the proposed and final APC assignments and rates, including costs associated with diagnostic radiopharmaceuticals and contrast agents, for the CY 2012 OPPS are available for purchase under a CMS data use agreement through the CMS Web site at: *http://www.cms.gov/hospitalOutpatientPPS*. This Web site includes information about purchasing the ''OPPS Limited Data Set,'' which now includes the additional variables previously available only in the OPPS Identifiable Data Set, including ICD–9–CMS diagnosis codes and revenue code payment amounts. We typically have not posted the offset amounts by APC until publication of the final rule because we assign services to APCs based on our estimate of their full resource cost, including, but not limited to, packaged diagnostic radiopharmaceuticals.

In CY 2009, we adopted a final policy to package payment for all nonpass-through implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) like our longstanding policy that packaged payment for all implantable nonbiological devices without pass-through status. We finalized a policy in CY 2010 to package payment for nonpass-through implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) into the body, considering them to be devices.

For CY 2012, we proposed to continue to package payment for nonpass-through implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) into the body, considering them to be devices. Three of the products with expiring pass-through status for CY 2012 are biologicals that, according to their FDA-approved indications, are only surgically implanted. These products are described by HCPCS codes C9361 (Collagen matrix nerve wrap (NeuroMend Collagen Nerve Wrap), per 0.5 centimeter length), C9362 (Porous purified collagen matrix bone void filler (Integra Mozaik Osteoconductive Scaffold Strip), per 0.5 cc), and C9364 (Porcine implant, Permacol, per square centimeter). Like the two implantable biologicals with expiring pass-through status in CY 2011 that were discussed in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71948 through 71950), we believe that the three biologicals specified above with expiring pass-through status for CY 2012 differ from other biologicals paid under the OPPS in that they specifically function as surgically implanted devices. As a result of our proposed packaged payment methodology for nonpass-through implantable biologicals, we proposed to package payment for HCPCS codes C9361, C9362, and C9364 and assign them status indicator ''N'' for CY 2012. In addition, any new biologicals without pass-through status that are surgically inserted or implanted (through a surgical incision or a natural orifice) would be packaged in CY 2012. Moreover, for nonpass-through biologicals that may sometimes be used as implantable devices, we continue to instruct hospitals to not bill separately for the HCPCS codes for the products when used as implantable devices. This reporting ensures that the costs of these products that may be, but are not always, used as implanted biologicals are appropriately packaged into payment for the associated implantation procedures. We received no comments regarding our proposed packaging of nonpass-through implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) into the body.

After consideration of the public comments we received, we are finalizing our CY 2012 proposals, without modification, to continue to package payment for all nonpass-through diagnostic radiopharmaceuticals and contrast agents, and implantable biologicals that are surgically inserted or implanted into the body through a surgical incision or a natural orifice, regardless of their per day costs. Given the inherent function of contrast agents and diagnostic radiopharmaceuticals as ancillary and supportive to the performance of an independent procedure and the similar functions of implantable biologicals and nonbiological devices as integral to and supportive of the separately paid surgical procedures in which either may be used, we continue to view the packaging of payment for contrast agents, diagnostic radiopharmaceuticals, and implantable biologicals as a logical expansion of packaging payment for drugs and biologicals. In addition, as we initially established in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66768), we will continue to identify diagnostic radiopharmaceuticals specifically as those Level II HCPCS codes that include the term ''diagnostic'' along with a radiopharmaceutical in their long code descriptors, and therapeutic radiopharmaceuticals as those Level II HCPCS codes that include the term ''therapeutic'' along with a radiopharmaceutical in their long code descriptors. We believe that the current descriptors accurately discriminate between those pharmaceuticals which are used to gather information and those which are intended to improve the patient's medical condition.

In addition, any new biological lacking pass-through status that is surgically inserted or implanted through a surgical incision or natural orifice would be packaged in CY 2012. For three biologicals with expiring pass-through status and which differ from other biologicals paid under the OPPS in that they specifically function as surgically implanted devices, we are finalizing our proposal to package the products described by HCPCS code C9361, C9362, and C9364 and assign them status indictor ''N'' for this final rule with comment period.

We also are finalizing our proposal to package payment for contrast agents into the payment of the associated echocardiography imaging procedure, regardless of whether the agent met the OPPS drug packaging threshold. We refer readers to section III.D.1.e. of this final rule with comment period for more information on CMS' final echocardiography payment policy. For more information on how we set CY 2012 payment rates for nuclear medicine procedures in which diagnostic radiopharmaceuticals are used and echocardiography services provided with and without contrast agents, we refer readers to the CY 2010 OPPS/ASC final rule with comment period for a detailed discussion of nuclear medicine and echocardiography services (74 FR 35269 through 35277).

3. Payment for Drugs and Biologicals Without Pass-Through Status That Are Not Packaged

a. Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable and Packaged Drugs and Biologicals

Section 1833(t)(14) of the Act defines certain separately payable radiopharmaceuticals, drugs, and biologicals and mandates specific

payments for these items. Under section 1833(t)(14)(B)(i) of the Act, a ''specified covered outpatient drug'' (SCOD) is a covered outpatient drug, as defined in section 1927(k)(2) of the Act, for which a separate APC has been established and that either is a radiopharmaceutical agent or is a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002.

Under section 1833(t)(14)(B)(ii) of the Act, certain drugs and biologicals are designated as exceptions and are not included in the definition of ''specified covered outpatient drugs''. These exceptions are—

- A drug or biological for which payment is first made on or after January 1, 2003, under the transitional pass-through payment provision in section 1833(t)(6) of the Act.
- A drug or biological for which a temporary HCPCS code has not been assigned.
- During CYs 2004 and 2005, an orphan drug (as designated by the Secretary).

Section 1833(t)(14)(A)(iii) of the Act requires that payment for SCODs in CY 2006 and subsequent years be equal to the average acquisition cost for the drug for that year as determined by the Secretary, subject to any adjustment for overhead costs and taking into account the hospital acquisition cost survey data collected by the Government Accountability Office (GAO) in CYs 2004 and 2005, and later periodic surveys conducted by the Secretary as set forth in the statute. If hospital acquisition cost data are not available, the law requires that payment be equal to payment rates established under the methodology described in section 1842(o), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary. Most physician Part B drugs are paid at ASP+6 percent pursuant to sections 1842(o) and 1847A of the Act.

Section 1833(t)(14)(E) of the Act provides for an adjustment in OPPS payment rates for overhead and related expenses, such as pharmacy services and handling costs. Section 1833(t)(14)(E)(i) of the Act required MedPAC to study pharmacy overhead and related expenses and to make recommendations to the Secretary regarding whether, and if so how, a payment adjustment should be made to compensate hospitals for overhead and related expenses. Section 1833(t)(14)(E)(ii) of the Act authorizes the Secretary to adjust the weights for ambulatory procedure classifications for SCODs to take into account the findings of the MedPAC study.

In the CY 2006 OPPS proposed rule (70 FR 42728 through 42731), we discussed the June 2005 report by MedPAC regarding pharmacy overhead costs in HOPDs and summarized the findings of that study:

- Handling costs for drugs, biologicals, and radiopharmaceuticals administered in the HOPD are not insignificant;
- Little information is available about the magnitude of pharmacy overhead costs;
- Hospitals set charges for drugs, biologicals, and radiopharmaceuticals at levels that reflect their respective handling costs; and
- Hospitals vary considerably in their likelihood of providing services that utilize drugs, biologicals, or radiopharmaceuticals with different handling costs.

As a result of these findings, MedPAC developed seven drug categories for pharmacy and nuclear medicine handling costs based on the estimated level of hospital resources used to prepare the products (70 FR 42729). Associated with these categories were two recommendations for accurate payment of pharmacy overhead under the OPPS.

1. CMS should establish separate, budget neutral payments to cover the costs hospitals incur for handling separately payable drugs, biologicals, and radiopharmaceuticals.

2. CMS should define a set of handling fee APCs that group drugs, biologicals, and radiopharmaceuticals based on attributes of the products that affect handling costs; CMS should instruct hospitals to submit charges for these APCs and base payment rates for the handling fee APCs on submitted charges reduced to costs.

In response to the MedPAC findings, in the CY 2006 OPPS proposed rule (70 FR 42729), we discussed our belief that, because of the varied handling resources required to prepare different forms of drugs, it would be impossible to exclusively and appropriately assign a drug to a certain overhead category that would apply to all hospital outpatient uses of the drug. Therefore, our CY 2006 OPPS proposed rule included a proposal to establish three distinct Level II HCPCS C-codes and three corresponding APCs for drug handling categories to differentiate overhead costs for drugs and biologicals (70 FR 42730). We also proposed: (1) To combine several overhead categories recommended by MedPAC; (2) to establish three drug handling categories, as we believed that larger groups would minimize the number of drugs that may fit into more than one category and would lessen any undesirable payment policy incentives to utilize particular forms of drugs or specific preparation methods; (3) to collect hospital charges for these HCPCS C-codes for 2 years; and (4) to ultimately base payment for the corresponding drug handling APCs on CY 2006 claims data available for the CY 2008 OPPS.

In the CY 2006 OPPS final rule with comment period (70 FR 68659 through 68665), we discussed the public comments we received on our proposal regarding pharmacy overhead. The overwhelming majority of commenters did not support our proposal regarding pharmacy overhead and urged us not to finalize this policy, as it would be administratively burdensome for hospitals to establish charges for HCPCS codes for pharmacy overhead and to report them. Therefore, we did not finalize this proposal for CY 2006. Instead, we established payment for separately payable drugs and biologicals at ASP+6 percent, which we calculated by comparing the estimated aggregate cost of separately payable drugs and biologicals in our claims data to the estimated aggregate ASP dollars for separately payable drugs and biologicals, using the ASP as a proxy for average acquisition cost (70 FR 68642). Hereinafter, we refer to this methodology as our standard drug payment methodology. We concluded that payment for drugs and biologicals and pharmacy overhead at a combined ASP+6 percent rate would serve as an acceptable proxy for the combined acquisition and overhead costs of each of these products.

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68091), we finalized our proposed policy to provide a single payment of ASP+6 percent for the hospital's acquisition cost for the drug or biological and all associated pharmacy overhead and handling costs. The ASP+6 percent rate that we finalized was higher than the equivalent average ASP-based amount calculated from claims of ASP+4 percent according to our standard drug payment methodology, but we adopted payment at ASP+6 percent for stability while we continued to examine the issue of the costs of pharmacy overhead in the HOPD and awaited the accumulation of CY 2006 data as discussed in the CY 2006 OPPS/ASC final rule with comment period.

In the CY 2008 OPPS/ASC proposed rule (72 FR 42735), in response to ongoing discussions with interested parties, we proposed to continue our methodology of providing a combined payment rate for drug and biological acquisition and pharmacy overhead

costs while continuing our efforts to improve the available data. We also proposed to instruct hospitals to remove the pharmacy overhead charge for both packaged and separately payable drugs and biologicals from the charge for the drug or biological and report the pharmacy overhead charge on an uncoded revenue code line on the claim. We believed that this would provide us with an avenue for collecting pharmacy handling cost data specific to drugs in order to package the overhead costs of these items into the associated procedures, most likely drug administration services. Similar to the public response to our CY 2006 pharmacy overhead proposal, the overwhelming majority of commenters did not support our CY 2008 proposal and urged us to not finalize this policy (72 FR 66761). At its September 2007 meeting, the APC Panel recommended that hospitals not be required to separately report charges for pharmacy overhead and handling and that payment for overhead be included as part of drug payment. The APC Panel also recommended that CMS continue to evaluate alternative methods to standardize the capture of pharmacy overhead costs in a manner that is simple to implement at the organizational level (72 FR 66761).

Because of concerns expressed by the APC Panel and public commenters, we did not finalize the proposal to instruct hospitals to separately report pharmacy overhead charges for CY 2008. Instead, in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66763), we finalized a policy of providing payment for separately payable drugs and biologicals and their pharmacy overhead at ASP+5 percent as a transition from their CY 2007 payment of ASP+6 percent to payment based on the equivalent average ASP-based payment rate calculated from hospital claims according to our standard drug payment methodology, which was ASP+3 percent for the CY 2008 OPPS/ASC final rule with comment period. Hospitals continued to include charges for pharmacy overhead costs in the line-item charges for the associated drugs reported on claims.

For CY 2009, we proposed to pay separately payable drugs and biologicals at ASP+4 percent, including both SCODs and other drugs without CY 2009 OPPS pass-through status, based on our standard drug payment methodology. We also continued to explore mechanisms to improve the available data. We proposed to split the ''Drugs Charged to Patients'' cost center into two cost centers: One for drugs with high pharmacy overhead costs and one for drugs with low pharmacy overhead costs (73 FR 41492). We noted that we expected that CCRs from the proposed new cost centers would be available in 2 to 3 years to refine OPPS drug cost estimates by accounting for differential hospital markup practices for drugs with high and low overhead costs. After consideration of the public comments received and the APC Panel recommendations, we finalized a CY 2009 policy (73 FR 68659) to provide payment for separately payable nonpass-through drugs and biologicals based on costs calculated from hospital claims at a 1-year transitional rate of ASP+4 percent, in the context of an equivalent average ASP-based payment rate of ASP+2 percent calculated according to our standard drug payment methodology from the final rule claims data and cost report data. We did not finalize our proposal to split the single standard ''Drugs Charged to Patients'' cost center into two cost centers largely due to concerns raised by hospitals about the associated administrative burden. Instead, we indicated in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68659) that we would continue to explore other potential approaches to improve our drug cost estimation methodology, thereby increasing payment accuracy for separately payable drugs and biologicals.

In response to our proposals for the CY 2008 and CY 2009 OPPS, a group of pharmacy stakeholders (hereinafter referred to as the pharmacy stakeholders), including some cancer hospitals, some pharmaceutical manufacturers, and some hospital and professional associations, commented that we should pay an acquisition cost of ASP+6 percent for separately payable drugs, should substitute ASP+6 percent for the packaged cost of all packaged drugs and biologicals on procedure claims, and should redistribute the difference between the aggregate estimated packaged drug cost in claims and payment for all drugs, including packaged drugs at ASP+6 percent, as separate pharmacy overhead payments for separately payable drugs. They indicated that this approach would preserve the aggregate drug cost observed in the claims data, while significantly increasing payment accuracy for individual drugs and procedures by redistributing drug cost from packaged drugs. Their suggested approach would provide a separate overhead payment for each separately payable drug or biological at one of three different levels, depending on the pharmacy stakeholders' assessment of the complexity of pharmacy handling associated with each specific drug or biological (73 FR 68651 through 68652). Each separately payable drug or biological HCPCS code would be assigned to one of the three overhead categories, and the separate pharmacy overhead payment applicable to the category would be made when each of the separately payable drugs or biologicals was paid.

In the CY 2010 OPPS/ASC proposed rule (74 FR 35332), we acknowledged the limitations of our data and our availability to find a method to improve that data in a way that did not impose unacceptable administrative burdens on providers. Accepting that charge compression was a reasonable but unverifiable supposition, we proposed to redistribute between one-third and one-half of the estimated overhead cost associated with coded packaged drugs and biologicals with an ASP. This proposed redistribution resulted in our proposal to pay for the acquisition and pharmacy overhead costs of separately payable drugs and biologicals that did not have pass-through payment status at ASP+4 percent. We calculated estimated overhead cost for coded packaged drugs and biologicals by determining the difference between the aggregate claims cost for coded packaged drugs and biologicals with an ASP and the ASP dollars (ASP multiplied by the drug's or biological's units in the claims data) for those same coded drugs and biologicals. This difference was our estimated overhead cost for coded packaged drugs and biologicals.

In the CY 2010 OPPS/ASC proposed rule (74 FR 35326 through 35333), we stated that we believed that between one-third and one-half of the estimated $395 million total in pharmacy overhead costs included in our claims data for coded packaged drugs and biologicals with reported ASP data, specifically approximately $150 million of those costs, should be attributed to separately payable drugs and biologicals. We stated that the $150 million serves as the adjustment for the pharmacy overhead costs of separately payable drugs and biologicals. As a result, we also proposed to reduce the costs of coded drugs and biologicals that are packaged into payment for procedural APCs to offset the $150 million adjustment to payment for separately payable drugs and biologicals. In addition, we proposed that any redistribution of pharmacy overhead cost that may arise from the CY 2010 final rule with comment period data would occur only from some drugs and biologicals to other drugs and biologicals, thereby maintaining the

estimated total cost of drugs and biologicals that we calculate based on the charges and costs reported by hospitals on claims and cost reports. As a result of this approach, no redistribution of cost would occur from other services to drugs and biologicals or vice versa.

Using our CY 2010 proposed rule data, and applying our longstanding methodology for calculating the total cost of separately payable drugs and biologicals in our claims compared to the ASP dollars for the same drugs and biologicals, without applying the proposed overhead cost redistribution, we determined that the estimated aggregate cost of separately payable drugs and biologicals (status indicators ''K'' and ''G''), including acquisition and pharmacy overhead costs, was equivalent to ASP − 2 percent. Therefore, under the standard methodology for establishing payment for separately payable drugs and biologicals, we would have paid for those drugs and biologicals at ASP − 2 percent for CY 2010, their equivalent average ASP-based payment rate. We also determined that the estimated aggregate cost of coded packaged drugs and biologicals with an ASP (status indicator ''N''), including acquisition and pharmacy overhead costs, was equivalent to ASP+247 percent.

While we had no way of assessing whether this current distribution of overhead cost to coded packaged drugs and biologicals with an ASP was appropriate, we acknowledged in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60499 through 60518) that the established method of converting billed charges to costs had the potential to ''compress'' the calculated costs to some degree. Further, we recognized that the attribution of pharmacy overhead costs to packaged or separately payable drugs and biologicals through our standard drug payment methodology of a combined payment for acquisition and pharmacy overhead costs depends, in part, on the treatment of all drugs and biologicals each year under our annual drug packaging threshold. Changes to the packaging threshold may result in changes to payment for the overhead cost of drugs and biologicals that do not reflect actual changes in hospital pharmacy overhead cost for those products. For these reasons, we stated that we believed some portion, but not all, of the total overhead cost that is associated with coded packaged drugs and biologicals (the difference between aggregate cost for those drugs and biologicals on the claims and ASP dollars for the same drugs and biologicals), should, at least for CY 2010, be attributed to separately payable drugs and biologicals based on our standard methodology.

We acknowledged that the observed combined payment for acquisition and pharmacy overhead costs of ASP − 2 percent for separately payable drugs and biologicals may be too low and ASP+247 percent for coded packaged drugs and biologicals with reported ASP data in the CY 2010 claims data may be too high (74 FR 35327 and 35328). In addition, we stated that we believed that the pharmacy stakeholders' recommendation to set packaged drug and biological dollars to ASP+6 percent was inappropriate, given our understanding that an equal allocation of indirect overhead costs among packaged and separately payable drugs and biologicals would lead to a higher observed ASP+X percent than ASP+6 percent for packaged drugs and biologicals. Further, we indicated that indirect overhead costs that are common to all drugs and biologicals have no relationship to the cost of an individual drug or biological or to the complexity of the handling, preparation, or storage of that individual drug or biological. Therefore, we indicated that we believed that indirect overhead cost alone for an inexpensive drug or biological which would be packaged could be far in excess of the ASP for that inexpensive product. We also explained that layered on these indirect costs are direct costs of staff, supplies, and equipment that are directly attributable only to the storage, handling, preparation, and distribution of drugs and biologicals and which do vary, sometimes considerably, depending upon the drug being furnished.

Therefore, we stated that a middle ground would represent the most accurate redistribution of pharmacy overhead cost. Our assumption was that approximately one-third to one-half of the total pharmacy overhead cost currently associated with coded packaged drugs and biologicals in the CY 2008 claims data offered a more appropriate allocation of drug and biological cost to separately payable drugs and biologicals (74 FR 35328). One third of the $395 million of pharmacy overhead cost associated with packaged drugs and biologicals was $132 million, whereas one-half was $198 million.

Within the one-third to one-half parameters, we proposed that reallocating $150 million in drug and biological cost observed in the claims data from coded packaged drugs and biologicals with an ASP to separately payable drugs and biologicals for CY 2010 would more appropriately distribute pharmacy overhead cost among packaged and separately payable drugs and biologicals. Based on this redistribution, we proposed a CY 2010 payment rate for separately payable drugs and biologicals of ASP+4 percent. Redistributing $150 million represented a reduction in cost of coded packaged drugs and biologicals with reported ASP data in the CY 2010 proposed rule claims data of 27 percent.

We also proposed that any redistribution of pharmacy overhead cost that may arise from CY 2010 final rule data would occur only from some drugs and biologicals to other drugs and biologicals, thereby maintaining the estimated total cost of drugs and biologicals in our claims data (no redistribution of cost would occur from other services to drugs and biologicals or vice versa) (74 FR 35332). We further proposed that the claims data for 340B hospitals be included in the calculation of payment for drugs and biologicals under the CY 2010 OPPS, and that hospitals that participate in the 340B program would be paid the same amounts for separately payable drugs and biologicals as hospitals that do not participate in the 340B program (74 FR 35332 through 35333). Finally, we proposed that, in accordance with our standard drug payment methodology, the estimated payments for separately payable drugs and biologicals would be taken into account in the calculation of the weight scaler that would apply to the relative weights for all procedural services (but would not apply to separately payable drugs and biologicals) paid under the OPPS, as required by section 1833(t)(14)(H) of the Act (74 FR 35333).

In the CY 2010 OPPS final rule with comment period, we adopted a transitional payment rate of ASP+4 percent based on a pharmacy overhead adjustment methodology for CY 2010 that redistributed $200 million from packaged drug and biological cost to separately payable drug cost. We refer readers to the CY 2010 OPPS/ASC final rule with comment period for a complete discussion of the pharmacy overhead adjustment methodology (74 FR 60499 through 60518). This $200 million included the proposed $150 million redistribution from the pharmacy overhead cost of coded packaged drugs and biologicals for which an ASP is reported and an additional $50 million dollars from the total uncoded drug and biological cost to separately payable drugs and biologicals as a conservative estimate of the pharmacy overhead cost of uncoded packaged drugs and biologicals that should be appropriately associated with

the cost of separately payable drugs and biologicals (74 FR 60517). We believed that our proposal to reallocate $150 million of costs from coded packaged drugs and biologicals, or one-third of the pharmacy overhead costs of these products, based upon the claims data available for the CY 2010 final rule, to separately payable drugs and biologicals was appropriate (74 FR 60511). We also acknowledged that, to some unknown extent, there are pharmacy overhead costs being attributed to the items and services reported under the pharmacy revenue code without HCPCS codes that are likely pharmacy overhead for separately payable drugs. Therefore, we reallocated $50 million or 8 percent of the total cost of uncoded packaged drug and biological cost in order to represent the pharmacy overhead cost of uncoded packaged drugs and biologicals that should be appropriately associated with the cost of separately payable drugs and biologicals. This was an intentionally conservative estimate as we could not identify definitive evidence that uncoded packaged drug and biological cost included a pharmacy overhead amount comparable to that of coded packaged drugs and biologicals with an ASP. We stated that we could not know the amount of overhead associated with these drugs without making significant assumptions about the amount of pharmacy overhead cost associated with the drug and biologicals captured by these uncoded packaged drug costs (74 FR 60511 through 60513).

We noted that our final CY 2010 payment policy for separately payable drugs and biologicals at ASP+4 percent fell within the range of ASP–3 percent (that would have resulted from no pharmacy overhead cost redistribution from packaged to separately payable drugs and biologicals), to ASP+7 percent (that would have resulted from redistribution of pharmacy overhead cost based on expansive assumptions about the nature of uncoded packaged drug and biological cost). We finalized a policy of redistributing pharmacy overhead cost from some drugs and biologicals to other drugs and biologicals, thereby maintaining the estimated total cost of drugs and biologicals in our claims data (no redistribution of cost would occur from other services to drugs and biologicals or vice versa). We also reiterated our commitment to continue in our efforts to refine our analyses.

For CY 2011, we continued the CY 2010 pharmacy overhead adjustment methodology (74 FR 60500 through 60512). We determined the total cost of separately payable drugs using CY 2009 claims data and compared these costs to the ASP dollars (April 2010 ASP quarterly payment rates multiplied by units for the separately payable drugs and biologicals in the claims data) for the same drugs and biologicals. We determined that the total estimated payment for separately payable drugs and biologicals (status indicators ''K'' and ''G''), including acquisition and pharmacy overhead costs, was ASP–1 percent, which also would be the ASP-based payment rate under the standard methodology that we established in CY 2006 (75 FR 46275). Additionally, we determined that the total estimated aggregate cost for packaged drugs and biologicals with a HCPCS code for which manufacturers report ASP data (status indicator ''N''), including acquisition and pharmacy overhead costs, was equivalent to ASP+296 percent. Finally, we determined that the total estimated cost for both packaged drugs and biologicals with a HCPCS code and separately payable drugs and biologicals (status indicators ''N,'' ''K,'' and ''G'') for which we also have ASP data, including acquisition and pharmacy overhead costs, was ASP+13 percent. Consistent with our supposition that the combined payment for average acquisition and pharmacy overhead costs under our standard methodology may understate the cost of separately payable drugs and biologicals and related pharmacy overhead for those drugs and biologicals, we redistributed $150 million from the pharmacy overhead cost of coded packaged drugs and biologicals with an ASP and redistributed $50 million from the cost of uncoded packaged drugs and biologicals, for a total redistribution of $200 million from costs for coded and uncoded packaged drugs to separately payable drugs and biologicals, with the result that we pay separately paid drugs and biologicals at ASP+5 percent for CY 2011. The redistribution amount of $150 million in overhead cost from coded packaged drugs and biologicals with an ASP and $50 million in costs from uncoded packaged drugs and biologicals without an ASP were within the parameters established in the CY 2010 OPPS/ASC final rule. In addition, as in prior years, we described some of our work to improve our analyses during the preceding year, and reiterated our commitment to continue to refine our drug pricing methodology.

b. CY 2012 Payment Policy

Section 1833(t)(14)(A)(iii) of the Act, as described above, continues to be applicable to determining payments for SCODs for CY 2012. This provision requires that payment for SCODs be equal to the average acquisition cost for the drug for that year as determined by the Secretary, subject to any adjustment for overhead costs and taking into account the hospital acquisition cost survey data collected by the GAO in CYs 2004 and 2005 and later periodic surveys conducted by the Secretary as set forth in the statute. If hospital acquisition cost data are not available, section 1833(t)(14)(A)(iii)(II) of the Act requires that payment be equal to payment rates established under the methodology described in section 1842(o) of the Act, section 1847A of the Act (ASP+6 percent as paid for physician Part B drugs), or section 1847B of the Act (CAP), as the case may be, as calculated and adjusted by the Secretary as necessary. In accordance with sections 1842(o) and 1847A of the Act, payments for most Medicare non-OPPS Part B drugs furnished on or after January 1, 2005, are paid based on the ASP methodology. Medicare Part B drugs generally fall into three categories: Physician-administered drugs (drugs furnished incident to a physician's service), drugs delivered through DME (drugs furnished under the durable medical equipment benefit), and drugs specifically covered by a statutory provision (certain oral anti-cancer and immunosuppressive drugs). Section 1833(t)(14)(E)(ii) of the Act authorizes, but does not require, the Secretary to adjust APC weights to take into account the 2005 MedPAC report relating to overhead and related expenses, such as pharmacy services and handling costs. As discussed in V.B.3.a. of this final rule with comment period, since CY 2006, we have used ASP data and costs estimated from charges on hospital claims data as a proxy for the sum of the average hospital acquisition cost that the statute requires for payment of SCODs and the associated pharmacy overhead cost in order to establish a combined payment rate for acquisition cost and pharmacy overhead. Prior to CY 2010, we applied this methodology to payment for all separately payable drugs and biologicals without pass-through status, including both SCODs and other drugs and biologicals that do not meet the statutory definition of SCODs.

For the CY 2010 OPPS, as part of our ongoing efforts to improve the validity of our payments, we revised the standard methodology to include an adjustment for pharmacy overhead. As explained previously, we have acknowledged, and continue to believe, that the established method of converting billed charges to costs had the potential to ''compress'' the calculated costs to some degree. We

recognized that the attribution of pharmacy overhead costs to packaged or separately payable drugs and biologicals through our standard drug payment methodology of a combined payment for acquisition and pharmacy overhead costs depends, in part, on the treatment of all drugs and biologicals each year under our annual drug packaging threshold. To some unknown extent, we believe that some pharmacy overhead costs attributed to packaged drugs and biologicals may include pharmacy overhead costs for separately payable drugs.

For the CY 2012 OPPS/ASC proposed rule, we proposed to continue to use our standard methodology for determining the total cost of separately payable drugs and biologicals in our CY 2010 claims data and comparing these costs to the ASP dollars (April 2011 ASP quarterly payment rates multiplied by units for the separately payable drugs and biologicals in the claims data) for the same drugs and biologicals. We determined that the total estimated payment for separately payable drugs and biologicals (status indicators ''K'' and ''G''), including acquisition and pharmacy overhead costs, is ASP–2 percent, which also would be the ASP-based payment rate under the standard methodology that we established in CY 2006 (75 FR 46275). Additionally, we determined that the total estimated aggregate cost for packaged drugs and biologicals with a HCPCS code for which manufacturers report ASP data (status indicator ''N''), including acquisition and pharmacy overhead costs, is equivalent to ASP+188 percent. Finally, we determined that the total estimated cost for both packaged drugs and biologicals with a HCPCS code and separately payable drugs and biologicals (status indicators ''N,'' ''K,'' and ''G'') for which we also have ASP data, including acquisition and pharmacy overhead costs, is ASP+11 percent. Table 31 of the proposed rule (76 FR 42260) displays our findings with regard to the percentage of ASP in comparison to the cost for packaged coded drugs and biologicals and for separately payable coded drugs and biologicals before application of the proposed overhead adjustment methodology.

Comment: Although many commenters urged CMS to adopt a payment rate for separately payable drugs that was at least equivalent to the ASP+6 payment provided for similar drugs in the physician offices and used the methodology described in section 1842(o), section 1847A, or section 1847B of the Act, commenters were generally supportive of our proposal to not use the standard methodology for establishing payment in CY 2012. Many commenters stated that they believe charge compression, which is the hospital practice of attaching a higher mark-up to charges for low cost supplies and a lower mark-up to charges for higher cost supplies, continues to have a distorting influence on the standard methodology. Commenters further asserted that payment for SCODs that is based on the standard methodology of ASP − 2 would be far below many hospitals' acquisition costs for separately payable drugs, and may force hospitals to be unable to provide a full range of necessary treatment options.

Response: We appreciate the commenters' support.

Our findings, based on final rule claims data, with regard to the percentage of ASP in comparison to the cost for packaged coded drugs and biologicals and for separately payable coded drugs and biologicals before application of the proposed overhead adjustment methodology is displayed in Table 37 below.

TABLE 37.—CY 2012 FINAL RULE DATA: ASP+X CALCULATION UNDER STANDARD METHODOLOGY

	Total ASP Dollars for Drugs and Biologicals in Claims Data (in millions)*	Total Cost of Drugs and Biologicals in Claims Data (in millions)**	Ratio of Cost to ASP (column 3/column 2)	ASP+X Percent
Uncoded Packaged Pharmaceutical Revenue Code Costs	Unknown	$666***	Unknown	Unknown
Coded Packaged Drugs and Biologicals with a reported ASP	$251	$734	2.92	ASP+192
Separately Payable Drugs and Biologicals with a reported ASP	$4,137	$4,043	0.98	ASP-2
All Coded Drugs and Biologicals with a reported ASP	$4,388	$4,777	1.09	ASP+9

*Total July 2011 ASP dollars (ASP multiplied by drug or biologicals units in CY 2010 claims) for drugs and biologicals with a HCPCS code and ASP information.

**Total cost in the CY 2010 claims data for drugs and biologicals

***Pharmacy revenue code costs without HCPCS codes.

We acknowledge that the combined payment for average acquisition and pharmacy overhead costs under our standard methodology may understate the cost of separately payable drugs and biologicals and related pharmacy overhead for those drugs and biologicals. Specifically, we recognize that payment at ASP − 2 percent for such costs may not be sufficient. We also acknowledge that ASP+188 percent may overstate the combined acquisition and pharmacy overhead cost of packaged drugs and biologicals. Therefore, in the CY 2012 OPPS/ASC proposed rule (76 FR 42260 through 42262), we proposed to continue the CY 2010 and CY 2011 overhead adjustment methodology, as first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60501 through 60517), which redistributes $200 million in cost from packaged drugs with an ASP and uncoded packaged drugs.

For CY 2012, we proposed to continue to make an overhead adjustment for another year because we believed it was appropriate to account for inflation that has occurred since the overhead redistribution amount of $200 million was applied in CY 2011. Therefore, we proposed to apply an inflation allowance to account for inflation and changes in the prices of pharmaceuticals in the overall economy. We proposed to adjust the overhead redistribution amount of $200 million using the PPI for Pharmaceuticals for Human Use. The PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics (BLS) series code WPUSI07003), provided through CMS' Office of the Actuary (OACT), is a price series that reflects price changes associated with

the average mix of all pharmaceuticals in the overall economy. We refer to this series generally as the PPI for Prescription Drugs. We believe that this price series is appropriate to use to update the overhead redistribution amount because the PPI for Prescription Drugs is publicly available and regularly published and because we have successfully utilized the PPI for Prescription Drugs for the past 5 years to update the drug packaging threshold as described in section V.B.2.a. of this final rule with comment period.

In order to apply the inflation allowance to the overhead redistribution amount for CY 2012, we used the most recent forecast of yearly index levels for the PPI for Prescription Drugs to calculate an updated overhead redistribution amount. After adjusting the $200 million overhead redistribution amount for inflation using the PPI for Prescription Drugs, we determined that $161 million would need to be redistributed from coded packaged drugs and biologicals with reported ASP data and $54 million would need to be redistributed from the cost of uncoded packaged drugs and biologicals without an ASP to separately payable drugs and biologicals. The proposed redistribution amount of $161 million in overhead cost from coded packaged drugs and biologicals is within the redistribution parameters established in the CY 2010 OPPS/ASC final rule with comment period of roughly one-third to one-half of overhead cost in coded packaged drugs and biologicals. The total proposed redistribution amount from both coded and uncoded packaged drugs and biologicals to separately paid drugs and biologicals would therefore be $215 million.

Having determined to redistribute overhead, in the proposed rule, we also continued to believe that the methodology to redistribute a portion of drug overhead cost from packaged coded and uncoded drugs and biologicals to separately payable drugs and biologicals while keeping the total cost of drugs and biologicals in the claims data constant continued to be appropriate for the reasons set forth in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60501 through 60517). Therefore, for CY 2012, we proposed to redistribute a total overhead redistribution amount, adjusted for inflation, of $215 million from coded and uncoded packaged drugs and biologicals to separately payable drugs and biologicals.

In the CY 2010 OPPS/ASC final rule with comment period, we reallocated $150 million in overhead cost from coded packaged drugs and biologicals with an ASP to separately payable drugs and biologicals with an ASP, or one-third of the pharmacy overhead cost of these products based upon the claims data available for the CY 2010 final rule. In addition, we noted that some of the cost associated with uncoded packaged drugs and biologicals was appropriate to redistribute to separately payable drugs and biologicals. Therefore, we made a conservative estimate, as compared with the case of coded packaged drugs and biologicals with an ASP for which we had a specific pharmacy overhead cost estimate in relationship to their known ASPs, and reallocated $50 million, or 8 percent of the total cost of uncoded packaged drugs and biologicals with no ASP. We made the assumption that whatever pharmacy overhead cost inappropriately associated with uncoded packaged drugs and biologicals would not be less than 8 percent of total uncoded drugs and biologicals cost.

In the CY 2012 OPPS/ASC proposed rule, we noted that continuing to redistribute $200 million (or $215 million with the adjustment for inflation) falls within the parameters originally established in the CY 2010 OPPS/ASC final rule with comment period. A redistribution amount of $161 million in overhead cost from coded packaged drugs and biologicals with an ASP or approximately 35 percent falls within one-third to one-half of the estimated pharmacy overhead cost. In addition, we noted that a redistribution amount of $54 million in overhead cost from uncoded packaged drugs and biologicals, or approximately 11 percent, is not less than 8 percent of the total cost of uncoded packaged drugs and biologicals. Therefore, our proposal to redistribute $215 million is consistent with the overhead adjustment methodology first implemented in CY 2010. We continue to believe that a middle ground of approximately one-third to one-half of the total pharmacy overhead cost currently associated with coded packaged drugs and biologicals in the CY 2010 claims data represents the most accurate redistribution of pharmacy overhead cost.

In the CY 2012 OPPS/ASC proposed rule, we estimated the overhead cost for coded packaged drugs to be $544 million ($705 million in total cost for coded packaged drugs and biologicals with a reported ASP, less $161 million in total ASP dollars for coded packaged drugs and biologicals with a reported ASP). As we did in CY 2010 and CY 2011, we proposed for CY 2012 that any redistribution of pharmacy overhead cost would occur only among drugs and biologicals in our claims data, and that no redistribution of cost would occur from other services to drugs and biologicals or vice versa. We believe that redistributing $215 million from packaged to separately payable drugs and biologicals, which includes an adjustment for inflation, is an appropriate redistribution of pharmacy overhead costs to address any charge compression in the standard methodology. We indicated that this would result in a proposed CY 2012 payment rate for separately payable drugs and biologicals of ASP+4 percent. We noted that, in past years, the proposed ASP+X amount decreased by at least 1 percentage point when we updated the ASP data, claims data, and cost report data between the proposed rule and the final rule with comment period.

As indicated in Table 31 of the proposed rule (76 FR 42260), if we were to propose to establish payment for separately payable drugs and biologicals under the standard methodology established in CY 2006 without applying a pharmacy overhead adjustment, we would have had to propose to pay for separately payable drugs and biologicals at ASP − 2 percent. However, because we are concerned about the possibility of underpaying for separately payable drugs and biologicals, we believe that a pharmacy overhead adjustment using a redistribution methodology for determining the amount of payment for drugs and biologicals, as we did for CY 2011, is appropriate for CY 2012. We acknowledge that the observed ASP − 2 percent may reflect some amount of charge compression and variability attributable to the choice of a packaging threshold. We displayed the effect of this proposed adjustment payment methodology in Table 32 of the proposed rule (76 FR 42262).

Comment: The majority of commenters urged CMS to adopt an ASP+X amount that is higher than ASP+4 for CY 2012. Many commenters stated that CMS should simply adopt the default payment rate of ASP+6 percent for CY 2012, rather than use the redistribution methodology proposed in the CY 2012 OPPS/ASC proposed rule. Noting that section 1833(t)(14)(A) of the Act requires CMS to pay for separately payable drugs at a rate that is equal to the average acquisition cost for the drug for a year, as determined by the GAO or CMS surveys of hospital acquisition cost, and that the most recent survey available is ''outdated'' because it was performed in CY 2004 by the GAO, the commenters urged CMS to pay for separately payable drugs at ASP+6 percent or the rate applicable in the

physician's office setting. The commenters stated that CMS has the authority to pay for separately payable drugs at ASP+6 percent under the statute. Many of these commenters suggested that CMS discontinue the use of the standard methodology and the overhead redistribution methodology, and instead use the default payment rate of ASP+6 percent, as is given by Congress in statute.

Response: While the commenters are correct that the statute provides for the use of the methodology described in section 1842(o), section 1847A, or section 1847B of the Act, as the case may be, as calculated and adjusted by the Secretary as necessary, payment under these provisions for a SCOD is required only when the average hospital acquisition cost for the drug for that year are unavailable (which at the option of the Secretary may vary by hospital group (as defined by the Secretary based on the volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D). We continue to believe that we have established both our hospital claims data and ASP data as an appropriate proxy for average hospital acquisition cost, taking the GAO survey information into account for the base year (70 FR 68641). Many of the drugs and biologicals covered under the OPPS are provided a majority of the time in the hospital setting, and we believe that the ASP information we collect is an adequate proxy for hospital acquisition cost. Further, the commenters have not disputed the accuracy of the total drug and biological cost estimated in our claims data, only the estimated cost of separately payable drugs and biologicals. We continue to believe that average sales prices for separately paid drugs and biologicals represent a generally appropriate source of hospital average acquisition cost for drugs and biologicals. As we stated in the CY 2006 OPPS final rule, we intend for the quarterly updates of the ASP-based payment rates for separately paid drugs and biologicals to function as the surveys of hospital acquisition costs that are required by section 1833(t)(14)(D)(ii) of the Act (70 FR 68641). Prices calculated using the ASP methodology account for sales to all purchasers, and are net of most discounts, nominal sales, and other sales that are otherwise exempt from the Medicaid Best Price calculations. Given that purchase price generally equals sales price for any transaction, we believe that the ASP is an accurate proxy for hospitals' average acquisition cost for separately paid drugs and biologicals. Therefore, we disagree that we are not complying with the statute by not performing a survey and not paying at the physician's office rate. For the reasons explained above, we do not believe that it is appropriate at this time to provide payment at an amount other than average acquisition cost based on the drug and biological costs observed in hospital claims data and pricing information observed in ASP data, as adjusted with a redistribution for pharmacy overhead.

Comment: One commenter stated that the statute requires that CMS make payment for SCODs at ASP+6 percent, citing that cost data derived from claims data cannot accurately be said to equal average acquisition cost. The commenter noted that CMS' methodology in using claims data reduced by CCRs to derive proxies for hospital costs is a methodology dependent on assumptions about the relationship between charges and costs and, therefore, does not typify actual hospital costs for drugs and biologicals. These cost data, the commenter argued, therefore cannot equal average acquisition cost for drugs and biologicals.

Response: As we discussed in the response to the previous comment, we believe that ASP is an appropriate proxy for the acquisition cost of drugs. With respect to establishing the total estimated cost of drugs and biologicals, including both pharmacy overhead and acquisition cost of drugs and biologicals, we use hospital charges and cost report data. We believe that our claims data and cost report data provide the best estimate of the national aggregate total cost of drugs and biologicals. We do not believe that this methodology for estimating the total cost of drugs and biologicals, including pharmacy overhead cost, is based on assumptions about costs and charges, but the actual relationship between costs and charges for the same hospital for the same services. We estimate costs from charges submitted on claims for payment, and cost and charge information from cost report data that are certified to be correct by the hospital. We note that we view the ASP data, not the cost data, to be the appropriate proxy for hospital acquisition cost for drugs and biologicals, without pharmacy overhead costs, while the cost of drugs and biologicals that we estimate from claims and cost report data is the only source of the total cost of drugs and biologicals, that includes both pharmacy overhead and acquisition cost.

Comment: MedPAC remained concerned about our policy of setting payment rates for drugs and biologicals as a percentage of ASP because, as MedPAC stated, pharmacy overhead, as a percentage of total costs, varies widely across individual drugs. MedPAC previously had recommended that CMS collect data on hospitals' pharmacy overhead costs separately from drug acquisition costs and that these data could be used to create separate payment to hospitals for pharmacy overhead and drug acquisition costs.

Response: While we acknowledge that pharmacy overhead varies by the drug to which it applies, we believe that as long as payment is distributed among hospitals in a manner that, on average, reflects relative costs of drugs and biologicals they furnish, including pharmacy overhead, the goals of the OPPS are met as it is a system of averages. With regard to the comment that CMS should collect data on hospitals' pharmacy overhead costs separately from drug acquisition costs and that these data could be used to create separate payment to hospitals for pharmacy overhead and drug acquisition costs, as we discussed in detail above, we proposed to create HCPCS codes for pharmacy overhead services so that hospitals could charge for these services and provide us a basis for making separate payments for pharmacy overhead. However, hospitals strongly objected and provided convincing arguments that to do so would impose an enormous burden on them and on other payers that would not provide an offsetting benefit. We believe that hospitals would find any option requiring them to identify the cost associated with the overhead component of a drug or biological or a class of drugs or biologicals burdensome and imprecise.

Comment: A few commenters expressed concern that when CMS applies a single CCR to adjust charges to costs for drugs and biologicals, charge compression leads to misallocation of pharmacy overhead costs associated with high and low cost drugs and biologicals during ratesetting. The commenters noted that hospitals disproportionately mark up their charges for low cost drugs and biologicals to account for pharmacy overhead costs. Therefore, some commenters suggested using the costs of both packaged drugs and separately payable drugs when calculating the equivalent average ASP-based payment amount for separately payable drugs. They argued that this would provide a more accurate ASP-based payment amount for separately payable drugs. As

an alternative, the commenters recommended that CMS eliminate the drug packaging threshold and provide separate payment for all Part B drugs under the OPPS at an ASP+X percent amount calculated from the cost for all drugs with HCPCS codes.

Several commenters objected to the inclusion of data from hospitals that receive Federal discounts on drug prices under the 340B program in the ASP calculation for separately payable drugs and biologicals. The commenters pointed out that hospital participation in the 340B program had grown substantially over the past few years, and will further increase due to the provisions in the Affordable Care Act. The commenters believed that the costs from these hospitals now constituted a significant proportion of hospital drug costs on CY 2010 OPPS claims. The commenters stated that including 340B hospital claims data when comparing aggregate hospital costs based on claims data to ASP rates contributed to an artificially low equivalent average ASP-based payment rate because ASP data specifically exclude drug sales under the 340B program.

In addition, MedPAC encouraged CMS to exclude data from 340B hospitals from the ratesetting. MedPAC stated that analysis indicates that exclusion of the 340B hospitals would increase CMS' estimates of the cost of separately paid drugs by about 3.5 percent above the estimate obtained when the 340B hospital claims data are included in the ratesetting calculations and that excluding the 340B hospital claims data would result in payment rates for separately paid drugs that more accurately reflect the costs incurred by other hospitals.

Response: In proposing to continue our CY 2010 overhead adjustment methodology for CY 2012, we attempted to address the issue of charge compression by redistributing some portion of the estimated overhead cost equivalent to the CY 2011 redistribution amount indexed for the increase in the PPI for Prescription Drugs for coded packaged drugs ($161 million), and a conservative estimate of overhead cost in the uncoded packaged drug cost ($54 million). Further, we have made several proposals in the past to more precisely identify pharmacy overhead costs and to address charge compression in the pharmacy revenue center, which were not finalized due to objections raised in public comments. As we noted in our discussion of the MedPAC comment above, for the CY 2006 OPPS, we proposed to establish three distinct Level II HCPCS C-codes and three corresponding APCs for drug handling categories to differentiate overhead costs for drugs and biologicals (70 FR 42730). In the CY 2008 OPPS/ASC proposed rule (72 FR 42735), we proposed to instruct hospitals to remove the pharmacy overhead charge for both packaged and separately payable drugs and biologicals from the charge for the drug or biological and report the pharmacy overhead charge on an uncoded revenue code line on the claim. We believed that this would provide us with an avenue for collecting pharmacy handling cost data specific to drugs in order to package the overhead costs of these items into the associated procedures, most likely drug administration services. However, we did not finalize these proposals due to strong objection from hospitals. For CY 2009, we proposed to split the ''Drugs Charged to Patients'' cost center into two cost centers: One for drugs with high pharmacy overhead costs and one for drugs with low pharmacy overhead costs (73 FR 41492). We noted that we expected that CCRs from the proposed new cost centers would be available in 2 to 3 years to refine OPPS drug cost estimates by accounting for differential hospital markup practices for drugs with high and low overhead costs. However, we did not finalize any of these proposals due to concerns from the hospital community that these proposals would create an overwhelming burden on hospitals and staff. By proposing to continue our CY 2010 overhead adjustment methodology, we were once again attempting to address the issue of charge compression without requiring any changes to current hospital reporting practices.

It has been our policy since CY 2006 to only use separately payable drugs and biologicals in the calculation of the equivalent average ASP-based payment amount under the OPPS. We do not include packaged drugs and biologicals in this standard analysis because cost data for these items are already accounted for within the APC ratesetting process through the median cost calculation methodology discussed in section II.A. of this final rule with comment period. To include the costs of coded packaged drugs and biologicals in both our APC ratesetting process (for associated procedures present on the same claim) and in our ratesetting process to establish an equivalent average ASP-based payment amount for separately payable drugs and biologicals would give these data disproportionate emphasis in the OPPS by skewing our analyses, as the costs of these packaged items would be, in effect, counted twice. Accordingly, we are not adopting the suggestion from commenters that we include all packaged and separately payable drugs and biologicals when establishing an equivalent average ASP-based rate to provide payment for the hospital acquisition and pharmacy handling costs of drugs and biologicals. However, we remind commenters that because the costs of packaged drugs and biologicals, including their pharmacy overhead costs, are packaged into the payment for the procedures in which they are administered, the OPPS provides payment for both the drugs and the associated pharmacy overhead costs through the applicable procedural APC payments.

Furthermore, we disagree with the commenters who recommended that we should pay separately for all drugs and biologicals with HCPCS codes. We continue to believe that packaging is a fundamental component of a prospective payment system that contributes to important flexibility and efficiency in the delivery of high quality hospital outpatient services. Therefore, we believe it is appropriate to maintain a modest drug packaging threshold that packages the costs of inexpensive drugs into payment for the associated procedures. We also note that hospitals have been particularly sensitive to any increased administrative burden, and we are aware that the burden of separate reporting for a multitude of very low cost packaged drugs is significant.

With respect to the comment that we should not include data from hospitals that receive discounts on outpatient drug prices under the 340B program in our estimation of the total cost of separately paid drugs and biologicals and pharmacy overhead, as we stated in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60517) and the CY 2011 OPPS/ASC final rule with comment period (75 FR 71963), we continue to believe that excluding data from hospitals that participate in the 340B program from our ASP+X calculation, and paying those hospitals at that derived payment amount, would inappropriately redistribute payment to drugs and biologicals from payment for other services under the OPPS. The ASP-equivalent cost of drugs under the OPPS that would be calculated only from claims data for hospitals that do not participate in the 340B program, would likely be higher than the cost of all drugs from our aggregate claims from all hospitals. To set drug payment rates for all hospitals based on a subset of hospital cost data, determined only from claims data from hospitals that do not participate in the 340B program would increase the final APC payment weights for drugs in a manner that does not

reflect the drug costs of all hospitals, although all hospitals, including 340B hospitals, would be paid at these rates for drugs. Furthermore, as a consequence of the statutory requirement for budget neutrality, increasing the payment weights for drugs by excluding 340B hospital claims would reduce the relative payment weight for other services in a manner that does not reflect the procedural costs of all hospitals relative to the drug costs of all hospitals, thereby distorting the relativity of payment weights for services based on hospital costs. Many commenters on the CY 2009 OPPS/ASC final rule with comment period were generally opposed to differential payment for hospitals based on their 340B participation status, and we do not believe it would be appropriate to exclude claims from this subset of hospitals in the context of a CY 2012 drug and biological payment policy that is based on average acquisition cost and pays all hospitals at the same rate for separately payable drugs and biologicals.

Comment: One commenter requested that CMS provide more information regarding the outcomes of the analysis referenced in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71962) finding that matching the ASP data with the time of the cost report would remove a downward bias in the standard methodology, but that the upward bias of later charges from claims generally offsets the increases in prices in a more recent ASP file. The commenter further stated that they believed the use of later ASP data in a final rule may be directly attributable to the tendency of the relationship between ASP and total costs of separately payable drugs to decline by 1 percentage point in the final rule.

Response: We are uncertain what additional information the commenters are seeking regarding our finding in the CY 2011 OPPS/ASC final rule with comment period that the slightly higher estimated cost created by using a CCR from the year prior to the claim year generally offsets the increases in prices in a more recent ASP file (75 FR 71962). However, as described below, in our analysis of the ASP+X methodology for this CY 2012 final rule with comment period, we have found that a primary cause in the decline of the methodologically-derived ASP+X percent is the inclusion of a whole year's data for the final rule while keeping the drug overhead redistribution amount constant, and not the use of later ASP data, as the commenter suggested. Had we finalized our proposed redistribution methodology without modification in CY 2012, this would have again yielded a 1 percent decline, from ASP+4 to ASP+3, in the final CY 2012 ASP+X percent.

Comment: A few commenters recommended that CMS require hospitals to bill all drugs with HCPCS codes under revenue code 0636 in order to improve its data on packaged drugs. The commenter also recommended that CMS require hospitals to report J3490 (Unclassified drugs) for drugs without a HCPCS code. One commenter asserted that requiring that hospitals take these additional steps for packaged drugs could occur with minimal additional administrative burden to hospitals since hospitals are now required to report national drug codes (NDCs) to State Medicaid programs. Other commenters asked that CMS require mandatory reporting of all drugs using either specific HCPCS codes or J3490, and that CMS should leave the choice of the revenue code that must be reported on the line to the discretion of the hospital.

Response: We did not propose to require hospitals to report all drugs and biologicals using HCPCS codes and report drugs and biologicals that do not have specific HCPCS codes using HCPCS code J3490 for the CY 2012 OPPS. Therefore, we do not accept the commenters' recommendation that CMS require these products to be reported. We do not believe that it would be appropriate to impose such a requirement without first proposing it and considering the comments of the public.

However, we continue to believe that OPPS ratesetting is most accurate when hospitals report charges for all items and services that have HCPCS codes using those HCPCS codes, regardless of whether payment for the items and services is packaged. As we state in this final rule with comment period, it is our standard ratesetting methodology to rely on hospital cost report and charge information as it is reported to us through the claims data. We continue to believe that more complete data from hospitals identifying the specific drugs that were provided during an episode of care will improve payment accuracy for separately payable drugs in the future. Therefore, we continue to encourage hospitals to change their reporting practices if they are not already reporting HCPCS codes for all drugs and biologicals furnished, where specific HCPCS codes are available for those drugs and biologicals.

Comment: Several commenters characterized our proposed redistribution methodology as arbitrary in nature, in part because CMS does not truly know the amount of overhead to move for the proposed overhead adjustment. A few commenters generally agreed with CMS' proposal to redistribute pharmacy overhead cost from packaged drugs and biologicals to separately payable drugs and biologicals. However, several commenters expressed concern that, under this methodology, the projected CY 2012 ASP+X amount of ASP+4 percent may decline to ASP+3 percent in the final rule with comment period. The commenters reasserted their belief that payment at less than ASP+6 percent is insufficient for payment for separately payable drugs and biologicals.

Several commenters supported the payment of ASP+6 percent for separately paid drugs and biologicals and the redistribution methodology on a whole, but did not support the proposed redistribution amount of $215 million from packaged drugs and biologicals ($161 million from coded packaged drugs and biologicals and $54 million from uncoded packaged drugs and biologicals). A majority of commenters recommended that CMS increase the amount redistributed from coded and uncoded packaged drugs and biologicals to separately payable drugs and biologicals. A few of these commenters stated that a larger portion of the overhead costs should be reallocated from uncoded packaged drugs and biologicals to separately payable drugs and biologicals, noting that coded and uncoded drugs and biologicals have similar overall charge mark-up and, therefore, warrant a similar redistribution of costs. Several commenters recommended that an equal or close to equal amount of cost should be redistributed from packaged coded and uncoded drug and biological cost to separately payable drugs and biologicals.

Response: We are not convinced by the commenters that we should pay separately paid drugs and biologicals at ASP+6 percent or higher for CY 2012. We disagree with commenters' assertions that payment at less than ASP+6 percent would be insufficient to adequately pay for the costs of separately paid drugs and biologicals because our review of claims and cost report data provides no evidence that supports that payment at less than ASP+6 percent is insufficient to pay adequately for the costs of separately paid drugs and biologicals. To the contrary, the utilization of drugs and biologicals continues to increase. In addition, we note that payment for pharmacy overhead is not only paid through payment for specifically identified drugs and biologicals, but

pharmacy overhead payment also is packaged into payment for the procedure in which the cost of packaged drugs and biologicals is included. When a separately paid drug or biological is furnished during a procedure, pharmacy overhead is being paid both through the ASP+X percent payment for the separately paid drug and biological and, to some extent, in the payment for the procedure, because the APC payment for any procedure includes the cost of packaged drugs and the overhead cost associated with those packaged drugs and biologicals.

Although several commenters recommended that CMS reallocate a larger portion of the estimated pharmacy overhead costs from packaged drugs to separately payable drugs for CY 2012 under the overhead adjustment methodology, and other commenters argued that we should redistribute an equal or nearly equal amount of cost from both packaged drugs and biologicals with HCPCS codes and packaged drugs and biologicals without HCPCS codes, for the reasons set forth below and consistent with our rationale outlined in the CY 2010 OPPS/ASC final rule with public comment period (74 FR 60511 through 60512) and the CY 2011 OPPS/ASC final rule with comment period (75 FR 71955), we do not believe that we should redistribute a higher portion of drug cost from coded packaged drugs and biologicals, nor can we assume that uncoded packaged drugs and biologicals have the same or higher pharmacy overhead costs as coded packaged drugs and biologicals. Therefore, we do not believe that we can treat them comparably for purposes of estimating overhead. With regard to redistributing more from uncoded packaged drugs and biologicals, first, as indicated in the preamble to the CY 2011 OPPS/ASC proposed rule (75 FR 46277 through 46278), conversations with stakeholders and hospitals have suggested that hospitals do not always report HCPCS codes for drugs for a variety of reasons. A key premise of the pharmacy overhead adjustment redistribution methodology is our assessment of the amount of drug cost in the claims data above aggregate ASP available as ''overhead'' for redistribution. Knowing the specific HCPCS codes for packaged drugs and their associated ASP allows us to assess the difference between the aggregate ASP and claims cost for packaged drugs and to assess the intensity of pharmacy overhead associated with these drugs. The inability to know which drugs are captured by uncoded drug charges on a claim is challenging because we cannot know the hospitals' charges for the drug, which include overhead costs, or what the overhead complexity may be. Therefore, we cannot be certain that the amount of uncoded pharmacy overhead costs is as high as the public has suggested or that hospitals mark up these uncoded drugs and biologicals in the same way as packaged drugs and biologicals with HCPCS codes. Second, we continue to believe that the information supplied to us by commenters urging us to redistribute a greater (or equivalent) fraction of costs for uncoded packaged drugs and biologicals is insufficient to enable us to isolate the portion of the uncoded packaged drug and biological cost that is pharmacy overhead cost. In order to isolate the portion of uncoded packaged drug and biological cost that is pharmacy overhead cost, we believe that we would need more drug specific information reported to us by hospitals, either through more reporting of packaged drugs on claims or through more granular cost centers on the cost report. In addition, we note that in our preparation for the CY 2011 rulemaking cycle, and as indicated in the CY 2011 OPPS/ASC proposed rule, we have also evaluated claims data in an effort to assess how much uncoded packaged drugs resemble coded packaged drugs (75 FR 46278). We found that most uncoded packaged drug costs appear with surgical services and that most coded packaged drug costs appear with medical services. In light of this information, we are not confident that the drugs captured by uncoded drug costs are the same drugs captured by the coded packaged drug cost. Therefore, we do not agree that we can assume that they are the same drugs, with comparable overhead and handling costs. Without being able to calculate an ASP for these drugs and without being able to gauge the magnitude of the overhead complexity associated with these drugs, we do not believe we should assume the same or a greater proportional overhead is appropriate for redistribution. Third, we also disagree with the commenter's assertions that pharmacy services and overhead costs for all uncoded packaged drugs are similar to the costs associated with coded packaged drugs and are a sufficient basis for redistributing equal or close to equal amount of dollars from uncoded packaged drugs as from coded packaged drugs to separately paid drugs under this overhead adjustment policy. This would be contrary to findings from MedPAC in Chapter 6 of its June 2005 Report to Congress that linked overhead to the seven complexity categories of delivery; this report can be viewed on the MedPAC Web site at: *http://www.medpac.gov/publications%5Ccongressional_reports%5CJune05_ch6.pdf.* As we have stated elsewhere, we remain committed to using hospital data as reported to us by hospitals to set OPPS payment rates. Therefore, we continue to believe that it would be inappropriate to assume that the costs reported under uncoded pharmacy revenue code lines are for the same drugs and biologicals with the same ASPs, as the costs of packaged drugs and biologicals reported with HCPCS codes. Therefore, for the reasons set forth above, we continue to believe that we should not make broad assumptions that the same overall charge markup exists for both coded and uncoded packaged drugs or that we should redistribute a similar or greater amount of cost from both coded and uncoded packaged cost to separately payable drugs and biologicals.

We also do not agree that our pharmacy overhead adjustment methodology is arbitrary. The basis for the proposed and final CY 2012 pharmacy overhead adjustment methodology is the same as our CY 2011 and 2010 final rules, but with one refinement for this final rule with comment period to enhance the intra-rulemaking stability of the ASP+X amount, as described below. As we stated in our CY 2010 proposed rule, we remain concerned that the ASP value derived using the standard methodology has the potential to ''compress'' costs for relatively high-cost products, including SCODs, due to hospital charging practices, and thus may understate the cost of separately payable drugs and biologicals and related pharmacy overhead for those drugs and biologicals. We cited the relatively low CY 2010 ASP value of ASP − 2 for separately covered drugs and biologicals and the relatively high ASP value of ASP+247 for packaged drugs and biologicals as evidence of this distortion. We further stated that we believe that, according industry stakeholders and MedPAC, approximately $150 million of handling and pharmacy overhead cost for coded packaged drugs, and approximately $50 million of costs attributed to pharmacy overhead cost for uncoded packaged drugs were appropriate to redistribute to separately payable drugs in CY 2010. We believed, and continue to believe, that between approximately one-third and one-half of the overhead cost associated with coded packaged drugs could be attributable to charge compression due to our cost estimation

methodology and our choice of a packaging threshold. In addition, redistributing $50 million of the total cost associated with uncoded packaged drugs and biologicals to separately payable drugs and biologicals falls in the approximate 8 percent range of total uncoded drug and biological costs using CY 2009 claims and the most recently available cost report data. This is a conservative estimate as we remain unwilling to make sweeping assumptions that uncoded packaged drugs and biologicals included a pharmacy overhead amount comparable to those of coded packaged drugs and biologicals with an ASP. Using our standard methodology to calculate ASP values in the CY 2011 OPPS/ASC proposed rule, we again found a relatively low ASP value for separately payable drugs and biologicals (ASP+0), and a relatively high ASP value for packaged drugs and biologicals (ASP+283). Thus, in the CY 2011 OPPS final rule with comment period (75 FR 71953 through 71967), we again finalized our proposed redistribution methodology, and redistributed $200 million in pharmacy overhead costs from packaged to separately payable drugs and biologicals. We note that our proposed CY 2012 policy of redistributing $161 million in overhead from coded packaged drugs and biologicals with an ASP, or 35 percent, falls within the one-third to one-half of the estimated pharmacy overhead cost in coded packaged drugs and biologicals. The CY 2010 policy for redistributing $150 million from coded packaged drugs and biologicals to separately payable drugs and biologicals was based on our assessments using both industry and MedPAC data (74 FR 60505 through 60507). We believed and continue to believe that between approximately one-third and one-half of the overhead cost in coded packaged drugs could be attributable to charge compression due to our cost estimation methodology and our choice of a packaging threshold.

The proposed CY 2012 policy of redistributing $53 million of the total cost of uncoded packaged drugs and biologicals to separately payable drugs and biologicals, or approximately 11 percent in overhead cost from uncoded packaged drugs and biologicals, falls into the parameter of not less than 8 percent of cost associated with these items, as discussed in the CY 2010 OPPS/ASC final rule with comment period. Further, as we indicated in the CY 2010 OPPS/ASC final rule with comment period, the proportion of uncoded packaged drug cost that is redistributed is a conservative estimate, as compared to the case of coded packaged drugs and biologicals with an ASP and for which we have a specific pharmacy overhead cost estimate in relationship to their known ASPs. As discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60511), we remain unwilling to make sweeping assumptions that uncoded packaged drug and biological cost included a pharmacy overhead amount comparable to those of coded packaged drugs and biologicals with an ASP. We continue to be confident that a conservative estimate of approximately 11 percent (or $54 million for redistribution in the proposed rule) from the cost of uncoded packaged drugs and biologicals to separately payable drugs and biologicals is an appropriate amount in light of our uncertainty about the relationship between ASP and pharmacy overhead costs for the uncoded drugs and biologicals. We also do not believe our redistribution policy is arbitrary because we finalized our CY 2010 policy for an overhead adjustment methodology in response to public commenter consensus that this approach was an appropriate avenue for addressing charge compression in the drug and biological payment rates for separately paid drugs. We believe that the consensus among commenters regarding the necessity of a redistribution methodology to correct for relatively high and low ASP values for packaged and separately payable drugs using our standard methodology is further evidence that the policy adopted in CY 2010 and CY 2011, and which we are continuing for CY 2012 with one refinement (as discussed below), has a rational basis and is not arbitrary.

Although we proposed to continue our established policy to redistribute one-third to one-half of overhead cost for coded packaged drugs, and not less than 8 percent of cost for uncoded packaged drugs and are finalizing this aspect of the proposed policy, we believe the intra-rulemaking fluctuation that can occur with the proposed methodology can be minimized, as requested by commenters. As commenters have stated, and as we warned in the CY 2012 OPPS/ASC proposed rule (76 FR 42261), the overhead redistribution methodology which we finalized in CY 2010 to redistribute $200 million in cost for packaged drugs, used again in CY 2011 to redistribute $200 million in cost for packaged drugs, and proposed to redistribute $215 million in cost for packaged drugs in CY 2012, has led to a decrease in the ASP+X amount between the proposed and final rules. Although in CY 2010 the magnitude was not large enough to prompt a decline in the final ASP+X percent due to rounding and due to the addition of $50 million in cost for uncoded packaged drugs in the CY 2010 final rule with comment period, it did result in a 1 percent decline in CY 2011 between the proposed rule and the final rule with comment period. We believe that this possible decrease in the ASP+X percent between the CY 2012 proposed rule and this final rule with comment period prompted several commenters, especially those commenters representing hospitals and hospital associations, to characterize the proposed overhead redistribution methodology as unstable.

In our consideration of commenters' concerns regarding this observed intra-rulemaking variability (that is, the fluctuation in the derived ASP+X value between the OPPS proposed rule and the final rule), in preparation for this CY 2012 final rule with comment period, we revisited this issue and analyzed cost and claims data in an effort to determine the cause of the fluctuation. We observed that much of this fluctuation occurs as a result of CMS adding additional cost and claims data between the proposed rule and the final rule with comment period in order to include a full year of data and, to a much lesser extent, our regular update of the ASP data. For example, in the CY 2012 proposed rule, we proposed to update the CY 2011 redistribution amount of $200 million by the PPI for Prescription Drugs and redistribute $215 million in overhead cost for packaged drugs, or about $161 million in overhead cost for coded packaged drugs and about $54 million in overhead cost for uncoded packaged drugs. This proposed redistribution amount resulted in a proposed ASP+X percent of ASP+4, because of the mathematical relationship between the proposed $215 million in redistributed drug overhead cost to the amount of total drug cost which, for the proposed rule, was approximately $4.7 billion based on the partial year data available to CMS at the time of the proposed rule. However, in our analysis of drug cost to derive the final CY 2012 ASP+X percent, we observed that, due to the inclusion of an entire year's worth of cost data (amounting to approximately $5.4 billion) in the calculation, the ASP+X percent based on the proposed $215 million redistribution of packaged drug overhead cost again dropped 1 percent from ASP+4 in the CY 2012 proposed

rule to ASP+3 if the proposed methodology was used, without modification, for the final calculation. We then analyzed our ASP+X calculations in 2011, and found the same effect, namely that inclusion of an entire year's worth of cost data for each respective year's final rule relative to a fixed redistribution amount resulted in a different and lower ASP+X value in the final rule than was proposed. Although the change in CY 2010 was less than one-half percent and thus prompted no change in the final ASP+X percent due to rounding, the inclusion of a whole year of costs caused a 1 percent decline in the ASP+X percent in CY 2011, just as it would in CY 2012 were CMS to finalize our proposed redistribution methodology with a fixed $215 million redistribution. This effect is illustrated in the following Table 38.

TABLE 38.—INTRA-RULEMAKING CHANGES IN THE ASP+X CALCULATION USING FIXED-AMOUNT REDISTRIBUTION METHODOLOGY

	Packaged Drug Redistribution Amount (in millions)		Total Drug Costs (in millions)		ASP+X Percent	
	Proposed	Final	Proposed	Final	Proposed	Final
CY 2010	$200	$200	$3,671	$4,136	ASP+4	ASP+4
CY 2011	$200	$200	$4,155	$4,604	ASP+6	ASP+5
CY 2012	$215	$215	$4,680	$5,443	ASP+4	ASP+3*

* ASP+3 is displayed here for illustrative purposes only, and would have only occurred had CMS finalized its proposed drug distribution methodology in CY 2012 without modification.

The observed decline in the ASP+X percent occurs because during the CY 2012 proposed rule CMS has only a partial year's worth of cost data to calculate the ASP+X percentage, which is itself an expression of the ratio of cost to ASP. However, when the analysis is repeated for each year's final rule, we use an entire year of cost data but a fixed dollar overhead redistribution amount. Because the amount of total drug cost data analyzed for the final rule is larger than it was for the proposed rule but the redistribution amount remains unchanged, the ASP+X value will always experience a decline in the intra-rulemaking period. We project that for most years this shrinking in the redistributed cost to total drug cost ratio that derives the ASP+X percent will cause a decrease in the ASP+X percent of at least 1 percent between the proposed and final rules when the proposed methodology is used. Specifically, as indicated in Table 38, if CMS were to finalize for CY 2012 our proposed redistribution of $161 million in overhead cost from coded packaged drugs and $54 million in overhead cost from uncoded packaged drugs, the ASP+X percent would decline from ASP+4 in the proposed rule to ASP+3 in the final rule. This occurs because an increase in total drug costs of $763 million analyzed for the final rule with no change to the redistribution amount changes the ratio of redistributed cost to total drug cost changes and prompts a 1 percent decrease in the ASP+X percent.

Comment: In general, commenters urged CMS to increase the stability and decrease the volatility of its payment policies wherever possible. The commenters stated that instability in the OPPS rates creates budgeting, planning, and operating problems for hospitals, and that as more care is provided on an outpatient, rather than inpatient basis, the need for stable payment rates from one year to the next becomes more important to hospitals. Regarding payment for SCODs and the ASP+X methodology in particular, commenters also cited instability as being problematic, particularly because of the intra-rulemaking decline in the ASP+X percent.

Response: For several years now we have made policy changes in our payment for separately payable drugs to ensure adequate and accurate payment and enhance the predictability of Medicare payment for these products. Although we had adopted the standard method in the CY 2006 final rule with comment period, we adopted an ASP+X percent of ASP+6 in the CY 2007 final rule with comment period in order to provide stability while we continued to examine the costs of pharmacy overhead. Observing declines in the equivalent average ASP+X percent calculated using the standard methodology, we provided a transitional rate of ASP+5 and ASP+4 for the CY 2008 and 2009 final rules, respectively, in order to enhance the stability of the ASP+X percent for those years. In CY 2010, we concluded that charge compression was likely distorting the equivalent average ASP+X percent calculated using the standard methodology. Therefore, in order to ensure adequate and stable payment, we implemented the overhead cost redistribution methodology described above and redistributed $200 million from packaged drug overhead cost to separately payable drugs in CY 2010 and 2011.

As in each of these prior years, in CY 2012, CMS' goal is to provide accurate payment for separately payable drugs that is based upon acquisition costs, while still ensuring stability to the payment levels. In continued pursuit of this goal, in CY 2012, we stated that we believe it is appropriate to account for inflation that has occurred since the overhead redistribution amount of $200 million was applied in CY 2011. Therefore, we proposed to apply an inflation allowance equal to the PPI for Prescription Drugs to the redistribution amount. The CY 2011 redistribution amount of $200 million updated by the PPI for Prescription Drugs yielded a proposed redistribution amount of $215 million in CY 2012 ($150 million in overhead cost from coded packaged

drugs updated by the PPI for Prescription Drugs was $161.25 million; $50 million in overhead from uncoded packaged drugs updated by the PPI for Prescription Drugs was $53.75 million) and prompted our proposed ASP+X value of ASP+4 in CY 2012. However, when we updated our analysis using a whole year of cost data in preparation for the CY 2012 final rule, holding the redistribution amount of $215 million constant but updating the analysis using a full year of costs, we observed a decline of 1 percent in the ASP+X amount to ASP+3. This result, and the concerns raised by commenters regarding the intra-rulemaking fluctuation in the methodologically-derived ASP+X percent with a fixed redistribution amount, prompted us to reexamine this issue in order to better understand the principal source of the intra-rulemaking fluctuation.

We note that since the implementation of the cost redistribution methodology, while we have always used an entire year of cost data to calculate the ASP+X percent in the final rule with comment period, we have not made adjustments in the redistribution amount to account for these additional data in the final rule. After further analysis, including 3 years of cost, claims, and redistribution data pertaining to the ASP+X calculation, we have determined that holding the redistribution amount constant between the proposed and final rules (as we did in the CY 2011 OPPS/ASC final rule with comment period and had proposed to again do for CY 2012) is the principal contributing factor to the intra-rulemaking fluctuation observed by commenters in CMS' current ASP+X methodology.

After performing the analysis described above, we believe the fluctuation in the methodologically-derived ASP+X percent in the intra-rulemaking period (that is, the period of time between the proposed and final rule) identified by commenters can be minimized, and greater stability in the ASP+X percent during the intra-rulemaking period achieved if CMS implements in CY 2012 a refinement to our ASP+X methodology that adjusts for the additional cost and claims data analyzed for the final rule. This refinement, in which we will redistribute a proportional amount of pharmacy overhead and handling costs from packaged to separately payable drugs instead of a fixed amount, is explained in detail below.

In the proposed rule, the $161 million of coded drug cost and $54 million in uncoded drug cost that we calculated using the CY 2011 redistribution amounts for coded and uncoded drugs indexed by the PPI for Prescription Drugs constituted 35 percent and 10.7 percent, respectively, of the drug handling and overhead costs for these categories. If we had redistributed the same amounts ($161 million of coded drug costs and $54 million of uncoded drug costs) for the final rule with comment period, due to the inclusion of a whole year's cost data in the final ASP+X calculation, each amount would constitute a substantially smaller proportion of all drug handling and pharmacy overhead costs and would cause the ASP+X to drop. However, because the final rule ASP+X calculation uses a whole year of data, while the proposed rule is based on a partial year, and because this additional data will, in most years, cause a decline in the ASP+X between the proposed rule and the final rule with comment period, we now believe that it is appropriate to hold constant the *proportions* of redistributed packaged drug cost from the proposed rule to the final rule with comment period instead of finalizing our prior years' methodology of redistributing a fixed amount of cost from coded and uncoded packaged drugs, and holding constant this *amount* of overhead that is redistributed from the proposed to the final rule.

We now believe that redistributing the same proportion, rather than the same amount, of coded and uncoded packaged drug cost in the final rule is appropriate because we believe this approach will enhance the intra-rulemaking stability for SCOD payment rates; the refinement will yield a final ASP +X value that in most cases does not change between the proposed rule and the final rule with comment period. Such a result occurs because this approach maintains the mathematical relationship between redistributed packaged drug pharmacy overhead and handling cost and total drug overhead and handling cost, so that when a whole year of cost data are analyzed for the final rule, the same proportional amount of coded and uncoded packaged drug cost is redistributed in order to calculate the ASP+X percent. Therefore, we believe that this approach is a small but important refinement in the redistribution methodology used to calculate the ASP+X amount and will lead to greater intra-rulemaking stability for SCOD payment rates.

It is important to note that this methodology redistributes a fixed proportion of the calculated overhead attributable to coded and uncoded packaged drugs so that the percent of overhead will not change between the proposed rule and the final rule with comment period. However, the percentage of total drug cost that is redistributed will be expected to change slightly between the proposed rule and the final rule with comment period. This is because each drug has a different fraction of its total cost attributed to pharmacy overhead and handling, and the ''mix'' of products (each with an individual pharmacy overhead cost) prescribed by physicians and billed to Medicare varies from month to month. The additional cost and claim data used to derive the ASP+X percent in the final rule with comment period will therefore reflect a slightly different mix of drugs and therefore a slightly different ratio of handling costs to total drug costs, when compared with the ratio from the proposed rule, which used less than a whole year of data. Table 39 below displays our findings with regard to the percentage of ASP in comparison to the cost for packaged coded drugs and biologicals and for separately payable coded drugs and biologicals after application of the final CY 2012 overhead adjustment methodology and amounts.

TABLE 39.—CY 2012 PHARMACY OVERHEAD ADJUSTMENT PAYMENT METHODOLOGY: ASP+X CALCULATION

	Total ASP Dollars for Drugs and Biologicals in Claims Data (in millions)*	Total Cost of Drugs and Biologicals in Claims Data *after adjustment* (in millions)**	Ratio of Cost to ASP (column 3/column 2)	ASP+X Percent
Uncoded Packaged Pharmaceutical Revenue Code Costs	Unknown	$595***	Unknown	Unknown
Coded Packaged Drugs and Biologicals with a reported ASP	$251	$565	2.25	ASP+125
Separately Payable Drugs and Biologicals with a reported ASP	$4,137	$4,284	1.04	ASP+4
All Coded Drugs and Biologicals with a reported ASP	$4,388	$4,777	1.09	ASP+9

*Total July 2011 ASP dollars (ASP multiplied by drug or biological units in CY 2010 claims) for drugs and biologicals with a HCPCS code and ASP information.

**Total cost in the CY 2010 claims data for drugs and biologicals

***Pharmacy revenue code costs without HCPCS codes.

In summary, for the reasons set forth above and considering the data limitations we have previously discussed, we are finalizing our proposal to continue our prior CY 2010 and CY 2011 acquisition cost proxy methodology and pharmacy overhead redistribution methodology in CY 2012, but with one refinement discussed below. In addition, we are finalizing our proposal to adjust the $200 million redistribution amount finalized in CY 2011 for inflation using the PPI for Prescription Drugs. For this final rule with comment period, we have analyzed the PPI-updated amount of $215 million, which is comprised of $161 million in overhead costs from coded packaged drugs and biologicals and $54 million in overhead costs from uncoded packaged drugs and biologicals, and noted that these updated amounts translate to approximately 35 percent of coded packaged drug overhead costs, and approximately 10.7 percent of uncoded packaged drug overhead costs. Rather than holding the redistribution amounts constant between the proposed rule and the final rule, for this CY 2012 OPPS final rule with comment period, we are instead holding constant the redistribution proportions of overhead cost for coded and uncoded packaged drugs in order to maintain the 35 percent and 10.7 percent ratios. Consequently, although the final redistribution amount is higher in this final rule with comment period than it was in the proposed rule, the proportion of redistributed overhead cost for coded and uncoded packaged drugs remains constant between the proposed and final rule. Therefore, for CY 2012, we will update the CY 2011 redistribution amounts by the PPI for Prescription Drugs (yielding $215 million, as described in the proposed rule), and then hold the proportions constant between the proposed rule and the final rule with comment period in order to redistribute $169 million (or 35 percent) of coded packaged drug overhead cost, and $71.3 million (or 10.7 percent) of uncoded packaged drug overhead cost, resulting in a total redistribution amount of $240.3 million.

The redistribution amount of $169 million in overhead cost from coded packaged drugs and biologicals is within the redistribution parameters established in the CY 2010 OPPS/ASC final rule with comment period of roughly one-third to one-half of overhead cost in coded packaged drugs and biologicals. The amount of 10.7 percent of drug cost in uncoded packaged drugs and biologicals would be redistributed to separately payable drugs for CY 2012. Therefore, this amount continues to be no less than 8 percent of the total uncoded drug and biological cost. The result of this methodology is an ASP+4 percent amount for CY 2012 when applied using July 2011 ASPs, data for claims for services furnished during CY 2010 and processed through the Common Working File before January 1, 2010, and the most current submitted cost reports as of January 1, 2011. For the reasons set forth above, we are finalizing an ASP+X percent of ASP+4 for separately payable drugs in CY 2012.

Further, we are finalizing our proposal to continue to include the claims data for 340B hospitals in the calculation of payment for drugs and biologicals under the CY 2012 OPPS. We believe excluding data from hospitals that participate in the 340B program from our ASP+X calculation, but paying those hospitals at that derived payment amount, would effectively redistribute payment to drugs or biologicals from payment for other services under the OPPS. Furthermore, we do not believe it would be appropriate to exclude claims from this subset of hospitals in the context of a proposed CY 2012 drug and biological payment policy that pays all hospitals the same rate for separately payable drugs and biologicals (74 FR 60517). In addition, we are finalizing our proposal that 340B hospitals continue to be paid the same amounts for separately payable drugs and biologicals as hospitals that do not participate in the 340B program for CY 2012 because commenters have generally opposed differential payment for hospitals based on their 340B participation status.

Finally, we are finalizing our proposal that the estimated payments for separately payable drugs and biologicals be taken into account in the calculation of the weight scaler that would apply to the relative weights for all procedural services (but would not apply to separately payable drugs and biologicals) paid under the OPPS, as required by section 1833(t)(14)(H) of the Act.

We note that although it is CMS' longstanding policy under the OPPS to refrain from instructing hospitals on the appropriate revenue code to use to charge for specific services, we continue to encourage hospitals to bill all drugs and biologicals with HCPCS codes, regardless of whether they are separately payable or packaged, and to ensure that drug costs are completely reported, using appropriate revenue codes. We also note that we make packaging determinations for drugs and biologicals annually based on cost information reported under HCPCS codes, and the OPPS ratesetting is best served when hospitals report charges for all items and services with HCPCS codes when they are available, whether or not Medicare makes separate payment for the items and services.

We also note that we continue to pursue the most appropriate methodology for establishing payment for drugs and biologicals under the OPPS. Because we are always trying to improve the integrity of our data, we have previously proposed multiple mechanisms to improve the cost data available to us, but have not implemented those proposals due to hospital concerns about the administrative burden. We continue to be interested in developing mechanisms that improve the cost data available to us while minimizing, to the extent possible, the administrative burden on hospitals. For the past 3 years, we have proposed an internal adjustment to redistribute an amount from packaged coded and uncoded drugs and biologicals to separately payable drugs and biologicals because the results of our standard drug payment methodology are unlikely to accurately reflect the full cost of acquisition and pharmacy overhead for separately payable and packaged drugs and biologicals due to hospital charging practices and our use of an annual drug packaging threshold. As we continue to work to refine our payment systems, a goal to which we have been consistently committed over the past several years, we encourage public input on alternative cost-based methodologies to aid in our ongoing evaluations that could improve upon the adopted methodology.

c. Payment Policy for Therapeutic Radiopharmaceuticals

Beginning in the CY 2005 OPPS final rule with comment period, we exempted radiopharmaceutical manufacturers from reporting ASP data for all radiopharmaceuticals for payment purposes under the OPPS. (For more information, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65811) and the CY 2006 OPPS final rule with comment period (70 FR 68655).) Consequently, we did not have ASP data for radiopharmaceuticals for consideration for OPPS ratesetting until we began collecting ASP for nonpass-through separately paid therapeutic radiopharmaceuticals for CY 2010. In accordance with section 1833(t)(14)(B)(i)(I) of the Act, we have classified therapeutic radiopharmaceuticals under the OPPS as SCODs. As such, we have paid for radiopharmaceuticals at average acquisition cost as determined by the Secretary and subject to any adjustment for overhead costs. For CYs 2006 and 2007, we used mean unit cost data from hospital claims to determine each radiopharmaceutical's packaging status and implemented a temporary policy to pay for separately payable radiopharmaceuticals based on the hospital's charge for each radiopharmaceutical adjusted to cost using the hospital's overall CCR. The methodology of providing separate radiopharmaceutical payment based on charges adjusted to cost through application of an individual hospital's overall CCR for CYs 2006 and 2007 was finalized as an interim proxy for average acquisition cost.

In CY 2008, we packaged payment for all diagnostic radiopharmaceuticals and we proposed and finalized a methodology to provide prospective payment for therapeutic radiopharmaceuticals (defined as those Level II HCPCS codes that include the term ''therapeutic'' along with a radiopharmaceutical in their long code descriptors) using mean costs derived from the CY 2006 claims data, where the costs were determined using our standard methodology of applying hospital-specific departmental CCRs to radiopharmaceutical charges, defaulting to hospital-specific overall CCRs only if appropriate departmental CCRs were unavailable (72 FR 66772). Following issuance of the CY 2009 OPPS/ASC proposed rule, section 142 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275) amended section 1833(t)(16)(C) of the Act, as amended by section 106(a) of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Pub. L. 110–173), to further extend the payment period for therapeutic radiopharmaceuticals based on hospitals' charges adjusted to cost through December 31, 2009. Therefore, for CY 2009, we finalized a policy to continue to pay hospitals for therapeutic radiopharmaceuticals at charges adjusted to cost through the end of CY 2009.

For CY 2010, we proposed and finalized a policy to pay for separately paid therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals. We allowed manufacturers to submit the ASP data in a patient-specific dose or patient-ready form in order to properly calculate the ASP amount for a given HCPCS code. This resulted in payment for nonpass-through separately paid therapeutic radiopharmaceuticals at ASP+4 percent for CY 2010 for products for which the manufacturer submitted ASP. We also finalized a policy to base therapeutic radiopharmaceutical payment on CY 2008 mean unit cost data derived from hospital claims if ASP information was unavailable. For CY 2011, we continued to pay for nonpass-through separately paid therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals, resulting in a payment rate for nonpass-through separately paid therapeutic radiopharmaceuticals of

ASP+5 percent. We also continued to base therapeutic radiopharmaceutical payment on CY 2009 mean unit cost data derived from hospital claims if ASP information was unavailable.

We believe that the rationale outlined in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524 through 60525) for applying the principles of separately payable drug pricing to therapeutic radiopharmaceuticals continues to be appropriate for nonpass-through separately payable therapeutic radiopharmaceuticals in CY 2012. Therefore, in the CY 2012 OPPS/ASC proposed rule (76 FR 42263), we proposed to continue to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals under the ASP+X payment level established using the proposed pharmacy overhead adjustment based on a redistribution methodology to set payment for separately payable drugs and biologicals (proposed at ASP+4 percent, as discussed in section V.B.3.b. of this final rule with comment period) based on ASP information, if available, for a ''patient ready'' dose and updated on a quarterly basis for products for which manufacturers report ASP data. For a full discussion of how a ''patient ready'' dose is defined, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60520 through 60521). We also proposed to rely on CY 2010 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable and to update the payment rates for separately payable therapeutic radiopharmaceuticals, according to our usual process for updating the payment rates for separately payable drugs and biologicals, on a quarterly basis if updated ASP information is available.

The proposed CY 2012 payment rates for nonpass-through separately payable therapeutic radiopharmaceuticals were included in Addenda A and B to the proposed rule (which is referenced in section XVII. of the proposed rule and available via the Internet).

Comment: A large number of commenters from consumers and disease-focused advocacy groups submitted comments regarding CMS' payment for BEXXAR® (Tositumomab and Iodine I 131 Tositumomab). The commenters stated that CMS payment for this product is inadequate and that payment rates may cause hospitals and physicians to be unable to make BEXXAR® available. Commenters also stated that CMS erred in treating certain portions of the BEXXAR® product as diagnostic, rather than therapeutic, because the presence of disease has already been diagnosed and affirmed prior to the administration of BEXXAR®. A few commenters characterized the proposed CY 2012 payment rate for BEXXAR® as being motivated by saving money. Some of these commenters stated that CMS was attempting to ''cut stipends'' or failing to fund cancer research. Other commenters suggested that CMS would no longer cover BEXXAR® or other radioimmunotherapies. One commenter submitted information on studies regarding the efficacy of BEXXAR® for treating Lymphoma. Several commenters stated that they were concerned about their ability to afford radioimmunotherapy services. One commenter suggested that CMS negotiate with drug manufacturers to reduce their charges.

Response: We do not agree with commenters' assertions that Medicare payment through the OPPS for BEXXAR® is inadequate. We analyzed this assertion against our standard methodologies and did not find evidence to support the commenters' assertion that OPPS payment for BEXXAR® is unusually low. In the comment letter to CMS, the manufacturer of BEXXAR® stated that it believed hospital acquisition cost for BEXXAR® is approximately $35,657, but the amount that Medicare has proposed to pay for CY 2012 is $33,982. We note that we pay for the majority of the cost of BEXXAR® treatment under the OPPS based on the manufacturer-supplied ASP plus, in CY 2012, 4 percent for hospital pharmacy handling and overhead, an amount calculated using hospital claims data. We also note that part of the administration costs for any therapy is typically bundled into prospective payments such as chemotherapy administration codes. In analyzing the elements of the treatment regimen described by commenters, we believe that all costs are accounted for in the various payment methods used by CMS to reimburse for the hot (therapeutic) and warm (diagnostic) doses of Tositumomab.

We also do not agree that our policy in paying portions of BEXXAR® as a diagnostic (rather than therapeutic) radiopharmaceutical is inappropriate. Although we acknowledge that certain components of BEXXAR® are therapeutic, other components of the therapy, most notably the ''warm'' dose of Tositumomab, are diagnostic in nature and are used in conjunction with imaging studies to determine whether future therapeutic services would be beneficial to the patient, and how to proceed with therapy. We note that diagnostic uses are characterized both by the inclusion of the word ''diagnostic'' in HCPCS long descriptors and by the use of the service to obtain information as opposed to improving the medical condition of the patient. We believe that commenters claiming that CMS is cutting stipends or failing to fund cancer research are mistaken; the Medicare program generally, and the OPPS in particular, does not provide stipends to cancer researchers, nor does it directly fund cancer research. We also wish to emphasize that CMS has not changed its coverage status for BEXXAR®, which remains a Medicare-covered treatment in the hospital outpatient department. Further, CMS has not made its proposed payment for BEXXAR® to save the Medicare program money. Payment for BEXXAR®, like most drugs and procedures in the OPPS, is determined by statute and is based on acquisition data furnished by drug manufacturers and costs reported to CMS by hospitals. Year-to-year fluctuations in payment for individual items and treatments are often the result of fluctuations in the submitted cost data, as it is in this case, and not the result of a policy decision to save the Medicare program money.

Finally, we are sympathetic to commenters' concern regarding the high cost of radioimmunotherapy services. We note that the national unadjusted copayment for the ''hot'' dose of Iodine I-131 Tositumomab is approximately $6,000, and can appreciate how many Medicare beneficiaries would have difficulties affording such a large coinsurance amount. Although we share commenters' concerns about the growth in health costs, CMS does not have the authority to directly negotiate with drug manufacturers on behalf of Medicare beneficiaries to get manufacturers to reduce their drug prices.

Comment: Several commenters requested that CMS create a HCPCS J-code for tositumomab, currently provided under a radioimmunotherapy regimen and billed as part of HCPCS code G3001 (Administration and supply of tositumomab, 450 mg). The commenter argued that because tositumomab is approved by the FDA as part of the BEXXAR® regimen and has its own National Drug Code (NDC), it should be recognized as a drug and, therefore, be paid as other drugs are paid under the OPPS methodology, instead of having a payment rate determined by hospital claims data. The commenters recommended that nonradiolabeled Tositumomab receive separate payment.

Response: We have consistently noted that unlabeled tositumomab is not

approved as either a drug or a radiopharmaceutical. It is a supply that is required as part of the radioimmunotherapy treatment regimen (the CY 2009 OPPS/ASC final rule with comment period (73 FR 68658), the CY 2008 OPPS final rule with comment period (72 FR 66765), the CY 2006 OPPS final rule with comment period (70 FR 68654), and the CY 2004 OPPS final rule with comment period (68 FR 63443)). We do not make separate payment for supplies used in services provided under the OPPS. Payments for necessary supplies are packaged into payments for the separately payable services provided by the hospital. Specifically, it is the administration of unlabeled tositumomab (the ''cold'' or diagnostic dose) that is a complete service that qualifies for separate payment under its own clinical APC, 0442. This diagnostic (information collecting, nontherapeutic) complete service is currently described by HCPCS code G3001, which includes tositumomab as a supply. Therefore, we do not agree with the commenter's recommendation that we should assign a separate HCPCS code to the supply of unlabeled tositumomab. Rather, we will continue to make separate payment for the administration of tositumomab, and payment for the supply of unlabeled tositumomab is packaged into the administration payment.

Comment: A majority of commenters supported CMS' proposal to continue to pay for separately payable therapeutic radiopharmaceuticals under the ASP+X payment level established using the proposed pharmacy overhead adjustment based on a redistribution methodology to set payment for separately payable drugs and biologicals based on ASP information, if available, for a ''patient ready'' dose and updated on a quarterly basis for products for which manufacturers report ASP data. Several commenters disagreed with the proposed payment rate for nonpass-through separately payable drugs, biologicals, and therapeutic radiopharmaceuticals at ASP+4 and instead recommended that CMS reimburse for these products at a set rate of ASP+6.

Several commenters disagreed with CMS' proposal to rely on CY 2010 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable. The commenters suggested that CMS instead use hospitals' charges adjusted to cost when ASP data are unavailable for nonpass-through separately payable therapeutic radiopharmaceuticals. Some commenters also recommended that CMS provide cost-based payment to hospitals when ASP is not available. A few commenters further noted that CMS should require all manufacturers of therapeutic radiopharmaceuticals to submit ASP data for all therapeutic radiopharmaceuticals currently paid under the OPPS.

Response: We appreciate the commenters' support. We continue to believe that providing payment for nonpass-through separately payable therapeutic radiopharmaceuticals based on ASP information, if available, for a ''patient ready'' dose, and updated quarterly for products for which the manufacturer reported ASP data or mean unit cost if ASP information is not available would provide appropriate payment for these products. As stated in the CY 2011 OPPS/ASC proposed rule (75 FR 46276), we believe that the ASP information collected under section 1847A(b)(1)(A) of the Act and our hospital claims data is a suitable proxy for the acquisition cost data, and that ASP+6 is an accurate payment for separately covered drugs and biologicals when it is derived using these data and our standard methodology. Therefore, we do not agree with commenters' assertion that we should as a matter of policy set payment for these items at ASP+6. When ASP data are not available, we believe that paying for therapeutic radiopharmaceuticals using mean unit cost would appropriately pay for the average hospital acquisition and associated handling costs of nonpass-through separately payable therapeutic radiopharmaceuticals. As we stated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71968) and the CY 2010 OPPS/ASC final rule with comment period (74 FR 60523), although using mean unit cost for payment for therapeutic radiopharmaceuticals when ASP data are not available is not the usual OPPS process (that relies on alternative data source, such as WAC or AWP, when ASP information is temporarily unavailable, prior to defaulting to the mean unit cost from hospital claims data), we continue to believe that WAC or AWP is not an appropriate proxy to provide OPPS payment for average therapeutic radiopharmaceutical acquisition cost and associated handling costs when manufacturers are not required to submit ASP data. In addition, we do not believe that we should provide payment at charges reduced to cost or reasonable cost when ASP data is not available. As we have stated previously in the CY 2008 OPPS/ASC final rule with comment period, we continue to believe that payment on a claim-specific basis is not consistent with the payment of items and services in a prospective payment system under the OPPS and may also lead to extremely high or low payments to hospitals for radiopharmaceuticals, even when those products would be expected to have relatively predictable and consistent acquisition and handling costs across individual clinical cases and hospitals. For CY 2012, Medicare will pay for only a few outpatient services at reasonable cost. These include, but are not limited to, corneal tissue acquisition and influenza vaccines. Corneal tissue acquisition and influenza vaccines are paid at reasonable cost in part because the input costs for future years are hugely unpredictable and to set a prospective payment rate for them may result in payment that is so deficient that hospitals would not be able to provide the services and the general public could be denied the benefits. In particular, it is not possible to forecast with confidence what the cost of influenza vaccine would be a year in advance because the composition of the vaccine is not constant from year to year. In contrast, however, the input costs of therapeutic radiopharmaceuticals are not hugely unpredictable. Therefore, we do not believe that therapeutic radiopharmaceuticals should be paid in the same manner as the few outpatient services paid at reasonable cost. We continue to believe that when ASP data are unavailable for therapeutic radiopharmaceuticals, payment based upon mean unit cost is an appropriate proxy for hospitals' acquisition and handling data.

We disagree with the commenters who suggested that CMS require all manufacturers of therapeutic radiopharmaceuticals to submit ASP data for all therapeutic radiopharmaceuticals currently paid under the OPPS. We continue to believe that requiring ASP data for all therapeutic radiopharmaceuticals currently paid under the OPPS would potentially be burdensome for manufacturers. Moreover, as we stated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71969) and the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524), the challenges involved in reporting ASP for a radiopharmaceutical are significant in many cases, given the variety of manufacturing processes and the frequent need for patient specific pre-processing. Therefore, due to the fact that the added administrative burden of direct reporting outweighs the expected

benefits, and given the relative accuracy of hospital claims data regarding such drugs, payment based on mean unit cost from historical hospital claims data offers the best proxy for average hospital acquisition cost and associated handling costs for a radiopharmaceutical in many situations. We continue to believe that we should allow, but not require, manufacturers to submit ASP information for therapeutic radiopharmaceuticals. If ASP information is unavailable for a therapeutic radiopharmaceutical because a manufacturer is not willing or not able to submit ASP information, we will provide payment based on the mean unit cost of the product that is applicable to payment rates for the year the nonpass-through therapeutic radiopharmaceutical is administered.

Comment: One commenter stated that while it supported paying separately payable therapeutic radiopharmaceuticals under the ASP+X payment methodology established in the CY 2012 proposed rule, it believed that payment for radiopharmaceuticals should be made at a higher level than other drugs and biologicals because of the unique pharmacy handling and overhead costs associated with radiopharmaceuticals. Therefore, the commenter recommended that CMS pay for radiopharmaceuticals at a payment rate of at least ASP+10 percent while continuing to develop detailed data on the overhead and handling costs associated with radiopharmaceuticals.

Response: We continue to believe that paying for therapeutic radiopharmaceuticals under the ASP+X payment amount established for separately payable drugs and biologicals under the OPPS, established at ASP+4 percent for CY 2012, is the most appropriate proxy for acquisition and pharmacy overhead and handling costs for separately payable therapeutic radiopharmaceuticals, regardless of the amount of pre-processing needed to create a ''patient ready'' dose. As we stated in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60522), we established our interpretation of ''patient-ready'' for purposes of the OPPS to mean that the ASP, reported in terms that reflect the applicable HCPCS code descriptor, should include the price for all component materials of the radiopharmaceutical as well as any additional processing, including radiolabeling, that is reflected in the price the manufacturer charges for the radiopharmaceutical, so long as the fees paid for such additional processing meet the ''bona fide service fee'' test under the regulations implementing section 1847A of the Act. We explicitly noted that because radiopharmaceuticals uniquely require radiolabeling of their component materials, we believe that radiolabeling could constitute a bona fide service on behalf of the manufacturer and the fees could meet the ''bona fide service fee'' test, for purposes of OPPS ASP reporting. Given our position on radiolabeling, we similarly believe that significant manufacturer processing costs associated with handling radiopharmaceuticals may be reflected in the prices used to calculate the manufacturer's ASP data for OPPS purposes. Therefore, the combined single payment for nonpass-through separately payable therapeutic radiopharmaceutical acquisition and overhead costs embodied in the ASP+4 percent payment rate for CY 2012 would address any other processing by the manufacturer for purposes of the OPPS, and we continue to believe this payment is sufficient to cover additional handling costs borne by the hospital (as calculated by hospital cost data). Under this interpretation of ''patient-ready'' dose, we do not believe that making an additional payment for more intensive handling costs is necessary.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals under the ASP+X payment level established using the pharmacy overhead adjustment based on a redistribution methodology to set payment for separately payable drugs and biologicals (as discussed in section V.B.3.b. of this final rule with comment period) based on ASP information, if available, for a ''patient ready'' dose and updated on a quarterly basis for products for which manufacturers report ASP data. For CY 2012, nonpass-through separately payable therapeutic radiopharmaceuticals will be paid at ASP+4 percent under the ASP+X payment methodology for nonpass-through separately payable drugs and biologicals. We will base nonpass-through, separately payable therapeutic radiopharmaceutical payment rates on mean unit cost derived from CY 2010 claims data when ASP pricing is not available. The final CY 2012 payment rates for nonpass-through separately payable therapeutic radiopharmaceuticals are included in Addenda A and B to this final rule with comment period (which are referenced in section XVII. of this final rule with comment period and available via the Internet).

4. Payment for Blood Clotting Factors

For CY 2011, we provided payment for blood clotting factors under the same methodology as other nonpass-through separately payable drugs and biologicals under the OPPS and continued paying an updated furnishing fee. That is, for CY 2011, we provided payment for blood clotting factors under the OPPS at ASP+5 percent, plus an additional payment for the furnishing fee. We note that when blood clotting factors are provided in physicians' offices under Medicare Part B and in other Medicare settings, a furnishing fee is also applied to the payment. The CY 2011 updated furnishing fee is $0.176 per unit.

In the CY 2012 OPPS/ASC proposed rule (76 FR 42263 through 42264), for CY 2012, we proposed to pay for blood clotting factors at ASP+4 percent, consistent with our proposed payment policy for other nonpass-through separately payable drugs and biologicals, and to continue our policy for payment of the furnishing fee using an updated amount. Our rationale for this proposed policy was first articulated in the CY 2006 OPPS final rule with comment period (70 FR 68661) and then later discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765). The proposed furnishing fee update was based on the percentage increase in the Consumer Price Index (CPI) for medical care for the 12-month period ending with June of the previous year. Because the Bureau of Labor Statistics releases the applicable CPI data after the MPFS and OPPS/ASC proposed rules are published, we are not able to include the actual updated furnishing fee in the proposed rules. Therefore, in accordance with our policy, as finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765), we would announce the actual figure for the percent change in the applicable CPI and the updated furnishing fee calculated based on that figure through applicable program instructions and posting on the CMS Web site at: *http://www.cms.gov/McrPartBDrugAvgSalesPrice/*.

Comment: A few commenters supported CMS' proposal to continue to apply the furnishing fee for blood clotting factors provided in the OPD. One commenter stated that the furnishing fee helps ensure patient access to blood clotting factors by increasing the payment rate for these items. Other commenters supported payment for blood clotting factors at no less than ASP+6 percent for CY 2011

and stated that payment at less than ASP+6 percent for all drugs and biologicals, especially blood clotting factors and all drugs and biologicals, is inappropriate.

Response: We appreciate the commenters' support. We continue to believe that applying the furnishing fee for blood clotting factors is appropriate for CY 2012. However, we see no compelling reason to provide payment for blood clotting factors under a different methodology for OPPS purposes at this time. For CY 2012, under this final rule with comment period, we will pay for blood clotting factors under the same methodology as other separately payable drugs and biologicals under the OPPS, and we will continue paying an updated furnishing fee. For the reasons we discussed in section V.B.3. of this final rule with comment period, we believe that the payment rate of ASP+4 percent is appropriate payment for the acquisition cost and pharmacy overhead related to drugs and biologicals that are not packaged, which includes blood clotting factors. In addition, because we recognize that there is additional work involved in acquiring the product, that is neither acquisition cost nor pharmacy overhead, we believe that it continues to be appropriate to pay a furnishing fee for blood clotting factors under the OPPS as is done in the physician's office setting and the inpatient hospital setting.

After consideration of the public comments we received, we are finalizing our CY 2012 proposal, without modification, to provide payment for blood clotting factors under the same methodology as other separately payable drugs and biologicals under the OPPS and to continue paying an updated furnishing fee. We will announce the actual figure for the percent change in the applicable CPI and the updated furnishing fee calculation based on that figure through the applicable program instructions and postings on the CMS Web site.

5. Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes, But Without OPPS Hospital Claims Data

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) does not address the OPPS payment in CY 2005 and after for drugs, biologicals, and radiopharmaceuticals that have assigned HCPCS codes, but that do not have a reference AWP or approval for payment as pass-through drugs or biologicals. Because there is no statutory provision that dictated payment for such drugs, biologicals, and radiopharmaceuticals in CY 2005, and because we had no hospital claims data to use in establishing a payment rate for them, we investigated several payment options for CY 2005 and discussed them in detail in the CY 2005 OPPS final rule with comment period (69 FR 65797 through 65799).

For CYs 2005 to 2007, we implemented a policy to provide separate payment for new drugs, biologicals, and radiopharmaceuticals with HCPCS codes (specifically those new drug, biological, and radiopharmaceutical HCPCS codes in each of those calendar years that did not crosswalk to predecessor HCPCS codes) but which did not have pass-through status, at a rate that was equivalent to the payment they received in the physician's office setting, established in accordance with the ASP methodology for drugs and biologicals, and based on charges adjusted to cost for radiopharmaceuticals. For CYs 2008 and 2009, we finalized a policy to provide payment for new drugs (excluding contrast agents and diagnostic radiopharmaceuticals) and biologicals (excluding implantable biologicals for CY 2009) with HCPCS codes, but which did not have pass-through status and were without OPPS hospital claims data, at ASP+5 percent and ASP+4 percent, respectively, consistent with the final OPPS payment methodology for other separately payable drugs and biologicals. New therapeutic radiopharmaceuticals were paid at charges adjusted to cost based on the statutory requirement for CY 2008 and CY 2009 and payment for new diagnostic radiopharmaceuticals was packaged in both years.

For CY 2010, we continued to provide payment for new drugs (excluding contrast agents) and nonimplantable biologicals with HCPCS codes that do not have pass-through status and are without OPPS hospital claims data at ASP+4 percent, consistent with the CY 2010 payment methodology for other separately payable nonpass-through drugs and nonimplantable biologicals. We also finalized a policy to extend the CY 2009 payment methodology to new therapeutic radiopharmaceutical HCPCS codes, consistent with our final policy in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60581 through 60526), providing separate payment for therapeutic radiopharmaceuticals that do not crosswalk to CY 2009 HCPCS codes, do not have pass-through status, and are without OPPS hospital claims data at ASP+4 percent. This policy was continued in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71970 through 71973), paying for new drugs, nonimplantable biologicals, and radiopharmaceuticals that do not crosswalk to CY 2010 HCPCS codes, do not have pass-through status, and are without OPPS hospital claims data at ASP+5 percent.

In the CY 2012 OPPS/ASC proposed rule (76 FR 42264 through 42266), we proposed to continue our payment policies for new drugs (excluding contrast agents and diagnostic radiopharmaceuticals), nonimplantable biologicals, and therapeutic radiopharmaceuticals that have HCPCS codes that do not crosswalk to CY 2011 HCPCS codes, do not have pass-through status, and are without OPPS hospital claims data. We proposed to provide payment for new CY 2012 drugs (excluding contrast agents and diagnostic radiopharmaceuticals), nonimplantable biologicals, and therapeutic radiopharmaceuticals, at ASP+4 percent, consistent with the proposed CY 2012 payment methodology for other separately payable nonpass-through drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals. We believed this proposed policy would ensure that new nonpass-through drugs, nonimplantable biologicals and therapeutic radiopharmaceuticals would be treated like other drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals under the OPPS, unless they are granted pass-through status. Only pass-through drugs, nonimplantable biologicals, or therapeutic radiopharmaceuticals would receive a different payment for CY 2012, which would be generally equivalent to the payment these drugs and biologicals would receive in the physician's office setting, consistent with the requirements of the statute.

We also proposed to continue our CY 2011 policy of packaging payment for all new nonpass-through diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals with HCPCS codes but without claims data (those new CY 2012 diagnostic radiopharmaceuticals, contrast agents, and implantable biological HCPCS codes that do not crosswalk to predecessor HCPCS codes). This is consistent with the proposed policy packaging all existing nonpass-through diagnostic radiopharmaceuticals, contrast agents and implantable biologicals, as discussed in more detail in sections V.B.2.d. and IV.A.2. of this final rule with comment period.

In accordance with the OPPS ASP methodology, in the absence of ASP data, for CY 2012, we proposed to

continue the policy we implemented beginning in CY 2005 of using the WAC for the product to establish the initial payment rate for new nonpass-through drugs and biologicals with HCPCS codes, but which are without OPPS claims data. However, we noted that if the WAC is also unavailable, we would make payment at 95 percent of the product's most recent AWP. We also proposed to assign status indicator ''K'' (for separately paid nonpass-through drugs and nonimplantable biologicals, including therapeutic radiopharmaceuticals) to HCPCS codes for new drugs and nonimplantable biologicals without OPPS claims data and for which we have not granted pass-through status. With respect to new, nonpass-through drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals for which we do not have ASP data, we proposed that once their ASP data become available in later quarterly submissions, their payment rates under the OPPS would be adjusted so that the rates would be based on the ASP methodology and set to the finalized ASP-based amount (proposed for CY 2012 at ASP+4 percent) for items that have not been granted pass-through status. This proposed policy, which is consistent with prior years' policies for these items, would ensure that new nonpass-through drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals would be treated like other drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals under the OPPS, unless they are granted pass-through status. Only pass-through drugs, nonimplantable biologicals, or therapeutic radiopharmaceuticals would receive a different payment for CY 2012, which would be generally equivalent to the payment these drugs and biologicals would receive in the physician's office setting, consistent with the requirements of the statute.

Similarly, we proposed to continue our CY 2011 policy to base the initial payment for new therapeutic radiopharmaceuticals with HCPCS codes, but which do not have pass-through status and are without claims data, on the WACs for these products if ASP data for these therapeutic radiopharmaceuticals are not available. If the WACs are also unavailable, we proposed to make payment for new therapeutic radiopharmaceuticals at 95 percent of the products' most recent AWP because we would not have mean costs from hospital claims data upon which to base payment. As we proposed with new drugs and biologicals, we proposed to continue our policy of assigning status indicator ''K'' to HCPCS codes for new therapeutic radiopharmaceuticals without OPPS claims data for which we have not granted pass-through status.

Consistent with other ASP-based payment, we proposed to announce any changes to the payment amounts for new drugs and biologicals in this CY 2012 OPPS/ASC final rule with comment period and also on a quarterly basis on the CMS Web site during CY 2012 if later quarter ASP submissions (or more recent WACs or AWPs) indicate that changes to the payment rates for these drugs and biologicals are necessary. The payment rates for new therapeutic radiopharmaceuticals would also be changed accordingly based on later quarter ASP submissions. We note that the new CY 2012 HCPCS codes for drugs, biologicals and therapeutic radiopharmaceuticals were not available at the time of development of the proposed rule. However, these agents are included in Addendum B to this CY 2012 OPPS/ASC final rule with comment period (which is referenced in section XVII. of this final rule with comment period and available via the Internet on the CMS Web site) where they are assigned comment indicator ''NI.'' This comment indicator reflects that their interim final OPPS treatment is open to public comment in this CY 2012 OPPS/ASC final rule with comment period.

There are several nonpass-through drugs and biologicals that were payable in CY 2010 and/or CY 2011 for which we did not have CY 2010 hospital claims data available for the proposed rule and for which there are no other HCPCS codes that describe different doses of the same drug, but which have pricing information available for the ASP methodology. We note that there are currently no therapeutic radiopharmaceuticals in this category. In order to determine the packaging status of these products for CY 2012, we calculated an estimate of the per day cost of each of these items by multiplying the payment rate of each product based on ASP+4 percent, similar to other nonpass-through drugs and biologicals paid separately under the OPPS, by an estimated average number of units of each product that would typically be furnished to a patient during one day in the hospital outpatient setting. This rationale was first adopted in the CY 2006 OPPS/ASC final rule with comment period (70 FR 68666 and 68667).

We proposed to package items for which we estimated the per day administration cost to be less than or equal to $80, which is the general packaging threshold that we proposed for drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals in CY 2012. We proposed to pay separately for items with an estimated per day cost greater than $80 (with the exception of diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals, which we proposed to continue to package regardless of cost as discussed in more detail in section V.B.2.d. of this final rule with comment period) in CY 2012. We proposed that the CY 2012 payment for separately payable items without CY 2010 claims data would be ASP+4 percent, similar to payment for other separately payable nonpass-through drugs and biologicals under the OPPS. In accordance with the ASP methodology paid in the physician's office setting, in the absence of ASP data we proposed to use the WAC for the product to establish the initial payment rate. However, we noted that if the WAC is also unavailable, we would make payment at 95 percent of the most recent AWP available.

The proposed estimated units per day and status indicators for these items are displayed in Table 33 of the proposed rule (76 FR 42265).

Comment: One commenter stated that it had been advised by the American Hospital Association Central office on HCPCS to report HCPCS code J1826 (Injection, interferon beta-1A-1A, 30 mcg). The commenter noted that HCPCS code J1826 currently has a status indicator of ''E'' and is not payable under OPPS but, because it is reportable, believed that it should receive a status indicator of ''K'' and be assigned to an APC. The commenter noted that HCPCS code Q3025 (K Interferon beta 1-a, 11 mcg for IM use) is reportable and is assigned to APC 9022 with a CY 2011 rate of approximately $222.

Response: HCPCS code J1826 was made effective January 1, 2011, and assigned a status indicator of ''E'' under the hospital OPPS and given a coverage indicator of ''Not payable by Medicare'' by the HCPCS Work Group. Although the HCPCS code is not payable by Medicare, other insurers may recognize it. Therefore, we advise hospitals to contact their health insurers for further reporting and/or payment information related to HCPCS code J1826.

The commenter is correct that hospitals can report HCPCS code Q3025, which is separately reportable under the OPPS. HCPCS code Q3025 is assigned to APC 9022, and for the July 2011 update, its payment rate is approximately $235. Hospitals are reminded that payments for OPPS drugs

are updated quarterly and posted on the CMS OPPS Web site, specifically at *https://www.cms.gov/HospitalOutpatientPPS/AU/list.asp#TopOfPage*. Because payments for OPPS drugs are updated on a quarterly basis, hospitals are advised to refer to either Addendum A, which is in APC order, or Addendum B, which is in HCPCS code order, for the latest payment information for items and services paid under the OPPS.

Comment: One commenter remarked that the ''list of acceptable analgesics for long bone fractures'' does not include products such as Motrin and ibuprofen. The commenter recommended that CMS add these products to the ''list of acceptable medications'' to treat pain for long bone fractures.

Response: We are uncertain what the commenter means in reference to a list of acceptable medications to treat long bone fractures as we are not aware of any such list established for Medicare payment in the hospital outpatient department for such injuries. In the CY 2012 OPPS/ASC proposed rule, we did not make any specific proposals regarding a list of analgesics, nor have we finalized any policies that pertain to a list of analgesics. Therefore, we believe that this comment is outside the scope of this final rule with comment period. However, we note that this discussion of drugs and biologicals discusses payment for all medically necessary drugs and therefore applies to those that are necessary for the treatment of pain in the HOPD, including NSAIDS such as ibuprofen. We further note that, although in most cases drugs necessary for the treatment of pain, including NSAIDS such as ibuprofen, do not receive separate payment under OPPS, their costs, as with costs associated with other supplies necessary during the visit, may be packaged into emergency department or clinic visit codes.

Although we did not receive any specific public comments regarding our proposed payment for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes, but without OPPS hospital claims data, many commenters supported our proposal to pay for separately payable drugs at ASP+4 percent in CY 2012, and other commenters recommended that we pay no less than ASP+6 percent for separately payable drugs in CY 2012. However, these comments were not specific to new drugs and biologicals with HCPCS codes but without OPPS claims data. For more information regarding payment for separately payable drugs, including general public comments and our responses, we refer readers to section V.B.3.b. of this final rule with comment period. In addition, commenters on the CY 2012 OPPS/ASC proposed rule objected to packaging payment for diagnostic radiopharmaceuticals and contrast agents in general, but these comments were not directed to new diagnostic radiopharmaceuticals or contrast agents with HCPCS codes but without OPPS claims data. We summarize these comments and provide our response in section V.A.2.d. of this final rule with comment period.

We are finalizing our CY 2012 proposal, without modification, as follows: Payment for new drugs (excluding contrast agents and diagnostic radiopharmaceuticals), nonimplantable biologicals, and therapeutic radiopharmaceuticals with HCPCS codes that do not crosswalk to CY 2011 HCPCS codes, but which do not have pass-through status and for which we do not have OPPS hospital claims data, will be made at ASP+4 percent for CY 2012, consistent with the final CY 2012 payment methodology for other new separately payable nonpass-through drugs, nonimplantable biologicals and therapeutic radiopharmaceuticals, described in section V.B.3.b. of this final rule with comment period. In cases where ASP information is not available, payment will be made using WAC, and, if WAC is also unavailable, payment will be made at 95 percent of the product's most recent AWP. Further, payment for all new nonpass-through diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals with HCPCS codes but for which we do not have OPPS claims data will be packaged for CY 2012. Finally, we are assigning status indicator ''K'' to HCPCS codes for new drugs and nonimplantable biologicals for which we do not have OPPS claims data and for which we have not granted pass-through status for CY 2012. With respect to new items for which we do not have ASP data, once their ASP data becomes available in later quarterly submissions, their payments will be adjusted so that the rates will be based on the ASP methodology and set to the finalized ASP amount of ASP+4 percent. This policy will ensure that payment is made for actual acquisition cost and pharmacy overhead for these new products.

For CY 2012, we also proposed to continue our CY 2011 policy to base payment for new therapeutic radiopharmaceuticals with HCPCS codes, but which do not have pass-through status and for which we do not have claims data, on the WACs for these products if ASP data for these therapeutic radiopharmaceuticals are not available. If the WACs are also unavailable, we proposed to make payment for a new therapeutic radiopharmaceutical at 95 percent of the product's most recent AWP because we would not have mean costs from hospital claims data upon which to base payment. Analogous to new drugs and biologicals, we proposed to continue our policy of assigning status indicator ''K'' to HCPCS codes for new therapeutic radiopharmaceuticals without OPPS claims data for which we have not granted pass-through status.

We did not receive any public comments specific to our proposal for new therapeutic radiopharmaceuticals with HCPCS codes but without pass-through status. However, commenters on the CY 2012 OPPS/ASC proposed rule were generally supportive of the ASP methodology for payment for therapeutic radiopharmaceuticals in the HOPD, and we are finalizing an ASP payment methodology for separately payable therapeutic radiopharmaceuticals for CY 2012, as discussed in section V.B.3.c. of this final rule with comment period.

We are finalizing our CY 2012 proposals, without modification, to provide payment based on WAC for new therapeutic radiopharmaceuticals with HCPCS codes but without pass-through status and for which we do not have claims data, if ASP data for these therapeutic radiopharmaceuticals is not available. If WAC information is also unavailable, we will make payment for new therapeutic radiopharmaceuticals at 95 percent of the product's most recent AWP. In addition, we are assigning status indicator ''K'' to HCPCS codes for new therapeutic radiopharmaceuticals without claims data in CY 2012 that do not have pass-through status.

Consistent with other ASP-based payments, for CY 2012, we proposed to announce any changes to the payment amounts for new drugs and biologicals in the CY 2012 OPPS/ASC final rule with comment period and also on a quarterly basis on the CMS Web site during CY 2012 if later quarter ASP submissions (or more recent WACs or AWPs) indicate that changes to the payment rates for these drugs and biologicals are necessary. The payment rates for new therapeutic radiopharmaceuticals will also be changed accordingly, based on later quarter ASP submissions. We note that the new CY 2012 HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals were not available at the time of development of the

proposed rule. However, they are included in Addendum B to this CY 2012 OPPS/ASC final rule with comment period. They are assigned comment indicator ''NI'' in Addendum B to reflect that their interim final OPPS treatment is open to public comment on this CY 2012 OPPS/ASC final rule with comment period.

We did not receive any public comments on our proposal to announce, via the CMS Web site, any changes to the OPPS payment amounts for new drugs and biologicals on a quarterly basis. Therefore, for the reasons described in the CY 2012 proposed rule, we are finalizing our proposal and will update payment rates for new drugs, biologicals, and therapeutic radiopharmaceuticals, as necessary, in association with our quarterly update process and provide this information on the CMS Web site.

There are several nonpass-through drugs and biologicals that were payable in CY 2010 and/or CY 2011, for which we did not have CY 2010 hospital claims data available for the proposed rule and for which there were no other HCPCS codes that describe different doses of the same drug. These drugs and biologicals do have pricing information available for the ASP methodology. In the CY 2012 OPPS/ASC proposed rule (76 FR 42265), we noted that there are currently no therapeutic radiopharmaceuticals in this category. In order to determine the packaging status of these products for CY 2012, we calculated an estimate of the per day cost of each of these items by multiplying the payment rate for each product based on ASP+4 percent, similar to other nonpass-through drugs and biologicals paid separately under the OPPS, by an estimated average number of units of each product that would typically be furnished to a patient during one day in the hospital outpatient setting. We proposed to package items for which we estimated the per day cost to be less than or equal to $80, which was the general packaging threshold that we proposed for drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals in CY 2012. We proposed to pay separately for items with an estimated per day cost greater than $80 (with the exception of diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals, which we proposed to continue to package regardless of cost (as discussed in more detail in section V.B.2.d. of this final rule with comment period)) in CY 2012. We proposed that the CY 2012 payment for separately payable items without CY 2010 claims data would be ASP+4 percent, similar to payment for other separately payable nonpass-through drugs and biologicals under the OPPS. In accordance with the ASP methodology used in the physician's office setting, in the absence of ASP data, we proposed to use the WAC for the product to establish the initial payment rate. However, we noted that if the WAC is also unavailable, we would make payment at 95 percent of the most recent AWP available.

We did not receive any public comments on our proposal to use estimated per day costs for these drugs and biologicals or on the resulting packaging status of these drugs and biologicals. However, upon receiving updated CY 2011 claims data for HCPCS codes J0364 (Injection, apomorphine hydrochloride, 1 mg), J0630 (Injection, calcitonin salmon, up to 400 units), and J9216 (Injection, interferon, gamma 1-b, 3 million units) for this final rule with comment period, we determined that we no longer needed to calculate an estimated average number of units for these three items because we now have sufficient data upon which to base payment. Therefore, for CY 2011, we calculated the packaging status for HCPCS codes J0364, J0630, and J9216 using our standard methodology as described above. These codes and their packaging status are discussed further in section V.B.2.b. of this final rule with comment period. Therefore, for the reasons described in our proposed rule, we are finalizing our CY 2012 proposal, with modification, to use the estimated number of units per day included in Table 40 below to determine estimated per day costs for the corresponding drugs and biologicals for CY 2012. Further, as we note in section V.B.2.b. of this final rule with comment period, the packaging threshold for CY 2012 has changed from $80 in the proposed rule to $75 in this final rule with comment period. As a result of this change, which occurred because of our use of the most recent forecast of the quarterly PPI index levels in our update of the CY 2012 packaging threshold for the final rule with comment period, we will package those drugs with an estimated per day cost less than or equal to $75 and provide separate payment for those drugs and biologicals (other than diagnostic radiopharmaceuticals, contrast agents and implantable biologicals) with estimated per day costs over $75 for CY 2012. For those drugs and biologicals without CY 2010 claims data that we determine to be separately payable in CY 2012, payment will be made at ASP+4 percent. If ASP information is not available, payment will be based on WAC, or 95 percent of the most recently published AWP if WAC is not available. The final estimated units per day and status indicators for these items are displayed in Table 40 below.

TABLE 40.—DRUGS AND BIOLOGICALS WITHOUT CY 2010 CLAIMS DATA

CY 2012 HCPCS Code	CY 2012 Long Descriptor	Estimated Average Number of Units Per Day	CY 2012 SI	CY 2012 APC
J0205	Injection, alglucerase, per 10 units	420	K	0900
J1680	Injection, human fibrinogen concentrate, 100 mg	49	K	1290
J2513	Injection, pentastarch, 10% solution, 100 ml	4	K	1222
J2724	Injection, protein c concentrate, intravenous, human, 10 iu	1540	K	1139
J3355	Injection, urofollitropin, 75 IU	2	K	1741
Q0515	Injection, sermorelin acetate, 1 microgram	70	K	3050

Finally, there were five drugs and biologicals, shown in Table 34 of the proposed rule (76 FR 42266), that were payable in CY 2010, but for which we lacked CY 2010 claims data and any other pricing information for the ASP methodology for the CY 2012 OPPS/ASC proposed rule. In CY 2009, for similar items without CY 2007 claims data and without pricing information for the ASP methodology, we previously stated that we were unable to determine their per day cost and we packaged these items for the year, assigning these items status indicator ''N.''

For CY 2010, we finalized a policy to change the status indicator for drugs and biologicals previously assigned a payable status indicator to status indicator ''E'' (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) whenever we lacked claims data and pricing information and were unable to determine the per day cost. In addition, we noted that we would provide separate payment for these drugs and biologicals if pricing information reflecting recent sales becomes available mid-year in CY 2010 for the ASP methodology. If pricing information became available, we would assign the products status indicator ''K'' and pay for them separately for the remainder of CY 2010. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71973), for CY 2011, we continued our CY 2010 policy to assign status indicator ''E'' to drugs and biologicals that lacked CY 2009 claims data and pricing information for the ASP methodology. We also continued our policy to change the status indicator for these products to ''K'' if pricing information became available, and pay for them separately for the remainder of CY 2011.

For CY 2012, we proposed to continue our CY 2011 policy to assign status indicator ''E'' to drugs and biologicals that lack CY 2010 claims data and pricing information for the ASP methodology. All drugs and biologicals without CY 2010 hospital claims data and data based on the ASP methodology that are assigned status indicator ''E'' on this basis at the time of the proposed rule for CY 2012 are displayed in Table 34 of the proposed rule (76 FR 42266). If pricing information becomes available, we proposed to assign the products status indicator ''K'' and pay for them separately for the remainder of CY 2012. We did not receive any public comments on these proposals.

We did not receive any public comments on our proposal to change the status indicators of drugs and biologicals without CY 2010 claims data or pricing information for the ASP methodology. After the proposed rule was published, we received pricing information for HCPCS code J9213 (Injection, interferon, alfa-2a, recombinant, 3 million units) for CY 2012, and it is included in Addendum B to this CY 2012 OPPS/ASC final rule with comment period (which is referenced in section XVII. of this final rule with comment period and available via the Internet on the CMS Web site) with an assigned CY 2012 status indicator of ''N.''

Further, as we have used updated claims data and ASP pricing information for this final rule with comment period, we have newly identified HCPCS codes J2265 (Injection, minocycline hydrochloride, 1 mg), Q4123 (Alloskin RT), Q4125 (Arthroflex), Q4126 (Memoderm), Q4127 (Talymed), Q4128 (Flexhd or alopatch hd), and Q4129 (Unite biomatrix) as lacking CY 2010 claims data and any other pricing information for the ASP methodology. Therefore, in addition to the HCPCS codes for which we proposed to assign status indicator ''E'' for CY 2012 due to a lack of claims data and any other pricing information in the proposed rule, we are assigning status indicator ''E'' to HCPCS codes J2265, Q4123, Q4125, Q4126, Q4127, Q4128, and Q4129. We are finalizing our CY 2012 proposal, without modification, to assign status indicator ''E'' to these drugs and biologicals. As was our policy in CY 2011, if pricing information becomes available for these products in CY 2012 we will assign the products status indicator ''K'' and pay for them separately for the remainder of CY 2012.

All drugs and biologicals without CY 2010 hospital claims data and data based on the ASP methodology that are assigned status indicator ''E'' on this basis at the time of this final rule with comment period for CY 2012 are displayed in Table 41 below.

TABLE 41.—DRUGS AND BIOLOGICALS WITHOUT CY 2010 CLAIMS DATA AND WITHOUT PRICING INFORMATION FOR THE ASP METHODOLOGY

CY 2012 HCPCS Code	CY 2012 Long Descriptor	CY 2012 SI
J2265	Injection, minocycline hydrochloride, 1 mg	E
J2940	Injection, somatrem, 1 mg	E
J3305	Injection, trimetrexate glucuronate, per 25 mg	E
J8650	Nabilone, oral, 1 mg	E
J9165	Injection, diethylstilbestrol diphosphate, 250 mg	E
Q4123	Alloskin RT	E
Q4125	Arthroflex	E
Q4126	Memoderm	E
Q4127	Talymed	E
Q4128	Flexhd or alopatch hd	E
Q4129	Unite biomatrix	E

VI. Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

A. Background

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payments for drugs, biologicals, radiopharmaceuticals, and categories of devices for a given year to an ''applicable percentage'' (currently 2.0 percent, as stated below) of total program payments estimated to be made for all covered services under the hospital OPPS furnished for that year. For a year (or portion of a year) before CY 2004, the applicable percentage was 2.5 percent; for CY 2004 and subsequent years, the applicable percentage is a percentage specified by the Secretary up to (but not to exceed) 2.0 percent.

If we estimate before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a uniform prospective reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded. We make an estimate of pass-through spending to determine not only whether payments exceed the applicable percentage, but also to determine the appropriate pro rata reduction to the conversion factor for the projected level of pass-through spending in the following year in order to ensure that total estimated pass-through spending for the prospective payment year is budget neutral, as required by section 1883(t)(6)(E) of the Act.

For devices, developing an estimate of pass-through spending in CY 2012 entails estimating spending for two groups of items. The first group of items consists of device categories that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2012. The CY 2008 OPPS/ASC final rule with comment period (72 FR 66778) describes the methodology we have used in previous years to develop the pass-through spending estimate for known device categories continuing into the applicable update year. The second group contains items that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2011 or beginning in CY 2012. Beginning in CY 2010, the pass-through evaluation process and pass-through payment for implantable biologicals newly approved for pass-through payment beginning on or after January 1, 2010, that are surgically inserted or implanted (through a surgical incision or a natural orifice; also referred to herein as ''implantable biologicals'') is the device pass-through process and payment methodology only (74 FR 60476). In the CY 2012 OPPS/ASC proposed rule (76 FR 42266), we proposed for the CY 2012 OPPS that the estimate of pass-through spending for implantable biologicals newly eligible for pass-through payment beginning in CY 2012 be included in the pass-through spending estimate for this second group of device categories. The sum of the CY 2012 pass-through estimates for these two groups of device categories would equal the total CY 2012 pass-through spending estimate for device categories with pass-through status.

For devices eligible for pass-through payment, section 1833(t)(6)(D)(ii) of the Act establishes the pass-through payment amount as the amount by which the hospital's charges for the device, adjusted to cost, exceeds the portion of the otherwise applicable OPPS fee schedule payment that the Secretary determines is associated with the device. As discussed in section IV.A.2. of the proposed rule and this final rule with comment period, we deduct from the pass-through payment for an identified device category eligible for pass-through payment an amount that reflects the portion of the APC payment amount that we determine is associated with the cost of the device, defined as the device APC offset amount, when we believe that the predecessor device costs for the device category newly approved for pass-through payment are already packaged into the existing APC structure. For each device category that becomes newly eligible for device pass-through payment, including implantable biologicals from CY 2010 forward, we estimate pass-through spending to be

the difference between payment for the device category and the device APC offset amount, if applicable, for the procedures that would use the device. If we determine that the predecessor device costs for the new device category are not already included in the existing APC structure, the pass-through spending estimate for the device category is the full payment at charges adjusted to cost.

For drugs and biologicals eligible for pass-through payment, section 1833(t)(6)(D)(i) of the Act establishes the pass-through payment amount as the amount by which the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary) exceeds the portion of the otherwise applicable fee schedule amount that the Secretary determines is associated with the drug or biological. Because we proposed to pay for most nonpass-through separately payable drugs and nonimplantable biologicals under the CY 2012 OPPS at ASP+4 percent, which represented the otherwise applicable fee schedule amount associated with most pass-through drugs and biologicals, and because we proposed to pay for CY 2012 pass-through drugs and nonimplantable biologicals at ASP+6 percent or the Part B drug CAP rate, if applicable, our estimate of drug and nonimplantable biological pass-through payment for CY 2012 would not be zero, as discussed below. Furthermore, payment for certain drugs, specifically diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals without pass-through status, will always be packaged into payment for the associated procedures because these products will never be separately paid. However, all pass-through diagnostic radiopharmaceuticals and contrast agents with pass-through status approved prior to CY 2012 would be paid at ASP+6 percent or the Part B drug CAP rate, if applicable, like other pass-through drugs and biologicals. Therefore, our estimate of pass-through payment for all diagnostic radiopharmaceuticals and contrast agents with pass-through status approved prior to CY 2012 is also not zero. We note that there are no implantable biologicals proposed to continue on pass-through status for CY 2012 and, therefore, we did not propose to include implantable biologicals in our estimate of pass-through payment. Payment for nonpass-through implantable biologicals will continue to be packaged into the payment for the associated procedure as described in section V.B.2.d of the proposed rule.

In section V.A.4. of the proposed rule and this final rule with comment period, we discuss our proposed and final policy to determine if the cost of certain ''policy-packaged'' drugs, including diagnostic radiopharmaceuticals and contrast agents, are already packaged into the existing APC structure. If we determine that a ''policy-packaged'' drug approved for pass-through payment resembles predecessor diagnostic radiopharmaceuticals or contrast agents already included in the costs of the APCs that would be associated with the drug receiving pass-through payment, in the proposed rule, we proposed to offset the amount of pass-through payment for diagnostic radiopharmaceuticals and contrast agents. For these drugs, the APC offset amount would be the portion of the APC payment for the specific procedure performed with the pass-through diagnostic radiopharmaceutical or contrast agent that is attributable to diagnostic radiopharmaceuticals or contrast agents, which we refer to as the ''policy-packaged'' drug APC offset amount. If we determine that an offset is appropriate for a specific diagnostic radiopharmaceutical or contrast agent receiving pass-through payment, we would reduce our estimate of pass-through payment for these drugs by this amount.

We note that the Part B drug CAP program has been postponed since January 1, 2009. We refer readers to the Medicare Learning Network (MLN) Matters Special Edition article SE0833 for more information, available via the CMS Web site at: *http://www.cms.gov/MLNMattersArticles/downloads/SE0833.pdf*. As of the publication of the proposed rule and this final rule with comment period, the postponement of the Part B drug CAP program is still in effect. As in past years, for the proposed rule and this final rule with comment period, we do not have an effective Part B drug CAP rate for pass-through drugs and biologicals.

Similar to pass-through estimates for devices, the first group of drugs and nonimplantable biologicals requiring a pass-through payment estimate consists of those products that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2012. The second group contains drugs and nonimplantable biologicals that we know are newly eligible, or project will be newly eligible, in the remaining quarters of CY 2011 or beginning in CY 2012. The sum of the CY 2012 pass-through estimates for these two groups of drugs and biologicals would equal the total CY 2012 pass-through spending estimate for drugs and biologicals with pass-through status.

B. Estimate of Pass-Through Spending

In the CY 2012 OPPS/ASC proposed rule (76 FR 42267), we proposed to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2012, consistent with our OPPS policy from CY 2004 through CY 2011 (75 FR 71975).

At the time of the proposed rule, for the first group of devices for pass-through payment estimation purposes, there was one device category eligible for pass-through payment for CY 2012, C1749 (Endoscope, retrograde imaging/illumination colonoscope device (implantable)). We estimated that CY 2012 pass-through expenditures related to device category C1749 would be approximately $35 million. However, for this final rule with comment period, for the first group of devices for pass-through payment estimate purposes, there currently are three device categories eligible for pass-through payment in CY 2012: C1749 that became effective October 1, 2010; C1830 (Powered bone marrow biopsy needle) that became effective October 1, 2011; and C1840 (Lens, intraocular (telescopic)) that became effective October 1, 2011. For this final rule with comment period, we estimate that CY 2012 pass-through expenditures related to these 3 categories will be approximately $47 million.

In estimating our proposed CY 2012 pass-through spending for device categories in the second group, which also includes any estimate for implantable biologicals that are eligible for pass-through payment, we include: Device categories that we know at the time of the development of the proposed rule would be newly eligible for pass-through payment in CY 2012 (of which there were none); additional device categories (including categories that describe implantable biologicals) that we estimate could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2012; and contingent projections for new device categories (including categories that describe implantable biologicals) established in the second through fourth quarters of CY 2012. We proposed to use the general methodology described in the

CY 2008 OPPS/ASC final rule with comment period (72 FR 66778), while also taking into account recent OPPS experience in approving new pass-through device categories. For the proposed rule, the estimate of CY 2012 pass-through spending for this second group of device categories was $10 million. Using our established methodology, we proposed that the total estimated pass-through spending for device categories for CY 2012 (spending for the first group of device categories ($35 million) plus spending for the second group of device categories ($10 million)) be $45 million.

Comment: One commenter was pleased with our estimate based on the one device category, C1749, in the CY 2012 OPPS/ASC proposed rule.

Response: We appreciate this comment.

For this CY 2012 OPPS/ASC final rule with comment period, 3 device categories, C1749, C1830, and C1840, will be eligible for pass-through payment for CY 2012, as mentioned earlier, and the pass-through spending estimate for those categories in $47 million. There also are possible new device categories for pass-through payment based on current applications and future applications. Therefore, the estimate of CY 2011 pass-through spending for the second group of device categories is $10 million.

For this CY 2012 final rule with comment period, we are finalizing the continued use of our established methodology. Employing our established methodology that the estimate of pass-through device spending in CY 2012 incorporates CY 2012 estimates of pass-through spending for known device categories with continuing pass-through status in CY 2012, those known or projected to be first effective January 1, 2012, and those device categories projected to be approved during subsequent quarters of CY 2011 or CY 2012, we estimate for this CY 2012 OPPS/ASC final rule with comment period the total pass-through spending for device categories for CY 2011 to be $57 million.

To estimate CY 2012 proposed pass-through spending for drugs and nonimplantable biologicals in the first group, specifically those drugs (including radiopharmaceuticals and contrast agents) and nonimplantable biologicals recently made eligible for pass-through payment and continuing on pass-through status for CY 2012, we proposed to utilize the most recent Medicare physician's office data regarding their utilization, information provided in the respective pass-through applications, historical hospital claims data, pharmaceutical industry information, and clinical information regarding those drugs or nonimplantable biologicals, to project the CY 2012 OPPS utilization of the products.

For the known drugs and nonimplantable biologicals (excluding diagnostic radiopharmaceuticals and contrast agents) that would be continuing on pass-through status in CY 2012, we estimated the proposed pass-through payment amount as the difference between ASP+6 percent or the Part B drug CAP rate, as applicable, and the proposed payment rate for nonpass-through drugs and nonimplantable biologicals that would be separately paid at ASP+4 percent, aggregated across the projected CY 2012 OPPS utilization of these products. Because payment for a diagnostic radiopharmaceutical or contrast agent would be packaged if the product were not paid separately due to its pass-through status, we proposed to include in the proposed CY 2012 pass-through estimate the difference between payment for the drug or nonimplantable biological at ASP+6 percent (or WAC+6 percent, or 95 percent of AWP, if ASP or WAC information is not available) and the ''policy-packaged'' drug APC offset amount, if we have determined that the diagnostic radiopharmaceutical or contrast agent approved for pass-through payment resembles predecessor diagnostic radiopharmaceuticals or contrast agents already included in the costs of the APCs that would be associated with the drug receiving pass-through payment. For the CY 2012 proposed rule, we proposed to continue to use the methodology used in CY 2011 to calculate a proposed spending estimate for this first group of drugs and biologicals to be approximately $5.7 million.

We did not receive any public comments on our proposed methodology for calculating the spending estimate for this first group of drugs and nonimplantable biologicals. Therefore, for this final rule with comment period, we are finalizing our proposed methodology. Using that methodology, we calculated a final spending estimate for this first group of drugs and biologicals to be $21.5 million.

To estimate CY 2012 pass-through spending for drugs and nonimplantable biologicals in the second group (that is, drugs and nonimplantable biologicals that we knew at the time of development of the proposed rule would be newly eligible for pass-through payment in CY 2012, additional drugs and nonimplantable biologicals that we estimate could be approved for pass-through status subsequent to the development of this proposed rule and before January 1, 2012, and projections for new drugs and nonimplantable biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2012), we proposed to use utilization estimates from pass-through applicants, pharmaceutical industry data, clinical information, recent trends in the per unit ASPs of hospital outpatient drugs, and projected annual changes in service volume and intensity as our basis for making the CY 2012 proposed pass-through payment estimate. We also considered the most recent OPPS experience in approving new pass-through drugs and nonimplantable biologicals. Using our proposed methodology for estimating CY 2012 pass-through payments for this second group of drugs, we calculated a proposed spending estimate for this second group of drugs and nonimplantable biologicals to be approximately $13.8 million.

We did not receive any public comments on our proposed policy and, therefore, are finalizing our proposed methodology for estimating CY 2012 pass-through payments for this second group of drugs. For this final rule with comment period, we calculated a final spending estimate for this second group of drugs and biologicals to be $10.6 million.

As discussed in section V.A. of the proposed rule and this final rule with comment period, radiopharmaceuticals are considered drugs for pass-through purposes. Therefore, we included radiopharmaceuticals in our proposed CY 2012 pass-through spending estimate for drugs and biologicals. Our proposed CY 2012 estimate for total pass-through spending for drugs and biologicals (spending for the first group of drugs and nonimplantable biologicals ($5.7 million) plus spending for the second group of drugs and nonimplantable biologicals ($13.8 million)) equaled $19.5 million.

The final estimate for pass-through spending for the first group of drugs and biologicals is $21.5 million for CY 2012. The final estimate for pass-through spending for the second group of drugs and biologicals is $10.6 million for CY 2012. As discussed in section V.A. of this final rule with comment period, radiopharmaceuticals are considered drugs for pass-through purposes. Therefore, we included radiopharmaceuticals in our final CY 2012 pass-through spending estimate for drugs and biologicals. Our CY 2012 allocation in this final rule with comment period for total estimated

pass-through spending for drugs and biologicals is $32.1 million.

In summary, in accordance with the methodology described above in this section, for this final rule with comment period, we estimate that total pass-through spending for the device categories and the drugs and nonimplantable biologicals that are continuing to receive pass-through payment in CY 2012 and those device categories, drugs, and nonimplantable biologicals that first become eligible for pass-through payment during CY 2012 will be approximately $89.1 million (approximately $57 million for device categories and approximately $32.1 million for drugs and nonimplantable biologicals), which represents 0.22 percent of total projected OPPS payments for CY 2012. We estimate that pass-through spending in CY 2012 will not amount to 2.0 percent of total projected OPPS CY 2012 program spending.

VII. OPPS Payment for Hospital Outpatient Visits

A. Background

Currently, hospitals report HCPCS visit codes to describe three types of OPPS services: Clinic visits; emergency department visits; and critical care services. For OPPS purposes, we recognize clinic visit codes as those codes defined in the CPT code book to report evaluation and management (E/M) services provided in the physician's office or in an outpatient or other ambulatory facility. We recognize emergency department visit codes as those codes used to report E/M services provided in the emergency department. Emergency department visit codes consist of five CPT codes that apply to Type A emergency departments and five Level II HCPCS codes that apply to Type B emergency departments. For OPPS purposes, we recognize critical care codes as those CPT codes used by hospitals to report critical care services that involve the ''direct delivery by a physician(s) of medical care for a critically ill or critically injured patient,'' as defined by the CPT code book. In Transmittal 1139, Change Request 5438, dated December 22, 2006, we stated that, under the OPPS, the time that can be reported as critical care is the time spent by a physician and/or hospital staff engaged in active face-to-face critical care of a critically ill or critically injured patient. Under the OPPS, we also recognize HCPCS code G0390 (Trauma response team associated with hospital critical care service) for the reporting of a trauma response in association with critical care services.

As we proposed in the CY 2012 OPPS/ASC proposed rule (76 FR 42268), we are continuing to recognize these CPT and HCPCS codes describing clinic visits, Type A and Type B emergency department visits, critical care services, and trauma team activation provided in association with critical care services for CY 2012. These codes are listed below in Table 42.

BILLING CODE 4120–01–P

TABLE 42.—HCPCS CODES USED TO REPORT CLINIC AND EMERGENCY DEPARTMENT VISITS AND CRITICAL CARE SERVICES

CY 2012 HCPCS Code	CY 2012 Descriptor
Clinic Visit HCPCS Codes	
99201	Office or other outpatient visit for the evaluation and management of a new patient (Level 1)
99202	Office or other outpatient visit for the evaluation and management of a new patient (Level 2)
99203	Office or other outpatient visit for the evaluation and management of a new patient (Level 3)
99204	Office or other outpatient visit for the evaluation and management of a new patient (Level 4)
99205	Office or other outpatient visit for the evaluation and management of a new patient (Level 5)
99211	Office or other outpatient visit for the evaluation and management of an established patient (Level 1)
99212	Office or other outpatient visit for the evaluation and management of an established patient (Level 2)
99213	Office or other outpatient visit for the evaluation and management of an established patient (Level 3)
99214	Office or other outpatient visit for the evaluation and management of an established patient (Level 4)
99215	Office or other outpatient visit for the evaluation and management of an established patient (Level 5)
Emergency Department Visit HCPCS Codes	
99281	Emergency department visit for the evaluation and management of a patient (Level 1)
99282	Emergency department visit for the evaluation and management of a patient (Level 2)
99283	Emergency department visit for the evaluation and management of a patient (Level 3)

99284	Emergency department visit for the evaluation and management of a patient (Level 4)
99285	Emergency department visit for the evaluation and management of a patient (Level 5)
G0380	Type B emergency department visit (Level 1)
G0381	Type B emergency department visit (Level 2)
G0382	Type B emergency department visit (Level 3)
G0383	Type B emergency department visit (Level 4)
G0384	Type B emergency department visit (Level 5)
Critical Care Services HCPCS Codes	
99291	Critical care, evaluation and management of the critically ill or critically injured patient; first 30-74 minutes
99292	Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes
G0390	Trauma response associated with hospital critical care service

BILLING CODE 4120–01–C

During the February 28–March 1, 2011, APC Panel meeting, the APC Panel recommended that CMS continue to report claims data for clinic and emergency department visits and observation, and, if CMS identifies changes in patterns of utilization or cost, it bring those issues before the Visits and Observation Subcommittee for future consideration. The APC Panel also recommended that the work of the Visits and Observation Subcommittee continue. In the CY 2012 OPPS/ASC proposed rule (76 FR 42269), we indicated that we are adopting these recommendations and plan to provide the requested data and analyses to the APC Panel at an upcoming meeting.

At its August 10–11, 2011, meeting, the APC Panel recommended that the work of the Visits and Observation Subcommittee continue. We are accepting this recommendation.

B. Policies for Hospital Outpatient Visits

1. Clinic Visits: New and Established Patient Visits

As reflected in Table 42, hospitals use different CPT codes for clinic visits based on whether the patient being treated is a new patient or an established patient. Beginning in CY 2009, we refined the definitions of a new patient and an established patient to reflect whether or not the patient has been registered as an inpatient or outpatient of the hospital within the past 3 years. A patient who has been registered as an inpatient or outpatient of the hospital within the 3 years prior to a visit would be considered to be an established patient for that visit, while a patient who has not been registered as an inpatient or outpatient of the hospital within the 3 years prior to a visit would be considered to be a new patient for that visit. We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68677 through 68680) for a full discussion of the refined definitions.

We stated in the CY 2012 OPPS/ASC proposed rule (76 FR 42269) that we continue to believe that defining new or established patient status based on whether the patient has been registered as an inpatient or outpatient of the hospital within the 3 years prior to a visit will reduce hospitals' administrative burden associated with reporting appropriate clinic visit CPT codes, as we stated in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68677 through 68680). For CY 2012, we proposed to continue recognizing the refined definitions of a new patient and an established patient, and applying our policy of calculating median costs for clinic visits under the OPPS using historical hospital claims data. As discussed in section II.A.2.e.(1) of the proposed rule and consistent with our CY 2011 policy, when calculating the median costs for the clinic visit APCs (0604 through 0608), we proposed to continue to utilize our methodology that excludes those claims for visits that are eligible for payment through the extended assessment and management composite APC 8002 (Level I Extended Assessment and Management Composite). We stated in the proposed rule that we continue to believe that this approach results in the most accurate cost estimates for APCs 0604 through 0608 for CY 2012.

Comment: Some commenters recommended that CMS remove the distinction between new and established patient clinic visits, arguing that the length of time between a patient's hospital visits has no bearing on services or resources provided during a specific hospital visit. According to commenters, facilities must expend the same level of resources to evaluate, manage, and treat the patient's current condition, regardless of whether the patient was registered as an inpatient or an outpatient in the hospital within the past 3 years. In addition, some commenters stated that there are significant operational issues involved with implementing the 3-year criterion for hospital clinic visit billing purposes. Some commenters acknowledged that CMS' claims data indicate a new patient visit involves more resources than an established patient visit, but argued that any differences in costs that are evident in claims data for new patient visits versus established patient visits would be the result of hospitals' erroneous reporting of these codes, rather than any real difference in the level of resources

expended treating a new versus an established patient. The commenters suggested that CMS recognize only the established patient visit codes and calculate payment rates for those codes by blending median costs for both the new and established patient visits. The commenters acknowledged this may result in reductions to the APC payment rates for established patient visits. The commenters stated that, if CMS chooses to continue to require hospitals to report both new and established patient visit codes, the distinction should be based upon whether the patient has a medical record.

Response: As we stated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71986) and the CY 2010 OPPS/ASC final rule with comment period (74 FR 60547), because hospital claims data continue to show significant cost differences between new and established patient visits, we continue to believe it is necessary and appropriate to recognize the CPT codes for both new and established patient visits and, in some cases, provide differential payment for new and established patient visits of the same level. Therefore, we do not believe it is appropriate to recognize only the established patient visit codes and calculate payment rates for those codes by blending median costs for both the new and established patient visits. For example, the final CY 2012 median cost for the Level 3 new patient clinic visit, described by CPT code 99203 and calculated using over 259,000 single claims from CY 2010, is approximately $103, while the final CY 2012 median cost for the Level 3 established patient clinic visit, described by CPT code 99213 and calculated using over 5.1 million single claims from CY 2010, is approximately $75. We believe this difference in median costs warrants continued assignment of these CPT codes to different APCs for CY 2012.

Given that we have a substantial volume of single claims from a significant number of hospitals upon which to calculate the median costs for all levels of clinic visits, we do not agree with the commenters that the differences in costs for new versus established patient visits are flawed or the result of hospitals' erroneous reporting of these codes. We expect hospitals to report all HCPCS codes in accordance with correct coding principles, CPT code descriptions, and relevant CMS guidance, which, in this case, specifies that the meanings of ''new'' and ''established'' patients as included in the clinic visit CPT code descriptors pertain to whether or not the patient has been registered as an inpatient or an outpatient of the hospital within the past 3 years (73 FR 68679). As we have stated in the past (74 FR 60547 and 75 FR 71986), we have no reason to believe that hospitals are systematically disregarding these principles to the extent that it would cause our median costs for clinic visits, which are based on data from millions of single claims, to be artificially skewed.

As we stated in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68678) and the CY 2011 OPPS/ASC final rule with comment period (75 FR 71986) concerning the commenters' request that the distinction between new and established patients be based upon whether the patient has a medical record, we continue to believe it is appropriate to include a time limit when determining whether a patient is new or established because we would expect that care of a patient who was not treated at the hospital for several years prior to a visit could require significantly greater hospital resources than care for a patient who was recently treated at the hospital.

Comment: One commenter recommended that CMS reassign HCPCS code G0379 (Direct admission of patient for hospital observation care) to APC 0616 (Level 5 Type A Emergency Visits) because of the consistent 2 times rule violation in APC 0604 (Level 1 Hospital Clinic Visits) and HCPCS code G0379's similarity in both median cost and clinical characteristics to CPT code 99285 (Emergency Department Visit Level 5). The commenter stated that CMS should create a new APC and assign HCPCS code G0379 as a single code to this separate APC if CMS does not agree with G0379's assignment to APC 0616. The commenter also stated that HCPCS code G0379 should be eligible for assignment to composite APC 8003 (Level II Extended Assessment and Management) along with CPT codes 99284 (Emergency Department Visit Level 4), 99285 (Emergency Department Visit Level 5), 99291 (Critical Care First Hour), and G0384 (Level 5 Hospital Type B ED Visit) because of the clinical similarity with the higher evaluation and management level codes. According to the commenter, the median costs for CPT codes 99205 (Office/Outpatient Visit New Level 5) and 99215 (Office/Outpatient Visit Established Level 5) are significantly lower than the median cost for HCPCS code G0379 and, therefore, would remain assigned to composite APC 8002 (Level I Extended Assessment and Management.)

Response: Consistent with our longstanding and established policy to pay for the direct referral for observation through the lowest level clinic APC, originally outlined in the CY 2003 OPPS final rule (67 FR 66794 though 66796), we believe HCPCS code G0379 is appropriately assigned to APC 0604. We continue to believe that the original rationale set forth in the CY 2003 OPPS final rule (67 FR 66794 through 66796) with respect to HCPCS code G0264 (Initial nursing assessment of patient directly admitted to observation with a diagnosis other than congestive heart failure, chest pain, or asthma), being assigned to the lowest level clinic visit APC is applicable to HCPCS code G0379, as HCPCS code G0379 may be used to describe services previously identified by HCPCS code G0264. Accordingly, we disagree with the commenter that HCPCS code G0379 is clinically similar to HCPCS codes 99284, 99285, 99291, and G0384 and should be eligible for assignment to composite APC 8003, and we also disagree that HCPCS code G0379 should be assigned to APC 0616 or as a single code to a newly created APC. Therefore, we are finalizing our proposal to continue to assign HCPCS code G0379 to APC 0604 and composite APC 8002.

After consideration of the public comments we received, we are finalizing our CY 2012 proposal, without modification, to continue to define new or established patient status for the purpose of reporting the clinic visit CPT codes, on the basis of whether or not the patient has been registered as an inpatient or outpatient of the hospital within the past 3 years. We also are finalizing our CY 2012 proposal, without modification, to continue our policy of calculating median costs for clinic visits under the OPPS using historical hospital claims data. As discussed in detail in section II.A.2.e.(1) of this final rule with comment period and consistent with our CY 2011 policy, when calculating the median costs for the clinic visit APCs (0604 through 0608), we utilized our methodology that excludes those claims for visits that are eligible for payment through the extended assessment and management composite APC 8002 (Level I Extended Assessment and Management Composite). We continue to believe that this approach results in the most accurate cost estimates for APCs 0604 through 0608 for CY 2012.

2. Emergency Department Visits

Since CY 2007, we have recognized two different types of emergency departments for payment purposes under the OPPS—Type A emergency departments and Type B emergency departments. As described in greater

detail below, by providing payment for two types of emergency departments, we recognize, for OPPS payment purposes, both the CPT definition of an emergency department, which requires the facility to be available 24 hours a day, and the requirements for emergency departments specified in the provisions of the Emergency Medical Treatment and Labor Act (EMTALA) (Pub. L. 99–272), which do not stipulate 24-hour availability but do specify other obligations for Medicare-participating hospitals with emergency departments. For more detailed information on the EMTALA provisions, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68680).

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68132), we finalized the definition of a Type A emergency department to distinguish it from a Type B emergency department. A Type A emergency department must be available to provide services 24 hours a day, 7 days a week, and meet one or both of the following requirements related to the EMTALA definition of a dedicated emergency department specified at 42 CFR 489.24(b), specifically: (1) It is licensed by the State in which it is located under the applicable State law as an emergency room or emergency department; or (2) it is held out to the public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment. For CY 2007 (71 FR 68140), we assigned the five CPT E/M emergency department visit codes for services provided in Type A emergency departments to five Emergency Visit APCs, specifically APC 0609 (Level 1 Emergency Visits), APC 0613 (Level 2 Emergency Visits), APC 0614 (Level 3 Emergency Visits), APC 0615 (Level 4 Emergency Visits), and APC 0616 (Level 5 Emergency Visits). We defined a Type B emergency department as any dedicated emergency department that incurred EMTALA obligations but did not meet the CPT definition of an emergency department. For example, a hospital department that may be characterized as a Type B emergency department would meet the definition of a dedicated emergency department but may not be available 24 hours a day, 7 days a week. Hospitals with such dedicated emergency departments incur EMTALA obligations with respect to an individual who presents to the department and requests, or has a request made on his or her behalf, examination or treatment for a medical condition.

To determine whether visits to Type B emergency departments have different resource costs than visits to either clinics or Type A emergency departments, in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68132), we finalized a set of five HCPCS G-codes for use by hospitals to report visits to all entities that meet the definition of a dedicated emergency department under the EMTALA regulations but that are not Type A emergency departments. These codes are called ''Type B emergency department visit codes.'' In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68132), we explained that these new HCPCS G-codes would serve as a vehicle to capture median cost and resource differences among visits provided by Type A emergency departments, Type B emergency departments, and clinics. We stated that the reporting of specific HCPCS G-codes for emergency department visits provided in Type B emergency departments would permit us to specifically collect and analyze the hospital resource costs of visits to these facilities in order to determine if, in the future, a proposal for an alternative payment policy might be warranted. We expected hospitals to adjust their charges appropriately to reflect differences in Type A and Type B emergency department visit costs.

As we noted in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68681), the CY 2007 claims data used for that rulemaking were from the first year of claims data available for analysis that included hospitals' cost data for these new Type B emergency department HCPCS visit codes. Based on our analysis of the CY 2007 claims data, we confirmed that the median costs of Type B emergency department visits were less than the median costs of Type A emergency department visits for all but the Level 5 visit. In other words, the median costs from the CY 2007 hospital claims represented real differences in the hospital resource costs for the same level of visits in a Type A or Type B emergency department. Therefore, for CY 2009, we adopted the August 2008 APC Panel recommendation to assign Levels 1 through 4 Type B emergency department visits to their own APCs and to assign the Level 5 Type B emergency department visit to the same APC as the Level 5 Type A emergency department visit.

As discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60548 through 60551), analyses of CY 2008 hospitals' cost data from claims data used for CY 2010 ratesetting for the emergency department HCPCS G-codes demonstrated that the pattern of relative cost differences between Type A and Type B emergency department visits was largely consistent with the distributions we observed in the CY 2007 data, with the exception that, in the CY 2008 data, we observed a relatively lower HCPCS code-specific median cost associated with Level 5 Type B emergency department visits compared to the HCPCS code-specific median cost of Level 5 Type A emergency department visits. As a result, for CY 2010, we finalized a policy to continue to pay Levels 1 through 4 Type B emergency department visits through four levels of APCs, and to pay for Level 5 Type B emergency department visits through new APC 0630 (Level 5 Type B Emergency Department Visit), to which the Level 5 Type B emergency department visit HCPCS code is the only service assigned.

As we noted in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71987), the pattern of relative cost differences between Type A and Type B emergency department visits is consistent with the distributions we observed in the CY 2008 claims data. Therefore, we finalized our proposal to continue to pay for Type B emergency department visits in CY 2011 based on their median costs through five levels of APCs: APC 0626 (Level 1 Type B Emergency Department Visit), APC 0627 (Level 2 Type B Emergency Department Visit), APC 0628 (Level 3 Type B Emergency Department Visit), APC 0629 (Level 4 Type B Emergency Department Visit), and APC 0630.

We stated in the CY 2012 OPPS/ASC proposed rule (76 FR 42270) that we continue to believe that this configuration pays appropriately for each level of Type B emergency department visits based on estimated resource costs from the most recent CY 2010 claims data. Therefore, we proposed to continue to pay for Type B emergency department visits in CY 2012 based on their median costs through the five levels of Type B emergency department APCs (APCs 0626 through 0630). We also noted that, as discussed in section II.A.2.e.(1) of the proposed rule and consistent with our CY 2011 policy, when calculating the median costs for the emergency department visit and critical care APCs (0609 through 0617 and 0626 through 0630), we proposed to utilize our methodology that excludes those claims for visits that are eligible for payment through the extended assessment and management composite APC 8002. We stated that we continue to believe that this approach

will result in the most accurate cost estimates for APCs 0604 through 0608 for CY 2012. Table 36 of the proposed rule displayed the proposed median costs for each level of Type B emergency department visit APCs under the proposed CY 2012 configuration, compared to the proposed CY 2012 median costs for each level of clinic visit APCs and each level of Type A emergency department visit APCs.

We did not receive any public comments on this proposal. We are finalizing our CY 2012 proposal, without modification, to continue paying for Type B emergency department visits in CY 2012, consistent with their median costs through five levels of Type B emergency department visit APCs: APC 0626 (Level 1 Type B Emergency Visits), APC 0627 (Level 2 Type B Emergency Visits), APC 0628 (Level 3 Type B Emergency Visits), APC 0629 (Level 4 Type B Emergency Visits), and APC 0630 (Level 5 Type B Emergency Visits). We are assigning HCPCS codes G0380, G0381, G0382, G0383, and G0384 (the levels 1, 2, 3, 4, and 5 Type B emergency department visit Level II HCPCS codes) to APCs 0626, 0627, 0628, 0629, and 0630, respectively, for CY 2012. We continue to believe that this configuration pays appropriately for each level of Type B emergency department visits based on estimated resource costs from the most recent claims data.

We also note that, as discussed in section II.A.2.e.(1) of this final rule with comment period and consistent with our CY 2011 policy, when calculating the median costs for the emergency department visit and critical care APCs (0609 through 0617 and 0626 through 0630), we utilized our methodology that excludes those claims for visits that are eligible for payment through the extended assessment and management composite APC 8002 (Level I Extended Assessment and Management Composite). We continue to believe that this approach will result in the most accurate cost estimates for APCs 0604 through 0608 for CY 2012.

Table 43 below displays the final median costs for each level of Type B emergency department visit APCs under the CY 2012 configuration, compared to the final CY 2012 median costs for each level of clinic visit APCs and each level of Type A emergency department visit APCs.

TABLE 43.—COMPARISON OF MEDIAN COSTS FOR CLINIC VISIT APCs, TYPE B EMERGENCY DEPARTMENT VISIT APCs, AND TYPE A EMERGENCY DEPARTMENT VISIT APCs

Visit Level	CY 2012 Clinic Visit Approximate APC Median Cost	CY 2012 Type B Emergency Department Approximate APC Median Cost	CY 2012 Type A Emergency Visit Approximate APC Median Cost
Level 1	$50	$41	$52
Level 2	$75	$59	$89
Level 3	$105	$94	$142
Level 4	$138	$141	$229
Level 5	$178	$271	$340

For CY 2010 and in prior years, the AMA CPT Editorial Panel defined critical care 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 (List separately in addition to code for primary service)) to include a wide range of ancillary services such as electrocardiograms, chest X-rays and pulse oximetry. As we have stated in manual instruction, we expect hospitals to report in accordance with CPT guidance unless we instruct otherwise. For critical care in particular, we instructed hospitals that any services that the CPT Editorial Panel indicates are included in the reporting of CPT code 99291 (including those services that would otherwise be reported by and paid to hospitals using any of the CPT codes specified by the CPT Editorial Panel) should not be billed separately. Instead, hospitals were instructed to report charges for any services provided as part of the critical care services. In establishing payment rates for critical care services, and other services, CMS packages the costs of certain items and services separately reported by HCPCS codes into payment for critical care services and other services, according to the standard OPPS methodology for packaging costs (Medicare Claims Processing Manual, Pub. 100–04, Chapter 4, Section 160.1).

For CY 2011, the AMA CPT Editorial Panel revised its guidance for the critical care codes to specifically state that, for hospital reporting purposes, critical care codes do not include the specified ancillary services. Beginning in CY 2011, hospitals that report in accordance with the CPT guidelines should report all of the ancillary services and their associated charges separately when they are provided in conjunction with critical care. Because the CY 2011 payment rate for critical care services is based on hospital claims data from CY 2009, during which time hospitals would have reported charges for any ancillary services provided as part of the critical care services, we stated in the CY 2011 OPPS/ASC final rule with comment period that we believe it is inappropriate to pay separately in CY 2011 for the ancillary services that hospitals may now report in addition to critical care services (75

FR 71988). Therefore, for CY 2011, we continued to recognize the existing CPT codes for critical care services and established a payment rate based on historical data, into which the cost of the ancillary services is intrinsically packaged. We also implemented claims processing edits that conditionally package payment for the ancillary services that are reported on the same date of service as critical care services in order to avoid overpayment. We noted in the CY 2011 OPPS/ASC final rule with comment period that the payment status of the ancillary services will not change when they are not provided in conjunction with critical care services. We assigned status indicator ''Q3'' (Codes That May Be Paid Through a Composite APC) to the ancillary services to indicate that payment for them is packaged into a single payment for specific combinations of services and made through a separate APC payment or packaged in all other circumstances, in accordance with the OPPS payment status indicated for status indicator ''Q3'' in Addendum D1 to the CY 2011 OPPS/ASC final rule with comment period. The ancillary services that were included in the definition of critical care prior to CY 2011 and that will be conditionally packaged into the payment for critical care services when provided on the same date of service as critical care services for CY 2011 were listed in Addendum M to that final rule with comment period. We noted in the CY 2011 OPPS/ASC final rule with comment period that our treatment of the revised CY 2011 critical care codes was open to public comment for 60 days following issuance of the CY 2011 OPPS/ASC final rule with comment period, and that we would respond to the comments in the CY 2012 final rule with comment period.

Because the proposed CY 2012 median costs for critical care services were based upon CY 2010 claims data, which reflect the CPT billing guidance that was in effect prior to CY 2011, in the CY 2012 OPPS/ASC proposed rule (76 FR 42271), we proposed to continue the methodology established in the CY 2011 OPPS/ASC final rule with comment period of calculating a payment rate for critical care services based on our historical data, into which the cost of the ancillary services is intrinsically packaged. We proposed to continue to implement claims processing edits that conditionally package payment for the ancillary services that are reported on the same date of service as critical care services in order to avoid overpayment.

Comment: Several commenters who responded to the CY 2011 OPPS/ASC final rule with comment period and the CY 2012 OPPS/ASC proposed rule supported the proposed policy to continue to conditionally package payment for ancillary services that are reported on the same date of service as critical care services. Some commenters recommended that a modifier be implemented to allow the identification of ancillary services provided to critical care patients during the same date of service as critical care services, but outside the critical care period, so that those services are not inappropriately packaged into the critical care services payment. Commenters also recommended that CMS, in setting the payment rate for critical care services by estimating the costs of the packaged ancillary services, establish a methodology that includes review of multiple cost report revenue centers and that CMS consult with the hospital industry on the appropriate methodology used to calculate the actual cost related to the provision of critical care services.

Response: We believe all services provided in conjunction with critical care, as part of a single clinical encounter, are included in the critical care period and, therefore, do not support the commenters' recommendation that a modifier be implemented to allow the identification of ancillary services provided to critical care patients during the same date of service as critical care services, but outside the critical care period. Hospitals may use HCPCS modifier ''-59'' to indicate when an ancillary procedure or service is distinct or independent from critical care when performed on the same day but during a different encounter. For CY 2012, CMS will continue to conditionally package payment for the ancillary services previously included in CPT's definition of critical care prior to CY 2011, when they are reported on the same date of service as critical care services.

In regard to the commenter who suggested that CMS include review of multiple cost report revenue centers when calculating the costs of the packaged ancillary services, we note that the methodology the commenters recommended is consistent with the methodology we already have in place. As discussed in section II.A.1.c. of this final rule with comment period, we calculate hospital-specific overall ancillary CCRs and hospital-specific departmental CCRs for each hospital for which we have claims data. We apply the hospital-specific CCR to the hospital's charges at the most detailed level possible, based on a revenue code-to-cost center crosswalk that contains a hierarchy of CCRs used to estimate costs from charges for each revenue code. Therefore, we base our cost estimation of each packaged ancillary service on the most specific cost center to which the revenue code reported with that service maps. We then package the cost that we estimate as a result of that process into the median cost calculation for critical care.

After consideration of the public comments we received, we are finalizing our CY 2012 proposal, without modification, to continue the methodology established in the CY 2011 OPPS/ASC final rule with comment period of calculating a payment rate for critical care services based on our historical data, into which the cost of the ancillary services is intrinsically packaged. We also will continue to implement claims processing edits that conditionally package payment for the ancillary services that are reported on the same date of service as critical care services in order to avoid overpayment.

3. Visit Reporting Guidelines

Since April 7, 2000, we have instructed hospitals to report facility resources for clinic and emergency department hospital outpatient visits using the CPT E/M codes and to develop internal hospital guidelines for reporting the appropriate visit level. Because a national set of hospital-specific codes and guidelines do not currently exist, we have advised hospitals that each hospital's internal guidelines that determine the levels of clinic and emergency department visits to be reported should follow the intent of the CPT code descriptors, in that the guidelines should be designed to reasonably relate the intensity of hospital resources to the different levels of effort represented by the codes.

As noted in detail in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66802 through 66805), we observed a normal and stable distribution of clinic and emergency department visit levels in hospital claims over the past several years. The data indicated that hospitals, on average, were billing all five levels of visit codes with varying frequency, in a consistent pattern over time. Overall, both the clinic and emergency department visit distributions indicated that hospitals were billing consistently over time and in a manner that distinguished between visit levels, resulting in relatively normal distributions nationally for the OPPS, as well as for specific classes of hospitals. The results of these analyses were

generally consistent with our understanding of the clinical and resource characteristics of different levels of hospital outpatient clinic and emergency department visits. In the CY 2008 OPPS/ASC proposed rule (72 FR 42764 through 42765), we specifically invited public comment as to whether there was still a pressing need for national guidelines at this point in the maturation of the OPPS, or if the current system where hospitals create and apply their own internal guidelines to report visits was more practical and appropriately flexible for hospitals. We explained that, although we have reiterated our goal since CY 2000 of creating national guidelines, this complex undertaking for these important and common hospital services was proving more challenging than we initially anticipated as we received new and expanded information from the public on current hospital reporting practices that led to appropriate payment for the hospital resources associated with clinic and emergency department visits. We stated our belief that many hospitals had worked diligently and carefully to develop and implement their own internal guidelines that reflected the scope and types of services they provided throughout the hospital outpatient system. Based on public comments, as well as our own knowledge of how clinics operate, it seemed unlikely that one set of straightforward national guidelines could apply to the reporting of visits in all hospitals and specialty clinics. In addition, the stable distribution of clinic and emergency department visits reported under the OPPS over the past several years indicated that hospitals, both nationally in the aggregate and grouped by specific hospital classes, were generally billing in an appropriate and consistent manner as we would expect in a system that accurately distinguished among different levels of service based on the associated hospital resources.

Therefore, we did not propose to implement national visit guidelines for clinic or emergency department visits for CY 2008. As we have done since publication of the CY 2008 OPPS/ASC final rule with comment period, we again examined the distribution of clinic and Type A emergency department visit levels based upon updated CY 2010 claims data available for the CY 2012 proposed rule and this final rule with comment period. Analysis of these data confirm that we continue to observe a normal and relatively stable distribution of clinic and emergency department visit levels in hospital claims compared to CY 2009 data. As we did in the proposed rule (76 FR 42272), we note that we have observed a slight shift over time toward higher numbers of Level 4 and Level 5 visits relative to the lower level visits, when comparing the distributions of Type A emergency department visit levels from CY 2005 claims data to those from CY 2010. We also note that, in aggregate, hospitals' charges for these higher level emergency department visits seem to be trending upward year over year. In the CY 2012 proposed rule, we welcomed comment on whether this is consistent with individual hospitals' experiences in developing, implementing, and refining their own guidelines over the last several years.

Comment: Commenters requested that, with respect to the slight shift over time toward higher numbers of Level 4 and Level 5 visits relative to the lower visit levels, CMS provide data regarding whether it has observed any shift in reporting ''new'' versus ''established'' patient visits after instituting the new definition of established patient in CY 2009, noting that CMS has 2 years of claims data since the definition change. According to commenters, if hospitals changed their reporting based on the new definition, the data should reflect a shift toward the higher level visits, because more patients would have been ''established'' patients under the new definition. The commenters stated that if CMS has not noticed this shift in the proportion of new and established patient visits beginning with CY 2009 claims, it suggested that hospitals may not have begun applying the revised definition and a shift in level 4 and 5 visits may have occurred more in response to the increasing trend of comorbid conditions in emergency department visits than from hospitals' response to CMS' visit guidelines. The commenters suggested that CMS evaluate secondary diagnoses on Level 4 and Level 5 Type A emergency department visit claims.

Another commenter stated that this trend is consistent with its observations and listed the following as possible reasons for the higher Medicare acuity: Some patients with low acuity problems are seeking care elsewhere because of long emergency department wait times and higher copayments; increasing options for faster, less expensive care for lower acuity problems (retail and hospital-based clinics and extended physician and urgent care office hours); public education regarding appropriate reasons for going to the emergency department; and patients delaying care for the above reasons and then presenting to the emergency department in a relatively sicker condition.

Response: We appreciate the commenters' discussion of possible contributing factors to the shift toward increasing numbers of higher level Type A emergency department visits. We will continue to examine our data and explore any changes or trends that correlate to the slight shift over time toward higher numbers of Level 4 and Level 5 Type A emergency department visits relative to the lower Type A emergency department visit levels. We note that information about claims volume for particular HCPCS codes for a given calendar year, including new and established patient visits, is publicly available in the median cost file made available for each OPPS final rule with comment period and located on the CMS Web site. As we stated in the proposed rule, we continue to believe that, generally, hospitals are billing in an appropriate and consistent manner that distinguishes among different levels of visits based on their required hospital resources.

Comment: Some commenters supported CMS' proposal to continue to recognize hospital-specific visit guidelines rather than implement national guidelines because hospitals have grown accustomed to using their own coding systems to assign visit levels. In contrast, many commenters urged CMS to move forward with the implementation of national guidelines for hospitals to report visits, asserting that CMS has poor data upon which to calculate visit APC payment rates because there are no standard definitions, and citing the challenges of having different guidelines in place by different payers. The commenters recommended that, in the absence of national guidelines for hospital visit reporting, CMS support a request to the American Medical Association CPT Editorial Panel to create unique CPT codes for hospital reporting of emergency department and clinic visits based on internally developed guidelines. In addition, some commenters expressed their appreciation for CMS' encouragement of its contractors to use a hospital's own guidelines when auditing and evaluating the appropriateness of codes assigned, but requested that hospitals be exempt from audits of visit billing until national guidelines are implemented.

Response: As we have in the past (74 FR 60553 and 75 FR 71989 through 71990), we acknowledge that it would be desirable to many hospitals to have national guidelines. However, we also understand that it would be disruptive and administratively burdensome to

other hospitals that have successfully adopted internal guidelines to implement any new set of national guidelines while we address the problems that would be inevitable in the case of any new set of guidelines that would be applied by thousands of hospitals. We will continue to regularly reevaluate patterns of hospital outpatient visit reporting at varying levels of disaggregation below the national level to ensure that hospitals continue to bill appropriately and differentially for these services. We reiterate our expectation that hospitals' internal guidelines fully comply with the principles listed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 68805), and we encourage hospitals with more specific questions related to the creation of internal guidelines to contact their servicing fiscal intermediary or MAC. Also, as originally noted in detail in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66648 through 66649), we continue to expect that hospitals will not purposely change their visit guidelines or otherwise upcode clinic and emergency department visits for purposes of extended assessment and management composite APC payment.

We continue to encourage fiscal intermediaries and MACs to review a hospital's internal guidelines when an audit occurs, as indicated in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66806). As we have stated in the past (75 FR 71990), if the AMA were to create facility-specific CPT codes for reporting visits provided in HOPDs [based on internally developed guidelines], we would consider such codes for OPPS use.

After consideration of the public comments we received, we are continuing to encourage hospitals to use their own internal guidelines to determine the appropriate reporting of different levels of clinic and emergency department visits. We note that it remains our goal to ensure that OPPS national or hospital-specific visit guidelines continue to facilitate consistent and accurate reporting of hospital outpatient visits in a manner that is resource-based and supportive of appropriate OPPS payments for the efficient and effective provision of visits in hospital outpatient settings.

VIII. Payment for Partial Hospitalization Services

A. Background

Partial hospitalization is an intensive outpatient program of psychiatric services provided to patients as an alternative to inpatient psychiatric care for individuals who have an acute mental illness. Sections 1861(ff)(1) and (ff)(2) of the Act specify the items and services that are defined as partial hospitalization services and some conditions under which Medicare payment for the items and services will be made. Section 1861(ff)(3) of the Act specifies that a partial hospitalization program (PHP) is a program furnished by a hospital or community mental health center (CMHC) that meets the requirements specified under that subsection of the Act.

In CY 2011, in accordance with section 1301(b) of the Health Care and Education Reconciliation Act of 2010 (HCERA 2010), we amended the description of a PHP in our regulations to specify that the program must be a distinct and organized intensive ambulatory treatment program offering less than 24-hour daily care ''other than in an individual's home or in an inpatient or residential setting.'' In addition, in accordance with section 1301(a) of HCERA 2010, we revised the definition of a CMHC in the regulations to conform to the revised definition now set forth at section 1861(ff)(3)(B) of the Act. We discussed our finalized policies for these two provisions of HCERA 2010 under section X.C. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71990). Section 1833(t)(1)(B)(i) of the Act provides the Secretary with the authority to designate the OPD services to be covered under the OPPS. The existing Medicare regulations that implement this provision specify, at 42 CFR 419.21, that payments under the OPPS will be made for partial hospitalization services furnished by CMHCs as well as those services furnished by hospitals to their outpatients. Section 1833(t)(2)(C) of the Act, in pertinent part, requires the Secretary to ''establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on median (or, at the election of the Secretary, mean) hospital costs'' using data on claims from 1996 and data from the most recent available cost reports. In pertinent part, subparagraph (B) provides that the Secretary may establish groups of covered OPD services, within a classification system developed by the Secretary for covered OPD services, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, CMS developed the APCs. Section 1833(t)(9)(A) of the Act requires the Secretary to ''review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.'' Because a day of care is the unit that defines the structure and scheduling of partial hospitalization services, we established a per diem payment methodology for the PHP APCs, effective for services furnished on or after August 1, 2000 (65 FR 18452 through 18455). Under this methodology, the median per diem costs are used to calculate the relative payment weights for PHP APCs.

From CY 2003 through CY 2006, the median per diem cost for CMHCs fluctuated significantly from year to year, while the median per diem cost for hospital-based PHPs remained relatively constant. We were concerned that CMHCs may have increased and decreased their charges in response to Medicare payment policies. Therefore, we began efforts to strengthen the PHP benefit through extensive data analysis and policy and payment changes in the CY 2008 update (72 FR 66670 through 66676). We made two refinements to the methodology for computing the PHP median: The first remapped 10 revenue codes that are common among hospital-based PHP claims to the most appropriate cost centers; and the second refined our methodology for computing the PHP median per diem costs by computing a separate per diem cost for each day rather than for each bill. A complete discussion of these refinements can be found in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66671 through 66676).

In CY 2009, we implemented several regulatory, policy, and payment changes, including a two-tiered payment approach for PHP services under which we paid one amount for days with 3 services (APC 0172 (Level I Partial Hospitalization)) and a higher amount for days with 4 or more services (APC 0173 (Level II Partial Hospitalization)). We refer readers to section X.C.2. of the CY 2009 OPPS/ASC final rule with comment period (73 FR 68688 through 68693) for a full discussion of the two-tiered payment system. In addition, for CY 2009, we finalized our policy to deny payment for any PHP claims for days when fewer than 3 units of therapeutic services are provided.

Furthermore, for CY 2009, we revised the regulations at 42 CFR 410.43 to codify existing basic PHP patient eligibility criteria and to add a reference

to current physician certification requirements at 42 CFR 424.24 to conform our regulations to our longstanding policy (73 FR 68694 through 68695). These changes have helped to strengthen the PHP benefit. We also revised the partial hospitalization benefit to include several coding updates. We refer readers to section X.C.2. of the CY 2009 OPPS/ASC final rule with comment period (73 FR 68695 through 68697) for a full discussion of these requirements.

For CY 2010, we retained the two-tiered payment approach for PHP services and used only hospital-based PHP data in computing the per diem payment rates. We used only hospital-based PHP data because we were concerned about further reducing both PHP APC per diem payment rates without knowing the impact of the policy and payment changes we made in CY 2009. Because of the 2-year lag between data collection and rulemaking, the changes we made in CY 2009 were reflected for the first time in the claims data that we used to determine payment rates for the CY 2011 rulemaking.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71994), we established four separate PHP APC per diem payment rates, two for CMHCs (for Level I and Level II services) and two for hospital-based PHPs (for Level I and Level II services). We proposed that CMHC APC rates would be based only on CMHC data and hospital-based PHP APC rates would be based only on hospital-based PHP data (75 FR 46300). As stated in the CY 2011 OPPS/ASC proposed rule (75 FR 46300) and final rule with comment period (75 FR 71991), for CY 2011, using CY 2009 cost data, CMHC costs had significantly decreased again. We attributed the decrease to the lower cost structure of CMHCs compared to hospitals, and not the impact of CY 2009 policies. CMHCs have a lower cost structure than hospital-based PHP providers, in part because the data showed that CMHCs provide fewer PHP services in a day and use less costly staff than hospital-based PHPs. Therefore, it was inappropriate to continue to treat CMHCs and hospital-based providers in the same manner regarding payment, particularly in light of such disparate differences in costs. We were concerned that paying hospital-based PHP programs at a lower rate than their cost structure reflects could lead to closures and possible access problems for hospital-based programs for Medicare beneficiaries. Creating the four payment rates (two for CMHCs and two for hospital-based PHPs) supported continued access to the PHP benefit, while also providing appropriate payment based on the unique cost structures of CMHCs and hospital-based PHPs. In addition, separation of cost data by provider type was supported by several hospital-based PHP commenters who responded to the CY 2011 OPPS/ASC proposed rule (75 FR 71992).

For CY 2011, we instituted a 2-year transition period for CMHC providers to the CMHC APC per diem payment rates based solely on CMHC data. For CY 2011, under the transition methodology, CMHC APC Level I and Level II rates were calculated by taking 50 percent of the difference between the CY 2010 final hospital-based medians and the CY 2011 final CMHC medians and then adding that number to the CY 2011 final CMHC medians. A 2-year transition under this methodology moved us in the direction of our goal, which is to pay appropriately for PHP services based on each provider type's cost data, while at the same time allowing providers time to adjust their business operations and protect access to care for beneficiaries. We also stated that we would review and analyze the data during the CY 2012 rulemaking cycle and may, based on these analyses, further refine the payment mechanism. We refer readers to section X.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991 through 71994) for a full discussion of these four payment rates.

After publication of the CY 2011 OPPS/ASC final rule with comment period, a CMHC and one of its patients filed an application for a preliminary injunction, challenging the OPPS rates for PHP services provided by CMHCs in CY 2011 as adopted in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71995). *See Paladin Cmty. Mental Health Ctr.* v. *Sebelius,* No. 10–949, 2011 WL 3102049 (W.D.Tex.), *appeal docketed,* No. 11–50682 (5th Cir. July 29, 2011) (*Paladin*). The plaintiffs in the Paladin case challenged the agency's use of cost data derived from both hospitals and CMHCs (in determining the relative payment weights for the OPPS rates for PHP services furnished by CMHCs), alleging that section 1833(t)(2)(C) of the Act requires that such relative payment weights be based on cost data derived solely from hospitals. As discussed above, section 1833(t)(2)(C) of the Act requires CMS to ''establish relative payment weights for covered OPD services (and any groups of such services * * *) * * * based on * * * hospital costs.'' Numerous courts have held that ''based on'' does not mean ''based exclusively on.'' Thus, on July 25, 2011, the district court dismissed the plaintiffs' complaint and dismissed the plaintiffs' application for preliminary injunction. The Court found that ''the Secretary has exercised her statutory authority and broad discretion to establish the 2011 payment rates for PHP services based on her interpretation of the terms of the Act.'' (*Paladin* at *4).

For CY 2012, as discussed in the CY 2012 OPPS/ASC proposed rule (76 FR 42274 through 42275), we proposed to determine the relative payment weights for PHP services by CMHCs based on cost data derived solely from CMHCs and the relative payment weights for hospital-based PHP services based exclusively on hospital cost data. The statute is reasonably interpreted to allow the relative payment weights for the OPPS rates for PHP services provided by CMHCs to be based solely on CMHC cost data and relative payment weights for hospital-based PHP services to be based exclusively on hospital cost data. Section 1833(t)(2)(C) of the Act requires the Secretary to ''establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on * * * hospital costs.'' In pertinent part, subparagraph (B) provides that ''the Secretary may establish groups of covered OPD services * * * so that services classified within each group are comparable clinically and with respect to the use of resources.'' In accordance with subparagraph (B), CMS developed the APCs, as set forth in § 419.31 of the regulations (65 FR 18446 and 18447; 63 FR 47559 and 47560). As discussed in the CY 2012 OPPS/ASC proposed rule (76 FR 42274) and this final rule with comment period, PHP services are grouped into APCs.

Based on section 1833(t)(2)(C) of the Act, we believe that the word ''establish'' can be interpreted as applying to APCs at the inception of the OPPS in 2000 or whenever a new APC is added to the OPPS. In creating the original APC for PHP services (APC 0033), we did ''establish'' the initial relative payment weight for PHP services, provided in hospital-based and CMHC-based settings, on the basis of only hospital data. Subsequently, from CY 2003 through CY 2008, the relative payment weights for PHP services were based on a combination of hospital and CMHC data. Similarly, we subsequently established new APCs for PHP services based exclusively on hospital costs. For CY 2009, we adopted a two-tiered APC methodology (in lieu of the original APC 0033) under which CMS paid one rate for days with 3 services (APC 0172) and a different payment rate for days with 4 or more services (APC 0173). These two new APCs were established using only

hospital data. For CY 2011, we added two new APCs (APCs 0175 and 0176) for PHP services provided by hospitals and based the relative payment weights for these APCs solely on hospital data. APCs 0172 and 0173 were designated for PHP services provided by CMHCs and were based on a mixture of hospital and CMHC data. As the Secretary argued in the Paladin case, the courts have consistently held that the phrase ''based on'' does not mean ''based exclusively on.'' Thus, the relative payment weights for the two APCs for CMHC-provided PHP services in CY 2011 were ''based on'' hospital data, no less than the relative payment weights for the two APCs for hospital-provided PHP services.

Although we used only hospital data to establish the original relative payment weights for APC 0033 and later used hospital data to establish four new relative payment weights for PHP services, we believe that we have the authority to discontinue the use of hospital data after the original establishment of the relative payment weights for a given APC. Other parts of section 1833(t)(2)(C) of the Act make plain that the data source for the relative payment weights is subject to change from one period to another. Section 1833(t)(2)(C) of the Act provides that, in establishing the relative payment weights, ''the Secretary shall [ ] us[e] data on claims from 1996 and us[e] data from the most recent available cost reports.'' However, we used 1996 data (plus 1997 data) in determining only the original relative payment weights for 2000; in the ensuing calendar year updates, we continually used more recent cost report data.

Moreover, section 1833(t)(9)(A) of the Act requires the Secretary to ''review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.'' For purposes of the CY 2012 update, we exercised our authority under section 1833(t)(9)(A) of the Act to change the data source for the relative payment weights for PHP services by CMHCs based on ''new cost data, and other relevant information and factors.''

B. PHP APC Update for CY 2012

In the CY 2012 OPPS/ASC proposed rule (76 FR 42274), to develop the proposed payment rates for the PHP APCs for CY 2012, we used CY 2010 claims data and computed median per diem costs in the following categories: Days with 3 services; and days with 4 or more services. These proposed median per diem costs were computed separately for CMHCs and hospital-based PHPs, as shown in Table 37 of the proposed rule, which is reprinted below.

PROPOSED RULE TABLE 37.—PROPOSED PHP MEDIAN PER DIEM COSTS FOR CMHC AND HOSPITAL-BASED PHPs, BY CATEGORY, BASED ON CY 2010 CLAIMS DATA

Category	CMHC PHPs	Hospital-Based PHPs
Days with 3 services	$97.78	$162.34
Days with 4 or more services	$113.62	$189.87

Using updated CY 2010 claims data and the refined methodology for computing PHP per diem costs adopted in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66671 through 66676), we computed proposed median per diem costs for CY 2012 for each provider type using provider-specific claims data. The data indicate that both CMHCs and hospital-based PHPs have a decrease in costs for Level I and Level II services from CY 2011 to CY 2012. However, the median per diem costs for CMHCs continue to be substantially lower than the median per diem costs for hospital-based PHPs for the same units of service. For CY 2012, the proposed median per diem costs for days with 3 services (Level I) were approximately $98 for CMHCs and approximately $162 for hospital-based PHPs. The proposed median per diem costs for days with 4 or more services (Level II) were approximately $114 for CMHCs and approximately $190 for hospital-based PHPs. The difference in costs between CMHC PHPs and hospital-based PHPs underscores the need to pay each provider type based on use of its own data.

As stated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991 through 71994), CMHCs' costs decreased from approximately $139 in CY 2009 (using CY 2007 data) to approximately $108 for CY 2011 (using CY 2009 data) for Level I services (days with 3 services) and from approximately $172 for CY 2009 to approximately $116 for CY 2011 for Level II services (days with 4 or more services) using only CMHC data. For the CY 2012 proposed rule, our analysis of claims data (using CY 2010 claims data) showed that CMHCs' approximate median per diem costs continued to decrease to approximately $98 for CY 2012 for Level I services (days with 3 services), and to approximately $114 for CY 2012 for Level II services (days with 4 or more services). We reasonably attributed some of the decrease in costs to targeted fraud and abuse efforts implemented by the Department's Center for Program Integrity and the Office of Inspector General, and by the U.S. Department of Justice, collectively (76 FR 42275). In the CY 2012 OPPS/ASC proposed rule (76 FR 42275), we also noted that hospital-based PHPs showed a decrease in costs for CY 2012 (using CY 2010 claims data). Although hospital-based PHPs have been historically consistent in their median costs since the inception of the OPPS, the CY 2010 claims data indicated a decrease in their proposed median per diem costs since last year. In the CY 2011 OPPS/ASC final rule with comment period (using CY 2009 claims data), hospital-based PHPs' median per diem costs were approximately $203 for Level I services (days with 3 services) and approximately $236 for Level II services (days with 4 or more services). In the CY

2012 OPPS/ASC proposed rule (using CY 2010 claims data), these numbers decreased to approximately $162 for Level I services (days with 3 services) and to approximately $190 for Level II services (days with 4 or more services). As explained in the CY 2012 OPPS/ASC proposed rule (76 FR 42275), we attributed this decrease in costs for CY 2012 to one provider whose costs inflated the CY 2011 hospital-based cost data and increased the CY 2011 hospital-based PHP median for Level II services by approximately $30. We included this provider in the CY 2011 ratesetting because this provider had paid claims in CY 2009. Subsequently, this provider did not bill for PHP services during CY 2010 and, therefore, was not included in the proposed CY 2012 rate setting.

Based on the results of our analysis of the CY 2010 claims data, in the OPPS/ASC proposed rule (76 FR 42275) for CY 2012, we proposed to calculate the CMHC PHP APC per diem payment rates for Level I and Level II services using only CMHC data and to calculate the hospital-based PHPs APC per diem payment rates for Level I and Level II services using only hospital-based PHP data. Basing payment rates specific to each type of provider's own data would continue to support access to the PHP benefit, including a more intensive level of care, while also providing appropriate payment commensurate with the cost structures of CMHC PHPs and hospital-based PHPs. We invited public comment on our proposal to calculate the CMHC PHP APC per diem payment rates using only CMHC claims data and the hospital-based PHP APC per diem payment rates using only hospital data.

Comment: Both hospital-based PHP providers and CMHCs expressed concern regarding the proposed rate reductions. Several commenters requested that CMS freeze the PHP rates at current CY 2011 levels or mitigate the rate reductions for both CMHCs and hospital-based PHPs. These commenters stated that, by freezing the rates or mitigating any payment reductions, providers would be allowed time to assess the impact of the rate reductions while ensuring continued beneficiary access to the PHP benefit.

Response: We understand the concerns raised by commenters about the proposed CMHC and hospital-based PHP per diem rate reductions and the potential impact the reductions may have on access to the PHP benefit in both provider settings. In response to hospital-based PHP providers' concerns regarding the proposed rate reductions, we believe that the CY 2012 medians reflect hospital-based PHP providers' typical medians. For example, the CY 2009 median per diem costs (using CY 2007 claims data) were approximately $157 for Level I services and $200 for Level II services (73 FR 68689) and the CY 2010 median per diem costs (using CY 2008 claims data) were approximately $148 for Level I services and $209 for Level II services. The CY 2011 median per diem costs (using CY 2009 claims data) were approximately $203 for Level I services and approximately $236 for Level II services. In the CY 2012 proposed rule (using CY 2010 data), these numbers decreased to approximately $162 for Level I services (for days with 3 services) and to approximately $190 for Level II services (for days with 4 or more services). We attributed the majority of the decrease in costs for CY 2012 to one provider whose costs inflated the CY 2011 hospital-based cost data and increased the CY 2011 hospital-based PHP median for Level II services by approximately $30. For this CY 2012 final rule with comment period, our analysis of claims data (using CY 2010 claims data) shows that hospital-based PHP median per diem costs are approximately $161 for Level I services (for days with 3 services) and approximately $191 for Level II services (for days with 4 or more services). Again, these median per diem costs are more consistent with past median per diem costs for this provider type and we believe accurately reflect the cost data of the hospital-based PHP provider.

In response to CMHCs concerns about the rate reductions, in the past, we have attempted to control the cost fluctuations in CMHCs in order to protect access to care and with the hope that the cost structures for both provider types would eventually become more consistent. However, the data continue to show the decline in costs for CMHCs. We believe that the proposed median per diem costs for CMHCs accurately reflect the cost data of the CMHCs.

For example, for this CY 2012 final rule with comment period, our analysis of claims data (using CY 2010 claims data for CMHCs only) shows that CMHCs' median per diem costs continue to decrease from approximately $108 for CY 2011 (using CY 2009 claims data for CMHCs only) to approximately $98 for CY 2012 for Level I services (days with 3 services), and from approximately $116 for CY 2011 (using CY 2009 claims data for CMHCs only) to approximately $114 for CY 2012 for Level II services (days with 4 or more services). Although we are not exactly clear about why the CMHC costs continue to decrease, we can reasonably attribute some of the decrease in costs to targeted fraud and abuse efforts implemented by the Department's Center for Program Integrity and the Office of Inspector General, and by the U.S. Department of Justice, collectively.

We have considered all suggestions, including the request to freeze the PHP payment rates at the CY 2011 levels or to mitigate rate reductions. However, we cannot continue to establish payment rates that do not accurately reflect the cost data, particularly given a further decline in the data for CY 2012. Moreover, we believe we have already allowed numerous opportunities for providers to adjust their business operations, including mitigating the rate reductions for CY 2011.

For these reasons, for CY 2012, we are not mitigating or freezing the payment rates and are finalizing our proposal to calculate the CMHC PHP APC per diem payment rates for Level I and Level II services using only CMHC data and to calculate the hospital-based PHP APC per diem payment rates for Level I and Level II services using only hospital-based PHP data. The CY 2012 PHP median per diem costs are as follows: For CMHCs, $97.64 for Level I services and $113.83 for Level II services and for hospital-based PHPs, $160.74 for Level I services and $191.16 for Level II services. We remain committed to the PHP benefit, including preserving access for our Medicare beneficiaries, and we plan to continue to monitor access to care for the benefit.

Comment: Almost all commenters expressed some concern that the proposed rate reductions would result in adverse outcomes, including program closures and subsequent access to care issues, exacerbating an existing problem of inadequate inpatient and outpatient hospital capacities in many communities caring for individuals with mental illness. The commenters reasoned that if closures were to result, this would have substantial and serious consequences for hospitals and for Medicare beneficiaries requiring PHP services. Several commenters stated that the reduction in CMHC rates will lead to closures, where critical access points for Medicare beneficiaries would no longer be available. The commenters reasoned that if this ''vulnerable population'' of Medicare beneficiaries were to go untreated, these patients could end up in inpatient hospitals, or in emergency departments. Because these are Medicare aged and disabled beneficiaries, their care in the inpatient or emergency room setting could potentially be more expensive than their PHP treatment would have been, thus increasing the overall Medicare costs if

PHP care is eliminated due to closures. Other commenters also reasoned that, without the PHP services, this vulnerable population may also enter prison systems, or wind up dead if they do not receive their medication. Some commenters asserted that CMS has essentially contradicted its principles, by acknowledging a patient's disability; but on the other hand, reducing the rate of reimbursement for their care. The commenters stated that this has the effect of denying access to treatment, which runs counter to ensuring essential care.

Response: The proposed median per diem costs for CY 2012 reflect each PHP provider type's (hospital-based and CMHC) costs, derived from CY 2010 claims data. We discussed in our proposed rule (76 FR 42274 and 42275) how the data results indicate that, although both CMHCs and hospital-based PHPs have decreased costs for Level I and Level II services from CY 2011 to CY 2012, the median per diem costs for CMHCs continue to be substantially lower than the median per diem costs for hospital-based PHPs. We also noted that hospital-based PHPs show a decrease in costs for CY 2012 based on CY 2010 claims data (76 FR 42275). Payment rates are based according to each specific provider type's own data, that is, CMHC rates are based on CMHC cost data and hospital-based PHP providers are based on their own cost data. The rates reflect the cost of what each provider type expends to maintain such programs so it is unclear why this would lead to program closure. The closure of PHPs may be due to any number of reasons, such as poor business management or marketing decisions, competition, over-saturation of certain geographic areas, Federal and State fraud and abuse efforts, among others. However, it does not directly follow that closure could be due to reduced reimbursement rates alone, especially when these rates reflect actual costs of PHP providers. CMS remains steadfast in its concern over access to care for all beneficiaries while also providing appropriate payments for such care. In terms of access to care, PHP for mental health treatment is not the only manner in which a Medicare beneficiary is able to receive needed care. Although not the equivalent of PHP, Medicare provides payment for outpatient mental health services in addition to PHP. Many beneficiaries in need of mental health treatment receive other outpatient services, and no evidence suggests that there is an increase in adverse outcomes, as the commenters suggested, due to lack of access to care. Other forms of access to mental health services remain available. If certain PHP providers decide for whatever reason to close their doors, we do not believe that access to care will become an issue, and we do not believe we have acted in a manner that is contradictory to our principles. In addition, the Social Security Administration has the authority to determine a person's disability, not CMS.

Comment: Some commenters noted that CMS recently issued the proposed conditions of participation (CoPs) for CMHCs that they will need to observe and, as a result of the Affordable Care Act, will now have to provide at least 40 percent of their services to non-Medicare patients. The commenters believed that, by adding a payment reduction on top of these requirements, CMHCs would be potentially facing closure.

Response: We acknowledge the commenters' concerns with section 1301 of HCERA, a component of the Affordable Care Act (Pub. L. 111–152, enacted on March 30, 2010). Section 1301 requires CMHCs to provide at least 40 percent of their services to non-Medicare patients. On June 17, 2011, CMS published a proposed rule to enforce this provision (76 FR 35684, 35693) as well as to propose conditions of participation addressing basic health and safety issues in CMHCs. By law, CMS must update the OPPS payment rates on an annual basis using the most current cost data.

Comment: Some commenters recommended that CMS establish a ratesetting task force to develop a new rate methodology that captures all relevant data and reflects real-time costs to providers. The commenters suggested that the recommended ratesetting task force be composed of CMS staff and a diverse group of stakeholders that include front-line providers of partial hospitalization services, representatives from the National Council for Community Behavioral Healthcare, the National Association of Psychiatric Health Systems, the American Association of Behavioral Healthcare, the National Alliance for the Mentally Ill, and the Medicare Payment Advisory Committee.

Response: CMS already has positive working relationships with various industry leaders representing both CMHCs and hospital-based PHP providers with whom we have consistently met with over the years to discuss industry concerns and ideas. These relationships have provided significant and valued input into PHP rate setting. Furthermore, CMS holds Hospital Outpatient Open Door Forum calls monthly, when individuals are welcome to participate and/or submit questions regarding specific issues, including questions related to PHP programs. Given the relationships that CMS has already established with various industry leaders, we believe that we receive adequate input regarding rate setting and take that input into consideration when applying the payment rates. We continue to welcome any input and information that the industry is willing to provide.

Comment: A few commenters stated that CMS misinterpreted the original intent of section 1833(t)(2)(C) of the Act and is now making a new interpretation of the statute by eliminating the requirement in section 1833(t)(2)(C) of the Act.

Response: As discussed above in this section, we believe the statute is reasonably interpreted to allow the relative payment weights for the OPPS rates for PHP services provided by CMHCs to be based solely on CMHC cost data and the relative payment weights for hospital-provided PHP services to be based exclusively on hospital cost data. Section 1833(t)(2)(C) of the Act requires the Secretary to ''establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on * * * hospital costs.'' In pertinent part, subparagraph (B) provides that ''the Secretary may establish groups of covered OPD services * * * so that services classified within each group are comparable clinically and with respect to the use of resources.'' In accordance with subparagraph (B), CMS developed the APCs, as set forth in § 419.31 of the regulations (65 FR 18446 and 18447; 63 FR 47559 and 47560). PHP services are grouped into APCs.

Based on section 1833(t)(2)(C) of the Act, we believe that the word ''establish'' can be interpreted as applying to APCs at the inception of the OPPS in 2000 or whenever a new APC is added to the OPPS. In creating the original APC for PHP services (APC 0033), we did ''establish'' the initial relative payment weight for PHP services, provided in hospital-based and CMHC-based settings, on the basis of only hospital data. Subsequently, from CY 2003 through CY 2008, the relative payment weights for PHP services were based on a combination of hospital and CMHC data. Similarly, we subsequently established new APCs for PHP services based exclusively on hospital costs. For CY 2009, we adopted a two-tiered APC methodology (in lieu of the original APC 0033) under which CMS paid one rate

for days with 3 services (APC 0172) and a different payment rate for days with 4 or more services (APC 0173). These two new APCs were established using only hospital data. For CY 2011, we added two new APCs (APCs 0175 and 0176) for PHP services provided by hospitals and based the relative payment weights for these APCs solely on hospital data. APCs 0172 and 0173 were designated for PHP services provided by CMHCs and were based on a mixture of hospital and CMHC data. As the Secretary argued in the *Paladin* case, the courts have consistently held that the phrase ''based on'' does not mean ''based exclusively on.'' Thus, the relative payment weights for the two APCs for CMHC-provided PHP services in CY 2011 were ''based on'' hospital data, no less than the relative payment weights for the two APCs for hospital-provided PHP services.

Although we used only hospital data to establish the original relative payment weights for APC 0033 and later used hospital data to establish four new relative payment weights for PHP services, we believe that we have the authority to discontinue the use of hospital data after the original establishment of the relative payment weights for a given APC. Other parts of section 1833(t)(2)(C) of the Act make plain that the data source for the relative payment weights is subject to change from one period to another. Section 1833(t)(2)(C) of the Act provides that, in establishing the relative payment weights, ''the Secretary shall [ ] us[e] data on claims from 1996 and us[e] data from the most recent available cost reports.'' However, we used 1996 data (plus 1997 data) in determining only the original relative payment weights for 2000; in the ensuing calendar year updates, we continually used more recent cost report data.

Moreover, section 1833(t)(9)(A) of the Act requires the Secretary to ''review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.'' For purposes of the CY 2012 update, we exercised our authority under section 1833(t)(9)(A) of the Act to change the data source for the relative payment weights for PHP services by CMHCs based on ''new cost data, and other relevant information and factors.''

Comment: Several commenters questioned how one provider's cost data could impact the rates so dramatically and how can CMS reasonably attribute some of the rate fluctuation to targeted fraud and abuse efforts on the part of CMS and other agencies. Commenters stated that fraud and abuse efforts did not decrease the operating cost of providers, but instead resulted in eliminating fraudulent providers from the program. Commenters also posed the question of whether CMS took into account the number of CMHCs that closed their doors in CY 2010 or only partially operated in CY 2010 due to inability to continue to operate.

Response: We calculate the PHP per diem medians using all PHP claims data. However, a provider who has a high volume of claims will impact the medians by either increasing the medians or decreasing the medians, depending on its cost data. For example, if a provider that has high cost data and a high volume of claims will saturate the overall cost data, resulting in high medians. Although fraud and abuse efforts do not decrease the operating cost of providers, the removal of a particular provider may have dramatic results on the overall medians. We acknowledge the commenters' concerns and plan to continue monitoring the data.

We do study the number of PHP provider closings and openings. We will continue to monitor any potential access problems.

Comment: A few commenters expressed concerns that the technical data on which CMS relies during the ratesetting process are fundamentally flawed, in that the data do not reflect the full scope of CMHC costs. These commenters also stated that, due to insufficient cost reporting instructions for CMHCs, they continue to incorrectly exclude owner's salary costs from their cost reports, contributing to their low median costs.

Response: Data within the cost report remain an essential component for CMS rate setting, and it is imperative that cost reports be completed with accuracy. Medicare cost reports are Federal documents in which providers certify and attest that the information contained in them is accurate. As a Medicare participating provider, it is the responsibility of the provider to complete and submit an accurate Medicare cost report. Because all providers must certify and attest to the accuracy of the report, we trust that the data are, in fact, accurate. We calculate rates using the data submitted to us.

There are several free resources available to providers who have questions or need help completing cost reports. Providers are always encouraged to work with their fiscal intermediaries/MACs to resolve any questions, including those related to cost reports. CMS provides manual instructions in Chapter 18 of the Provider Reimbursement Manual, Part II, located on the CMS Web site at: *https://www.cms.gov/Manuals/PBM/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS021935&intNumPerPage=10*.

CMS regional office and central office employees, including those in the Division of Cost Reporting, are also available resources who can answer questions. Furthermore, CMS offers cost reporting software free of charge at: *http://www.mutualmedicare.com/star/providers/*.

All of the abovementioned resources are free of charge. A provider may also purchase the services of accounting professionals to help with completing cost reports. We do caution that providers should choose a trusted accountant. We have become aware of some providers purchasing the services of accountants who profess to know Medicare cost reporting requirements, but in reality do not. Again, if an accountant completes the cost report, the provider is still responsible for the content of the cost report via certification and attestation.

In summary, after consideration of the public comments we received, we are finalizing our CY 2012 proposal, without modification, to update the four PHP per diem payment rates based on the median cost levels calculated using the most recent claims data for each provider type. The updated PHP APCs median per diem costs for PHP services that we are finalizing for CY 2012 are shown in Tables 44 and 45 below:

TABLE 44.--FINAL CY 2012 MEDIAN PER DIEM COSTS FOR CMHC PHP SERVICES

APC	Group Title	Final Median Per Diem Costs
0172	Level I Partial Hospitalization (3 services) for CMHCs	$97.64
0173	Level II Partial Hospitalization (4 or more services) for CMHCs	$113.83

TABLE 45.--FINAL CY 2012 MEDIAN PER DIEM COSTS FOR HOSPITAL-BASED PHP SERVICES

APC	Group Title	Final Median Per Diem Costs
0175	Level I Partial Hospitalization (3 services) for hospital-based PHPs	$160.74
0176	Level II Partial Hospitalization (4 or more services) for hospital-based PHPs	$191.16

C. Separate Threshold for Outlier Payments to CMHCs

In the CY 2004 OPPS final rule with comment period (68 FR 63469 through 63470), we indicated that, given the difference in PHP charges between hospitals and CMHCs, we did not believe it was appropriate to make outlier payments to CMHCs using the outlier percentage target amount and threshold established for hospitals. Prior to that time, there was a significant difference in the amount of outlier payments made to hospitals and CMHCs for PHP services. In addition, further analysis indicated that using the same OPPS outlier threshold for both hospitals and CMHCs did not limit outlier payments to high-cost cases and resulted in excessive outlier payments to CMHCs. Therefore, beginning in CY 2004, we established a separate outlier threshold for CMHCs. The separate outlier threshold for CMHCs has resulted in more commensurate outlier payments.

The separate outlier threshold for CMHCs resulted in $1.8 million in outlier payments to CMHCs in CY 2004 and $0.5 million in outlier payments to CMHCs in CY 2005. In contrast, in CY 2003, more than $30 million was paid to CMHCs in outlier payments. We believe this difference in outlier payments indicates that the separate outlier threshold for CMHCs has been successful in keeping outlier payments to CMHCs in line with the percentage of OPPS payments made to CMHCs.

In the CY 2012 OPPS/ASC proposed rule (76 FR 42275), we proposed to continue our policy of identifying 1.0 percent of the aggregate total payments under the OPPS for outlier payments for CY 2012. We proposed that a portion of that 1.0 percent, an amount equal to 0.14 percent of outlier payments (or 0.0014 percent of total OPPS payments), would be allocated to CMHCs for PHP outlier payments. In section II.G. of the proposed rule, for hospital outpatient outlier payments policy, we proposed to set a dollar threshold in addition to an APC multiplier threshold. Because the PHP APCs are the only APCs for which CMHCs may receive payment under the OPPS, we would not expect to redirect outlier payments by imposing a dollar threshold. Therefore, we did not propose to set a dollar threshold for CMHC outlier payments. We proposed to set the outlier threshold for CMHCs for CY 2012 at 3.40 times the APC payment amount and the CY 2012 outlier payment percentage applicable to costs in excess of the threshold at 50 percent. Specifically, we proposed to establish that if a CMHC's cost for partial hospitalization services, paid under either APC 0172 or APC 0173, exceeds 3.40 times the payment for APC 0173, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 0173 payment rate.

We did not receive any public comments regarding our proposed outlier policy. Therefore, we are finalizing our CY 2012 proposal to set a separate outlier threshold for CMHCs. As discussed in section II.G. of this final rule with comment period, using more recent data for this final rule with comment period, we set the target for hospital outpatient outlier payments at 1.00 percent of total estimated OPPS payments. We allocated a portion of that 1.00 percent, an amount equal to 0.12 percent of outlier payments or 0.0012 percent of total estimated OPPS payments to CMHCs for PHP outlier payments. For CY 2012, as proposed, we are setting the outlier threshold at 3.40 multiplied by the APC payment amount and the CY 2012 outlier percentage applicable to costs in excess of the threshold at 50 percent.

IX. Procedures That Will Be Paid Only as Inpatient Procedures

A. Background

Section 1833(t)(1)(B)(i) of the Act gives the Secretary broad authority to determine the services to be covered and paid for under the OPPS. Before implementation of the OPPS in August 2000, Medicare paid reasonable costs for services provided in the HOPD. The

claims submitted were subject to medical review by the fiscal intermediaries to determine the appropriateness of providing certain services in the outpatient setting. We did not specify in our regulations those services that were appropriate to provide only in the inpatient setting and that, therefore, should be payable only when provided in that setting.

In the April 7, 2000 final rule with comment period (65 FR 18455), we identified procedures that are typically provided only in an inpatient setting and, therefore, would not be paid by Medicare under the OPPS. These procedures comprise what is referred to as the ''inpatient list.'' The inpatient list specifies those services for which the hospital will be paid only when provided in the inpatient setting because of the nature of the procedure, the underlying physical condition of the patient, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged. As we discussed in that rule and in the November 30, 2001 final rule with comment period (66 FR 59884), we may use any of a number of criteria we have specified when reviewing procedures to determine whether or not they should be removed from the inpatient list and assigned to an APC group for payment under the OPPS when provided in the hospital outpatient setting. Those criteria include the following:

- Most outpatient departments are equipped to provide the services to the Medicare population.
- The simplest procedure described by the code may be performed in most outpatient departments.
- The procedure is related to codes that we have already removed from the inpatient list.

In the November 1, 2002 final rule with comment period (67 FR 66741), we added the following criteria for use in reviewing procedures to determine whether they should be removed from the inpatient list and assigned to an APC group for payment under the OPPS:

- A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis; or
- A determination is made that the procedure can be appropriately and safely performed in an ASC, and is on the list of approved ASC procedures or has been proposed by us for addition to the ASC list.

The list of codes that will be paid by Medicare in CY 2012 only as inpatient procedures is included as Addendum E to this final rule with comment period (which is referenced in section XVII. of this final rule with comment period and available via the Internet on the CMS Web site).

B. Changes to the Inpatient List

In the CY 2012 OPPS/ASC proposed rule (76 FR 42276), we proposed to use the same methodology for the CY 2012 OPPS described in the November 15, 2004 final rule with comment period (69 FR 65835) to identify a subset of procedures currently on the inpatient list that are being performed a significant amount of the time on an outpatient basis. Using this methodology, we identified two procedures that met the criteria for potential removal from the inpatient list for CY 2012. We then clinically reviewed these two potential procedures for possible removal from the inpatient list and found them to be appropriate candidates for removal from the inpatient list. During the February 8–March 1, 2011 meeting of the APC Panel, we solicited the APC Panel's input on the appropriateness of removing these two procedures from the CY 2012 inpatient list: CPT codes 21346 (Open treatment of nasomaxillary complex fracture (Lefort II type); with wiring and/or local fixation) and 54411 (Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue).

As we indicated in the CY 2011 final rule with comment period (75 FR 71996), we solicited the APC Panel's input on the appropriateness of removing the procedures described by CPT codes 35045 (Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for aneurysm, pseudoaneurysm, and associated occlusive disease, radial or ulnar artery) and 54650 (Orchiopexy, abdominal approach, for intra-abdominal testis (*e.g.,* Fowler-Stephens)), from the CY 2012 inpatient list. We also solicited the APC Panel's input on the appropriateness of removing the following procedures identified in a comment letter addressed to the APC Panel: CPT codes 61154 (Burr hole(s) with evacuation and/or drainage of hematoma, extradural or subdural); 61156 (Burr hole(s); with aspiration of hematoma or cyst, intracerebral); and 61210 (Burr hole(s); for implanting ventricular catheter, reservoir, eeg electrode(s), pressure recording device, or other cerebral monitoring device (separate procedure)). Following the discussion at its February 28–March 1, 2011 meeting, the APC Panel recommended that CMS remove from the CY 2012 inpatient list CPT codes 21346, 54411, 35045, 54650, and 61210. The APC Panel made no recommendation regarding CPT codes 61154 and 61156.

Additionally, during the February 28–March 1, 2011 meeting of the APC Panel, an APC Panel member requested removal of the following CPT codes from the CY 2012 inpatient list: 22551 (Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2); 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)); 22554 (Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below C2); 22585 (Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below C2, each additional interspace (List separately in addition to code for primary procedure)); 61107 (Twist drill hole(s) for subdural, intracerebral, or ventricular puncture; for implanting ventricular catheter, pressure recording device, or other intracerebral monitoring device); and 63267 (Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; lumbar). Following the discussion at its February 28–March 1, 2011 meeting, the APC Panel recommended that CMS remove from the CY 2012 inpatient list CPT codes 22551, 22552, 22554, 22585, 61107, and 63267.

In the CY 2012 OPPS/ASC proposed rule, for CY 2012, we proposed to accept the APC Panel's recommendation to remove the procedures described by CPT codes 21346, 35045, and 54650 from the inpatient list because we agree with the APC Panel that the procedures may be appropriately provided as hospital outpatient procedures for some Medicare beneficiaries, based upon the evaluation criteria mentioned above. We also proposed to not accept the APC Panel's recommendations to remove the procedures described by CPT codes 22551, 22552, 22554, 22585, 54411, 61107, 61210, and 63267 from the CY 2012 inpatient only list because upon further clinical review subsequent to the February 28–March 1, 2011 APC Panel meeting, we did not believe that these

procedures may be appropriately provided as hospital outpatient procedures for some Medicare beneficiaries, based upon the evaluation criteria mentioned above, due to the clinical intensity of the services provided. Furthermore, according to our utilization data, the procedures described by CPT codes 22551, 22552, 22554, 22585, 54411, 61107, 61210, and 63267 have very low volume in the outpatient hospital setting. We noted that despite its low overall volume, CPT code 54411 is performed a significant percentage of the time in the outpatient hospital setting; however, we do not believe that the outpatient procedures being performed are truly reflective of the intensity of services requisite when performing the procedure as described by the CPT code's long descriptor. We invited public comment on the inclusion of CPT code 54411 on the CY 2012 inpatient list.

At its August 10–12, 2011 meeting, the APC Panel recommended again that CMS remove CPT codes 22551, 22552, 22554, 22585, and 63267 from the CY 2012 inpatient only list and that CMS provide the APC Panel with clinical information on the appropriateness of removing HCPCS code 43279 (Laparoscopy, surgical, esophagomyotomy (Heller type), with fundoplasty, when performed) from the inpatient-only list and, if removed, to which APC it should be assigned.

Comment: Commenters supported the CMS proposal to accept the APC recommendation to remove CPT procedures codes 21346, 35045, and 54650 from the CY 2012 inpatient only list.

Response: We appreciate the commenters' support.

Comment: One commenter requested that CMS remove CPT code 54411 from the CY 2012 inpatient only list based on the specialty society's experience and additionally requested that CMS remove CPT code 54417 (Removal and replacement of a non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session) from the inpatient only list.

Response: We reevaluated data on CPT codes 54411 and 54417, utilizing further clinical review by CMS' medical advisors, and we remain convinced that these procedures can be safely performed only in the inpatient setting due to the invasive and complicated nature of these procedures.

Comment: One commenter requested that CMS create a modifier similar to modifier-CA (procedure payable only in the inpatient setting when performed emergently on an outpatient who expires prior to admission) to indicate procedure payable only in the inpatient setting when performed emergently on an outpatient who is transferred to another acute care facility prior to admission.

Response: We appreciate this comment. However, the issues discussed within this comment are outside the scope of the provisions of the proposed rule. We will take this comment into consideration in developing future rulemaking.

Comment: Several commenters requested that CMS remove all of the CPT codes recommended by the APC Panel, as well as remove 42 additional CPT codes from the CY 2012 inpatient only list based on their own experience, specialty society recommendation, or designation of a procedure as safe in the outpatient setting under one of the many clinical guidelines available, such as *Milliman Care Guidelines.*

Response: We reevaluated data on the 42 additional CPT codes requested by the commenters using more recent utilization data and further clinical review by CMS medical advisors. These codes are listed in Table 47 below. As a result of the reevaluation, we agree with the commenters that it would be appropriate to remove the following seven CPT codes from the CY 2012 inpatient only list because patients undergoing these procedures can typically be managed postoperatively as outpatients: 0184T (Excision of rectal tumor, transanal endoscopic microsurgical approach (ie, TEMS), including muscularis propria (ie, full thickness)); 20930 (Allograft for spine surgery; morselized); 20931 (Allograft for spine surgery only; structural (List separately in addition to code for primary procedure)); 43281 (Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; without implantation of mesh); 43770 (Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)); 22551 (Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2); and 22554 (Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below C2). We also note that although commenters requested that CPT code 37221(Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed) be removed from the CY 2012 inpatient only list, CPT code 37221 is not on the current inpatient only list, but is currently assigned a status indicator of ''T.'' In regard to the other 36 CPT codes that the commenters requested to be removed from the CY 2012 inpatient only list, we remain convinced that these procedures can be safely performed only in the inpatient setting due to the complexity and intensity of these services and the need for postoperative inpatient monitoring.

Comment: A number of commenters suggested that regulations should not supersede the physician's level of knowledge and assessment of the patient's condition, and that the physician can appropriately determine whether a procedure can be performed in a hospital outpatient setting. Other commenters stated that physician's payment should be aligned with the hospital payment; if the hospital is not paid, the physician payment should not be allowed. The commenters further stated that physicians have little incentive to ensure that inpatient only procedures are performed in the correct setting because their payments are not impacted by an incorrect site of service. One commenter believed that CMS and hospital efforts to educate physicians have not been effective. Many commenters suggested that the inpatient only list be eliminated in its entirety. The commenters indicated that hospitals already meet minimum safety standards through Joint Commission accreditation and the Medicare hospital conditions of participation. Commenters suggested that, if the inpatient only list cannot be eliminated in its entirety, an appeals process be developed. Commenters believed that an appeal process would give the hospital the opportunity to submit documentation on the physician's intent, the patient's clinical condition, and the circumstances that enabled the patient to be sent home safely without an inpatient stay. One commenter requested that CMS push its Medicare contractors' medical directors to develop local coverage determinations (LCDs) that define when selected procedures should be performed as inpatient or outpatient and that CMS develop a process to more quickly evaluate procedures for removal from the inpatient only list outside of the rulemaking process.

Response: We appreciate these comments and thoughtful suggestions. We continue to believe that the inpatient only list is a valuable tool for

ensuring that the OPPS only pays for services that can safely be performed in the hospital outpatient setting, and we will not eliminate the inpatient only list at this time. We believe that there are many surgical procedures that are never safely performed for a Medicare beneficiary in the hospital outpatient setting. Therefore, it would be inappropriate for us to assign them separately payable status indicators and establish payment rates in the OPPS. We recognize that hospitals already meet minimum safety standards through accreditation or State surveys which assure compliance with the Medicare hospital conditions of participation. However, while accreditation or State survey and certification of compliance with the hospital conditions of participation ensure that a hospital is generally a safe and appropriate environment for providing care, they do not determine whether a particular service can be safely provided in the outpatient setting to Medicare beneficiaries.

Although the commenters suggested that we apply the same payment restrictions to physicians and hospitals when inpatient procedures are performed inappropriately, payment for physicians' services is outside the scope of the payment policies governed by the OPPS and the provisions of this OPPS/ASC final rule with comment period. Notwithstanding concern that education has not yet been able to stop some physicians from performing a procedure on the inpatient only list in the hospital outpatient setting, we continue to believe that education is critical to ensuring that physicians do not inadvertently provide services in a hospital outpatient setting that are paid for only during an inpatient stay. We expect hospitals to be aware of the services that are being provided in the outpatient setting. Therefore, we do not believe that it is appropriate to pay the hospital for the ancillary services furnished when the patient receives an inpatient only service in the hospital outpatient setting. Further, we expect hospitals to use this knowledge and to educate physicians with regard to the appropriate setting for the procedures they furnish. We recognize that there are cases in which the patient expires before he or she can be admitted and has received an inpatient only service without being admitted. In these cases, we have a longstanding policy of making payment for the ancillary services provided to Medicare beneficiaries under APC 0375.

As we have stated in the past, we also are concerned about the impact of eliminating the inpatient only list on Medicare beneficiary liability. Elimination of the inpatient only list might lead to longer periods of stay in the hospital outpatient setting, during which Medicare beneficiaries are responsible for copayments for a complex surgery and any individual services supporting that surgery, as well as financial liability for most self-administrable drugs which are not covered under Medicare Part B. Cost-sharing is very different between the hospital inpatient setting and the hospital outpatient setting, and Medicare beneficiaries may incur higher out-of-pocket costs in the hospital outpatient setting for complex surgical procedures. We do not plan to adopt a specific appeals process for claims related to inpatient only procedures performed in the HOPD. Stakeholders can request changes to the inpatient only list through annual rulemaking, but they are responsible for knowing what procedures are currently on the list. We do not believe that a dedicated appeals process for cases involving inpatient only procedures performed in the outpatient setting is warranted and such a process could potentially undermine the disincentive for performing inpatient only procedures in an outpatient setting. We remain committed to reviewing the inpatient only list timely to reflect changes in medical practice, and we plan to continue our current practice of reviewing procedures for removal from the inpatient only list through the notice-and-comment rulemaking process.

After consideration of the public comments received, for CY 2012, we are modifying our proposal to accept the APC Panel's recommendations to remove the procedures described by CPT codes 22551 and 22554 from the CY 2012 inpatient only list because after additional discussion during the August 10–12, 2011 APC Panel meeting and further clinical review subsequent to the August 10–12, 2011 APC Panel meeting, we agree with the APC Panel that the procedures may be appropriately provided as hospital outpatient procedures for some Medicare beneficiaries, based upon the evaluation criteria mentioned above. We also are accepting the APC Panel's recommendation to provide the APC Panel with clinical information on the appropriateness of removing HCPCS code 43279 from the inpatient-only list and, if removed, to which APC it should be assigned. However, we are not accepting the APC Panel's recommendations to remove the procedures described by CPT codes, 22552, 22585, 54411, 61107, 61210, and 63267, because, upon further clinical review subsequent to the August 10–12, 2011 APC Panel meeting, we do not believe that these procedures may be appropriately provided as hospital outpatient procedures for some Medicare beneficiaries, based upon the evaluation criteria mentioned above, due to the clinical intensity of services provided.

We are finalizing our proposal, with modifications, to remove CPT codes 0184T, 20930, 20931, 21346, 22551, 22554, 35045, 43281, 43770, and 54650 from the inpatient only list. The 10 procedures we are removing from the inpatient only list for CY 2012 and their CPT codes, long descriptors, APC assignments, and status indictors are displayed in Table 46 below.

BILLING CODE 4120–01–P

TABLE 46.—PROCEDURES REMOVED FROM THE INPATIENT ONLY LIST AND THEIR APC ASSIGNMENTS FOR CY 2012

HCPCS Code	Long Descriptor	CY 2012 APC Assignment	CY 2012 Status Indicator
0184T	Excision of rectal tumor, transanal endoscopic microsurgical approach (ie, TEMS), including muscularis propria (ie, full thickness)	0149	T
20930	Allograft, morselized, or placement of osteopromotive material, for spine surgery only (List separately in addition to code for primary procedure)		N
20931	Allograft, structural, for spine surgery only (List separately in addition to code for primary procedure)		N
21346	Open treatment of nasomaxillary complex fracture (Lefort II type); with wiring and/or local fixation	0254	T
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2	0208	T
22554	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below C2	0208	T
35045	Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for aneurysm, pseudoaneurysm, and associated occlusive disease, radial or ulnar artery	0093	T
43281	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; without implantation of mesh	0132	T

HCPCS Code	Long Descriptor	CY 2012 APC Assignment	CY 2012 Status Indicator
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)	0131	T
54650	Orchiopexy, abdominal approach, for intra-abdominal testis (eg, Fowler-Stephens)	0154	T

TABLE 47.—ADDITIONAL PROCEDURES REQUESTED BY COMMENTERS TO BE REMOVED FROM THE INPATIENT ONLY LIST FOR CY 2012

HCPCS Code	Long Descriptor	CY 2012 Status Indicator
0075T	Transcatheter placement of extracranial vertebral or intrathoracic carotid artery stent(s), including radiologic supervision and interpretation, percutaneous; initial vessel	C
0184T	Excision of rectal tumor, transanal endoscopic microsurgical approach (ie, TEMS), including muscularis propria (ie, full thickness)	T
20661	Application of halo, including removal; cranial	C
20664	Application of halo, including removal, cranial, 6 or more pins placed, for thin skull osteology (eg, pediatric patients, hydrocephalus, osteogenesis imperfecta)	C
20930	Allograft, morselized, or placement of osteopromotive material, for spine surgery only (List separately in addition to code for primary procedure)	N
20931	Allograft, structural, for spine surgery only (List separately in addition to code for primary procedure)	N
20936	Autograft for spine surgery only (includes harvesting the graft); local (eg, ribs, spinous process, or laminar fragments) obtained from same incision (list separately in addition to code for primary procedure)	C
21141	Reconstruction midface, LeFort I; single piece, segment movement in any direction (eg, for long face syndrome), without bone graft	C

HCPCS Code	Long Descriptor	CY 2012 Status Indicator
21196	Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation	C
22114	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; lumbar	C
22585	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below C2, each additional interspace (List separately in addition to code for primary procedure)	C
22855	Removal of anterior instrumentation	C
22862	Revision including replacement of total disc arthroplasty (artificial disc) anterior approach, lumbar	C
22840	Posterior non-segmental instrumentation (eg, Harrington rod technique, pedicle fixation across one interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (list separately in addition to code for primary procedure)	C
23472	Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (eg, total shoulder))	C
27702	Arthroplasty, ankle; with implant (total ankle)	C
32662	Thoracoscopy, surgical; with excision of mediastinal cyst, tumor, or mass	C
35141	Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for aneurysm, pseudoaneurysm, and associated occlusive disease, common femoral artery (profunda femoris, superficial femoral)	C
35221	Repair blood vessel, direct; intra-abdominal	C
35372	Thromboendarterectomy, including patch graft, if performed; deep (profunda) femoral	C
35721	Exploration (not followed by surgical repair), with or without lysis of artery; femoral artery	C
35800	Exploration for postoperative hemorrhage, thrombosis or infection; neck	C

HCPCS Code	Long Descriptor	CY 2012 Status Indicator
37182	Insertion of transvenous intrahepatic portosystemic shunt(s) (tips) (includes venous access, hepatic and portal vein catheterization, portography with hemodynamic evaluation, intrahepatic tract formation/ dilatation, stent placement and all associated ima	C
37221	Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed	T
37617	Ligation, major artery (eg, post-traumatic, rupture); abdomen	C
38562	Limited lymphadenectomy for staging (separate procedure); pelvic and para-aortic	C
43281	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; without implantation of mesh	T
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric band restrictive device (eg, gastric band and subcutaneous port components)	T
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric band restrictive device and subcutaneous port components	C
43840	Gastrorrhaphy, suture of perforated duodenal or gastric ulcer, wound, or injury	C
44300	Placement, enterostomy or cecostomy, tube open (eg, for feeding or decompression or feeding) (separate procedure)	C
44314	Revision of ileostomy; complicated (reconstruction in-depth) (separate procedure)	C
44345	Revision of colostomy; complicated (reconstruction in-depth) (separate procedure)	C
44346	Revision of colostomy; with repair of paracolostomy hernia (separate procedure)	C
44602	Suture of small intestine (enterorrhaphy) for perforated ulcer, diverticulum, wound, injury or rupture; single perforation	C
49010	Exploration, retroperitoneal area with or without biopsy(s) (separate procedure)	C
49255	Omentectomy, epiploectomy, resection of omentum (separate procedure)	C

HCPCS Code	Long Descriptor	CY 2012 Status Indicator
51840	Anterior vesicourethropexy, or urethropexy (eg, marshall-marchetti-krantz, burch); simple	C
56630	Vulvectomy, radical, partial;	C
61624	Transcatheter permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method; central nervous system (intracranial, spinal cord)	C
63044	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional lumbar interspace (list separately in addition to code for primary procedure)	C
63710	Dural graft, spinal	C

BILLING CODE 4120–01–C

X. Policies for the Supervision of Outpatient Services in Hospitals and CAHs

A. Background

In the CY 2000 OPPS final rule with comment period, CMS established the hospital OPPS and indicated that direct supervision is the standard for all hospital outpatient therapeutic services covered and paid by Medicare in hospitals and in provider-based departments (PBDs) of hospitals (65 FR 18524 through 18526). Currently, as discussed in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72008), this standard requires the supervisory practitioner to be immediately available to furnish assistance and direction throughout the performance of a hospital outpatient therapeutic service or procedure. In the CY 2000 OPPS final rule with comment period, we established in the regulation at § 410.28(e) that outpatient diagnostic services furnished in PBDs of hospitals must be supervised at the level indicated in the Medicare Physician Fee Schedule (MPFS) for each service, that is, general, direct or personal supervision. Since that time, we have clarified and refined these rules in several ways. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71998 through 72001), we provided a comprehensive review of the history of the supervision policies for both outpatient therapeutic and diagnostic services from the inception of the OPPS through CY 2010. In this section, we provide a more condensed overview of our supervision policy during that time period, and present background on issues that have arisen during the CY 2011 payment year.

By way of overview, we have defined supervision in the hospital outpatient setting by using the three levels of supervision that CMS defined for the physician office setting at § 410.32(b) prior to establishment of the OPPS: General, direct, and personal supervision. Over time, we have tailored these definitions as needed to apply them in the hospital outpatient setting, so the definitions or applications in the OPPS may differ slightly from those in the physician office setting. This is the case in defining direct supervision, where the MPFS requires presence ''in the office suite,'' and the OPPS currently does not require presence within any specific physical boundary (in the past, the OPPS rules for direct supervision required presence on the hospital campus or in the PBD) (75 FR 72008, 72012).

To date, for purposes of the hospital outpatient setting, we have only defined direct and general supervision, and we have only defined general supervision insofar as it applies to the provision of nonsurgical extended duration therapeutic services (extended duration services) for which we require direct supervision during an initiation period, followed by a minimum standard of general supervision for the duration of the service (75 FR 72012). Under the OPPS, general supervision means that the service is furnished under the overall direction and control of the physician or appropriate nonphysician practitioner (NPP), but his or her physical presence is not required during the performance of the service. Direct supervision means that the physician or appropriate NPP is immediately available to furnish assistance and direction throughout the performance of a therapeutic service or procedure; however, he or she does not have to be present in the room where the service or procedure is being performed.

In the CY 2000 OPPS final rule with comment period (65 FR 18524 through 18526), we adopted physician supervision policies as a condition of payment under the OPPS to ensure that Medicare pays for high quality hospital outpatient services that are furnished in a safe and effective manner and consistent with Medicare requirements. The agency has long divided hospital outpatient services into the two categories of ''diagnostic'' services and ''therapeutic'' services that aid the physician in the treatment of patients (Section 3112 of the Medicare Part A Intermediary Manual (July 1987)). Thus, we considered all nondiagnostic services to be ''therapeutic services'' which would include, but not be limited to, the services listed under section 1861(s)(2)(B) of the Act as incident to the services of physicians. As early as 1985, the agency defined therapeutic services as those services and supplies (including the use of hospital facilities) that are incident to the services of

physicians in the treatment of patients (Section 3112.4 of the Medicare Part A Intermediary Manual (May 1985)). In recognition of this historic classification of services, we established a direct supervision standard for outpatient therapeutic services under our regulation at § 410.27, which establishes the conditions for payment for outpatient hospital services provided ''incident to'' physicians' services. In the text of § 410.27, we also established standards requiring that these services be furnished either by or under arrangements made by the participating hospital (§ 410.27(a)(1)(i)), and either in the hospital or in a location that the agency designates as a department of a provider under § 413.65 of the regulations (§ 410.27(a)(1)(iii)). Since 2000, we have maintained the classification of services as either diagnostic or therapeutic in our manual guidance that establishes the conditions of payment for hospital outpatient services under the OPPS (Sections 20.4 and 20.5, Chapter 6 of the Medicare Benefit Policy Manual (Pub. 100–02)). In the requirements for therapeutic services, in addition to the direct supervision standard, we applied the requirements of § 410.27(a)(1)(i) and (a)(1)(iii) regarding under arrangement and provider-based site of service to all outpatient therapeutic services that are paid under the OPPS (Section 20.5, Chapter 6 of the Medicare Benefit Policy Manual (Pub. 100–02)).

In the CY 2000 OPPS final rule with comment period, we amended our regulation at § 410.27 to specify that direct supervision is required for outpatient hospital services and supplies furnished incident to a physician's service in a location we designate as a department of a provider under § 413.65 of our regulations. We specified further in the regulation that direct supervision means the physician must be present on the premises of the location and immediately available to furnish assistance and direction throughout the performance of the service or procedure. The requirement to be ''immediately available'' was included in the regulation, although at that time we did not define the term. Although the regulation required the physician to be present on the premises of the location where services were being furnished, it specified that the physician did not have to be present in the room when the procedure was performed. In the CY 2000 OPPS final rule with comment period (65 FR 18525), we emphasized the importance of establishing a supervision standard for services furnished in departments of the hospital that are not located on campus, indicating that our amendment applies to services furnished at an entity that is located off the campus of a hospital that we designate as having provider-based status in accordance with the provisions of § 413.65. In response to a commenter, we stated that, in accordance with Section 3112.4(A) of the Intermediary Manual, we assume that the direct supervision standard is met when outpatient therapeutic services are provided incident to a physician's service in an on-campus department of a hospital.

In the CY 2000 OPPS final rule with comment period, we also defined the supervision standards for outpatient hospital diagnostic services furnished in PBDs of hospitals in § 410.28(e) of our regulations. The regulation at § 410.28(e) provided that diagnostic services furnished at facilities having provider-based status must be performed under the level of supervision indicated for the diagnostic test under the MPFS in accordance with the definitions in §§ 410.32(b)(3)(i), (b)(3)(ii), and (b)(3)(iii). In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60588 through 60591, and 60680), we revised § 410.28(e) to extend the supervision standards we had established for hospital outpatient diagnostic tests furnished in PBDs to also apply to services furnished in the hospital setting or any other location where diagnostic services may be provided under arrangement. The supervision rules for diagnostic services under the regulation at § 410.28(e) explicitly apply to hospitals that are paid in accordance with section 1833(t) of the Act, which is the statutory authority for the OPPS. As noted in the CY 2010 OPPS/ASC final rule with comment period, Medicare makes payments to CAHs in accordance with section 1834(g) of the Act. Accordingly, CAHs are not subject to the supervision requirements for hospital outpatient diagnostic services at this time. The supervision requirements for hospital outpatient diagnostic services were also set forth in Section 20.4, Chapter 6, of the Medicare Benefit Policy Manual.

In the years following establishment of the initial OPPS regulations, we began to receive inquiries from providers about the supervision requirements. Many of these inquiries led us to believe that some hospitals may have misunderstood our statement to the effect that we assume physician supervision requirements are met for services furnished on the hospital premises, and that some hospitals were providing either general supervision or no supervision for therapeutic services furnished incident to physicians' services in the outpatient setting and for which we had established a requirement of direct supervision. Therefore, in the CY 2009 OPPS/ASC proposed rule and final rule with comment period (73 FR 41518 through 41519 and 73 FR 68702 through 68704, respectively), we clarified and restated the various supervision requirements for outpatient hospital therapeutic and diagnostic services. We clarified that outpatient therapeutic services furnished in the hospital and in all PBDs of the hospital, specifically both on-campus and off-campus PBDs, must be provided under the direct supervision of physicians. We also reiterated that all outpatient diagnostic services furnished in PBDs, whether on or off the hospital's main campus, should be supervised according to the levels assigned for the individual tests under the MPFS. We received very few public comments regarding this clarification and restatement during the comment period.

In response to concerns about our policy restatement articulated by stakeholders after publication of the CY 2009 OPPS/ASC final rule with comment period, we further refined our supervision policies in the CY 2010 OPPS/ASC proposed rule and final rule with comment period (74 FR 35365 and 74 FR 60679 through 60680, respectively). We established rules for hospital outpatient diagnostic services furnished in locations other than PBDs (that is, in the hospital and under arrangement in nonhospital facilities). Accordingly, we expanded and refined the regulatory language regarding direct supervision of diagnostic services in those locations to refer to presence of the supervisory practitioner in the hospital or PBD (for services furnished in those locations) or in the office suite (for services furnished under arrangement in nonhospital space). For therapeutic services, we increased hospitals' flexibility regarding the direct supervision requirement by allowing all NPPs whose services are those the practitioner is legally authorized to perform under State law that ''would otherwise be covered if furnished by a physician or as an incident to a physician's service'' (''would be physicians' services'') to supervise hospital outpatient therapeutic services that are within their scope of practice under State law and their hospital-granted or CAH-granted privileges (sections 1861(s)(2)(K) through (N) of the Act; §§ 410.71 through 410.77 of the regulations). However, in implementing the new benefits for pulmonary rehabilitation (PR), cardiac

rehabilitation (CR) and intensive cardiac rehabilitation (ICR) services, we required that direct supervision of those services furnished in the hospital outpatient setting must be provided by a doctor of medicine or a doctor of osteopathy because, as we discussed in the CY 2010 and CY 2011 OPPS/ASC final rules with comment period (74 FR 60573 and 60582 and 75 FR 72009, respectively), the statute specifies that these services are physician-supervised (section 144(a) of the Medicare Improvements for Patients and Providers Act of 2008, Pub. L. 110–275). In addition, in the CY 2011 OPPS/ASC final rule with comment period, we revised our regulations at § 410.27 to remove the physical boundary requirements for direct supervision of hospital outpatient therapeutic services, and instead allow the supervisory practitioner to be ''immediately available,'' meaning physically present, interruptible, and able to furnish assistance and direction throughout the performance of the procedure, but without reference to any particular physical boundary.

In the CY 2010 OPPS/ASC final rule with comment period, we finalized a technical correction to the regulation at § 410.27 to clarify that the direct supervision requirement under that section applies to services furnished in CAHs as well as other types of hospitals. Specifically, we added the phrase ''or CAH'' in the title and throughout the regulation text wherever the text referred only to ''hospital,'' to clarify that the requirements for payment of hospital outpatient therapeutic services in that section apply to CAHs as well as other types of hospitals. As we discussed in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72000), we viewed this as a technical correction because the Act applies the same regulations to hospitals and CAHs when appropriate (CAHs are included if ''the context otherwise requires'' under section 1861(e) of the Act).

In response to our clarification that CAHs are subject to the direct supervision standard for payment of outpatient therapeutic services, CAHs and the hospital community at large suggested that CAHs should be exempt from this requirement because the requirement is at odds with longstanding and prevailing practices of many CAHs. For example, commenters noted that, due to a low volume of services, a practitioner retained on the campus of a small rural hospital or CAH to meet supervision requirements may not have other concurrent responsibilities or patient care, which could lead to inefficiencies. In their correspondence and discussion in public forums, CAHs and small rural hospitals explicitly raised concerns about services that extend after regular operating hours, especially observation services. They asserted that direct supervision is not clinically necessary for some outpatient services that have a significant monitoring component that is typically performed by nursing or other auxiliary staff, including IV hydration, blood transfusions, and chemotherapy. They stated that their facilities have protocols to safely deliver all of these services, relying on nursing or other hospital staff to provide the service and having a physician or NPP available by phone to furnish assistance and direction throughout the duration of the therapeutic service.

We provided guidance regarding the flexibility that we believe exists within our requirement for direct supervision for an emergency physician or NPP, who would be the most likely practitioners staffing a small rural hospital or CAH, to provide the supervision, on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS/05_OPPSGuidance.asp#TopOfPage.* However, these hospitals continued to express that they have difficulty in meeting the standard. Small rural hospitals and CAHs indicated that, regulations notwithstanding, many of them did not have appropriate staff arrangements to provide the required supervision of some services, particularly services being provided after hours or consisting of a significant monitoring component that last for an extended period of time. In addition, the broader hospital community began requesting that we modify our policy to permit a lower level of supervision for outpatient therapeutic services for all hospitals.

After consideration of these requests, on March 15, 2010, we issued a **Federal Register** notice of nonenforcement of the requirement for direct supervision of outpatient therapeutic services in CAHs (which is available on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS/Downloads/CMS_1504FC_OPPS_2011_FR_Physician_Supervision_Nonenf_Notice.pdf*). While CAHs remained subject to the direct supervision standard, we instructed our contractors not to evaluate or enforce the standard in CY 2010 until the agency could revisit the supervision policy during the CY 2011 rulemaking cycle.

As indicated above, in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71998 through 72013), we further adjusted the direct supervision standard for hospital outpatient therapeutic services to increase flexibility for hospitals while maintaining an appropriate level of quality and safety and consistent with the Medicare statute. Specifically, for these services we redefined direct supervision to remove all requirements that the supervisory practitioner remain present within a particular physical boundary, although we continued to require immediate availability. We also established a new category of services, ''nonsurgical extended duration therapeutic services'' (extended duration services), which have a substantial monitoring component. We specified that direct supervision is required for these services during an initiation period, but once the supervising physician or NPP has determined that the patient is stable, the service can continue under general supervision.

In addition, in response to concerns expressed by the industry about appropriate levels of supervision for certain outpatient therapeutic services furnished in various settings (for example, chemotherapy administration, and post-operative recovery services), we stated our intent to create through the CY 2012 rulemaking cycle an independent advisory review process for consideration of stakeholder requests that CMS assign supervision levels other than direct supervision for specific outpatient hospital therapeutic services. We stated that the review entity would evaluate services and recommend that CMS assign the same level of supervision (direct supervision), a lower level of supervision (general supervision), or a higher level of supervision (personal supervision) because in the course of evaluating a given service, the review entity may find that personal supervision is the most appropriate level (75 FR 72006). We also indicated that, as an interim measure while we are in the process of establishing an advisory review body, we would extend the nonenforcement policy for direct supervision of outpatient therapeutic services provided in CAHs for a second year through CY 2011 (which is available at the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS/Downloads/CMS_1504FC_OPPS_2011_FR_Physician_Supervision_Nonenf_Notice.pdf*). In addition, we expanded the nonenforcement notice to include small and rural hospitals that have 100 or fewer beds, as defined by Transitional Outpatient Payments (TOPs) criteria, because we believe that

these hospitals experience resource constraints that are similar to CAHs.

We indicated that we would consider the Federal Advisory Panel on Ambulatory Payment Classification Groups (APC Panel) as a potential candidate to serve as the independent review entity to consider requests for alternative service-specific supervision standards, and we requested public comment both on that idea and on other aspects of the review process, such as evaluation criteria and the potential structure of the process. We suggested the APC Panel could serve as the review entity because it is already funded and established by law under the Federal Advisory Committee Act (FACA, Pub. L. 92–463) to make independent recommendations to CMS. The APC Panel membership is geographically diverse, and it includes members with clinical as well as administrative, hospital billing, and coding expertise.

In response to our discussion in the CY 2011 OPPS/ASC final rule with comment period, we received public comments and other considerable input on these topics from the hospital and CAH community and from rural stakeholders. In the CY 2012 OPPS/ASC proposed rule (76 FR 42277 through 42285), we discussed these comments and further developed our proposals for the independent review process in CY 2012, taking into account the comments received in response to the CY 2011 OPPS/ASC final rule with comment period.

With respect to outpatient hospital diagnostic services, following our revisions to the regulation at § 410.28(e) in the CY 2010 OPPS/ASC final rule with comment period described above, we have received very few comments from stakeholders regarding our revised policy. Therefore, we did not propose any changes to those requirements in the CY 2012 proposed rule.

B. Issues Regarding the Supervision of Hospital Outpatient Therapeutic Services Raised by Hospitals and Other Stakeholders

1. Independent Review Process

In the CY 2012 OPPS/ASC proposed rule (76 FR 42277 through 42285), we proposed to establish an independent technical review process to consider service-specific requests that CMS assign supervision levels other than direct supervision to hospital outpatient therapeutic services. Our proposals focused on three primary topics: The potential nature of the review entity; the potential nature and structure of the review process; and potential means of evaluating services.

a. Selection of Review Entity

We proposed that the existing APC Panel serve as the independent review entity. However, we proposed to modify the APC Panel's scope and composition in order to create a body that is prepared to address supervision standards and that reflects the full range of parties subject to the standards. Specifically, we proposed to use the discretionary authority in the Panel charter to expand its scope to include the topic of supervision standards. We proposed to add several (2 to 4) representatives of CAHs as Panel members because CAHs are subject to the supervision rules for payment. We proposed that we would continue to exclude these members from deliberations about APC assignments under the OPPS, as these assignments do not affect CAHs. CAHs are not paid under the OPPS, and we do not believe that they are ''appropriate representative providers'' for the Panel's deliberations on APC groups and weights under the authorizing section 1833(t)(9) of the Act.

We proposed to use the APC Panel for many reasons. In addition to being already established and funded, we believed that the APC Panel would be inclusive and well-balanced because it is subject to the FACA rules. We also proposed to use the APC Panel because we believed it will be important to obtain advice that carries the weight of a Federal advisory recommendation, which may have greater legitimacy both with stakeholders and with CMS compared to the opinions of other types of groups.

Comment: Most commenters were in favor of the proposal to use the APC Panel, provided that CAHs and small rural PPS hospitals received appropriate representation. Many commenters requested that CMS add 4 representatives of CAHs and an additional 4 representatives of small rural PPS hospitals to the current 15 Panel members, to ensure a strong voice for small and rural hospitals and because both CAH and non-CAH rural hospitals are having difficulty complying with the direct supervision requirement. The commenters also recommended that small rural hospitals paid under the OPPS be permitted to participate in the Panel's deliberations about APC groupings and weights. One commenter requested an equal number of rural and urban provider representatives on the Panel. Another commenter urged CMS to ensure adherence to the FACA rules.

Response: We agree with commenters that the APC Panel is an appropriate entity to serve as the review body, provided CAHs and small rural hospitals are given appropriate representation on the Panel. Therefore, we are finalizing the APC Panel as the entity that will advise and make independent recommendations to the agency regarding the appropriate supervision level for individual hospital outpatient therapeutic services. We believe that it will be important to obtain advice that carries the weight of a Federal advisory recommendation. In addition to being already established and funded, the Federal advisory APC Panel will, of necessity, be inclusive and well-balanced because it is subject to the FACA rules. Panel members bring relevant clinical and nonclinical expertise to the discussions. Through amendment of the Panel charter, the Panel will be authorized under section 222 of the Public Health Service Act (42 U.S.C. 217(a)) to advise the Secretary of the Department of Health and Human Services and the CMS Administrator on the appropriate supervision level for individual hospital outpatient therapeutic services. Under this authority, we will also designate representatives of CAHs to serve on the Panel to advise CMS regarding supervision but they will not advise CMS regarding APC groups and weights.

As we discuss below, a recent study indicated significant differences between CAHs and non-CAH small rural hospitals in resources, quality of care, and outcomes (Joynt K, Harris Y, et al. Quality of Care and Patient Outcomes in Critical Access Rural Hospitals. JAMA. 2011;306(1):45–52). However, as we stated in our CY 2011 OPPS/ASC final rule with comment period (75 FR 72007), we believe that CAHs and small rural PPS hospitals may, at times, face similar resource constraints such as workforce shortages, which could lead to difficulty in meeting certain supervision standards. We believe that it would be appropriate for both small rural PPS hospitals and CAHs to have added representation on the Panel in a manner that would be balanced under the FACA rules. Therefore, as part of our final policy we are adding four new seats to the Panel. Two of these seats will be designated for representatives of CAHs and the other two will be designated for representatives of small rural PPS hospitals. We are defining ''small rural PPS hospital'' in the same manner as we defined ''small rural hospital'' for the notice of nonenforcement of direct supervision of therapeutic services in CAHs and small rural hospitals, that is, hospitals with 100 or fewer beds and either geographically located in a rural area or paid under the hospital OPPS with a

rural wage index (75 FR 72007; *https://www.cms.gov/HospitalOutpatientPPS/downloads/CMS_1504FC_OPPS_2011_FR_Physician_Supervision_Nonenf_Notice.pdf*). This is the same definition of small rural hospital that Congress recognizes for TOPs under section 1833(t)(7) of the Act. All PPS hospital representatives on the Panel, including the representatives of small rural PPS hospitals, will continue to advise CMS on the APC groups and weights as well as the appropriate supervision levels for individual hospital outpatient therapeutic services.

Comment: Several commenters addressed the types of practitioners that should be appointed to the Panel, and the degree to which CMS and the Panel should rely on clinical and specialty expertise. Two commenters suggested that recommendations and decisions about supervision levels be made only by clinicians, and that nonclinicians not be permitted to participate in the review process. One commenter supported the concept of an independent review process but opposed use of the APC Panel, stating that the Panel's members are selected based on their knowledge of payment and reimbursement systems rather than clinical judgment and expertise. The commenter believed that the Panel's recommendations should be based solely on clinical judgment, and pointed out that several current Panel members do not have clinical expertise. The commenter expressed concern that these individuals' recommendations would be based upon payment implications rather than clinical criteria. One commenter recommended that CMS involve its specialty society in its reviews. Another commenter encouraged CMS to include experts on the Panel that specialize in the particular service that is being evaluated, and to seek out the resources of specialty societies. One commenter noted that in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72011), in making the decision to exclude chemotherapy administration from the list of extended duration services pending an independent assessment, CMS noted a safety standard that was published by the American Society of Clinical Oncology and the Oncology Nursing Society. The commenter requested information as to how CMS might consider such specialty association guidelines in future decision-making.

Response: As we stated in the proposed rule (76 FR 42280), we believe that the APC Panel is an appropriate body to review supervision levels because, under the FACA rules, it must have a ''balanced'' composition. The Panel members must reflect expertise in the areas that are important for informed, representative decision-making on supervision which we believe includes both clinical and other types of expertise. In evaluating the supervision levels that are required for payment, we believe that the Panel will need input from individuals with knowledge in hospital billing, coding, and administration, as well as clinical matters. For example, in the past several OPPS rulemaking cycles, commenters have requested that CMS evaluate the surgical recovery period for a change in supervision level from direct to general supervision. Several commenters to the current (CY 2012) proposed rule were seeking additional information on how to request a change in supervision level for a ''service'' like the recovery period that is not defined by a CPT code but rather by phases assigned by a specialty society. As we discuss below, one commenter requested that CMS synchronize the supervision requirement for the recovery period with the phases into which the American Society of Anesthesiology (ASA) divides the recovery period. Individuals with billing and coding expertise may help inform these and similar issues.

In addition, we note that it is possible for both clinicians and nonclinicians to make recommendations that are inappropriately based on payment implications rather than clinical or other criteria that may be set forth. Clinicians must adhere to the supervision rules in order to receive payment for their services, and furnishing supervision uses resources that might otherwise be devoted to increasing payment by furnishing additional services. Thus, we believe there is some potential among clinicians and nonclinicians to give inappropriate weight to payment implications in making their recommendations. Excluding nonclinicians from the Panel would not necessarily prevent these types of considerations from affecting decision-making.

In accordance with the FACA rules, we will maintain balanced membership on the Panel. We encourage specialty associations and other entities with specialized expertise in services that may be under the Panel's consideration to nominate representatives to the Panel. We also encourage these groups to participate in the public Panel meetings, and to submit public presentations that would inform the Panel's deliberations. In setting supervision levels, CMS will continue to consider safety and other guidelines published by specialty associations, and the Panel may consider them as well.

Comment: Several commenters requested that Panel members include clinicians furnishing hospital outpatient services, certified registered nurse anesthetists (CRNAs), and other NPPs who furnish high volume services, especially registered nurses (RNs), physical therapists, and respiratory therapists. One commenter indicated that the Panel should seek input from providers who compete with physicians in the marketplace, and not restrict opportunities to inform the Panel to medical doctors only. Several commenters expressed concern about CMS' policy to not allow certain NPPs to supervise hospital outpatient therapeutic services, especially CRNAs and pharmacists. One commenter indicated that it will ask the Panel to consider allowing pharmacists to supervise hospital outpatient therapeutic services as appropriate, for example, medication management and, in States where it is authorized, collaborative drug therapy management. The commenter requested that, in the course of the review process, the Panel consider pharmacists to be NPPs who may furnish supervision. Another commenter believed that supervision of RNs by physicians will not necessarily prevent medical errors, and also stated that physicians have been implicated in the increase in wrong-patient and wrong-site surgical errors.

Response: We note again that, in accordance with the FACA rules, CMS will follow a balance plan for the Panel membership. For purposes of supervision deliberations, we believe that the clinicians on the Panel should largely represent the types of practitioners who furnish hospital outpatient services and those with supervisory responsibilities because they are most directly impacted by the rules. As we discussed in the proposed rule (76 FR 42282), the agency does not allow RNs to supervise hospital outpatient therapeutic services because they are not authorized under the Act to independently furnish ''would be physicians' services.'' For the same reason, CMS does not permit pharmacists to supervise these services. CRNAs have a narrow scope of practice, and we typically would seek practitioners that furnish a broader array of hospital outpatient services to serve as Panel members. However, these practitioners are eligible to serve on the Panel, depending on their areas of expertise. We note that, currently, one Panel member is an RN and Panel members in the past have been pharmacists. While we did not receive

any comments directly on the number of nurse practitioners, physician assistants or other supervisory NPPs that should serve on the Panel, we would encourage nominations of these types of practitioners, especially for the CAH seats because these types of practitioners might be used more frequently to furnish supervision in CAHs.

Regarding the Panel's supervision deliberations, we note that, as we proposed, the Panel's scope of review will be limited to addressing the level of supervision that should be furnished for a given hospital outpatient therapeutic service, and will not include the type of practitioner that should be permitted to furnish the supervision. The Panel will recommend the appropriate supervision level for a particular service, given the type of practitioner that is permitted to furnish and supervise the service under the current laws and regulations.

b. Review Process

We proposed to issue agency decisions based on APC Panel recommendations through a subregulatory process. We proposed a process similar to the one currently used to set supervision levels for diagnostic services under the MPFS, which are also applicable to those services when furnished in the hospital outpatient setting. We proposed that CMS' decisions, which would be based upon the Panel's recommendations, would be posted on the OPPS Web site for public review and comment, and would be effective either in July or January following the most recent APC Panel meeting, or only in January of the upcoming payment year. In setting the supervision levels for diagnostic services under the MPFS, there is no provision for public comment. However, given the strong stakeholder interest in the supervision requirements and the extent of prior dialogue with the various stakeholders, we proposed to provide a period of notice and comment on our posted decisions prior to finalizing them.

We reasoned that the flexibility of a subregulatory process in comparison to annual notice and comment rulemaking would allow stakeholders to submit, and for the APC Panel to consider, requests for evaluations of services on a more frequent basis (at least twice a year at APC Panel meetings) rather than only annually, which most commenters to the CY 2011 OPPS/ASC final rule with comment period had requested (75 FR 42280). It also would give CMS the ability to respond more rapidly to any issues that may arise in access to care or patterns of care. Subjecting CMS' decisions to notice-and-comment rulemaking would provide a more structured, formal review of decisions, but changes could only be made once a year due to the annual OPPS/ASC rulemaking cycle.

Comment: Most commenters opposed the agency issuing its decisions through a subregulatory process. The commenters requested that, to ensure the greatest transparency and allow sufficient time and opportunity for public comment, CMS subject its decisions to notice and comment through rulemaking. One commenter requested a 45- to 60-day comment period. A few commenters suggested that, to facilitate evaluations more than once a year, CMS could address supervision standards using both the OPPS rule and another non-OPPS rule. In response to the concerns expressed by the agency in the proposed rule that the review process should be nimble and flexible enough to address access or other urgent needs, several commenters noted that the agency possesses other means of assuring access, for example notices of nonenforcement, additional rulemaking, and other administrative powers. Several commenters requested that CMS not use any information that is presented by stakeholders in the course of the review process for enforcement purposes.

Response: As we indicated in the proposed rule, we believe that employing a subregulatory process to establish our final decisions will best serve the interests of beneficiaries and also meet the needs of other stakeholders. While rulemaking would arguably provide some additional procedural protections to stakeholders in terms of a more formal opportunity for notice and comment, due to practical considerations involved in rulemaking, it is very likely that we would only be able to accomplish changes in supervision levels once a year. We agree with commenters that the agency has several administrative means to respond to urgent problems associated with supervision levels, for example exercising our enforcement discretion. However, we believe it is preferable to have a more nimble means of addressing access or pattern-of-care concerns within a short timeframe. In addition, as we noted in the proposed rule, CMS has historically used subregulatory processes rather than rulemaking to issue changes in certain administrative specifications at the level of individual CPT codes due to a need for agility in making such changes. For example, CMS has used a subregulatory process to set supervision levels for individual diagnostic services under the MPFS, which are also applicable to those services when furnished in the hospital outpatient setting.

Given the strong stakeholder interest in our consideration of changes in supervision levels for hospital outpatient therapeutic services, we continue to believe that we should provide an opportunity for public comment on our decisions (which will be based upon the Panel's recommendations) prior to finalizing them. Therefore, we are finalizing our proposal to issue our decisions based on Panel recommendations at the subregulatory level. We will post our preliminary decisions on the OPPS Web site for public review and comment. Given that the issues will be service-specific and therefore narrow, we will allow for a 30-day public comment period. We will give careful consideration to the comments that we receive, and we anticipate finalizing decisions within 60 days of the end of the comment period. Our final decisions will be effective either in July or January following the most recent APC Panel meeting.

c. Evaluation Criteria

To begin evaluating services in CY 2012, we proposed to use the same APC Panel process that is currently used to solicit requests from stakeholders for APC and status indicator changes for services or categories of services to construct the agenda to solicit potential services for consideration of a change in supervision level. In addition, we proposed that CMS would have the ability to request that the Panel review the supervision level for services as necessary. If we receive an unmanageable number of requests, we proposed to prioritize requests by service volume, total expenditures and/or frequency of requests. We also proposed to give priority to services requested for review through public comment on the CY 2010 and CY 2011 OPPS/ASC rules. We proposed to require that requests include a justification for the change in supervision level that is sought, supported to the extent possible with clinical evidence. We also proposed that we would consider these justifications in deciding which services to forward to the APC Panel for evaluation.

We proposed to charge the Panel with recommending a supervision level (general, direct, or personal) to ensure an appropriate level of quality and safety for delivery of a given service, as defined by a CPT code. We proposed that the Panel should take into consideration the context in which the

service is delivered, that is, the clinical, payment, and quality context of a patient encounter. In recommending a supervision level to CMS, we proposed that the Panel assess whether there is a significant likelihood that the supervisory practitioner would need to reassess the patient and modify treatment during or immediately following the therapeutic intervention, or provide guidance or advice to the individual who provides the service. In answering that question, the Panel would consider the following:

- Complexity of the service;
- Acuity of the patients receiving the service;
- Probability of unexpected or adverse patient event; and
- Expectation of rapid clinical changes during the therapeutic service or procedure.

We noted that these criteria include, but extend well beyond, the likelihood of the need to manage medical emergencies during or after the provision of the service. As we have stated in previous rules (74 FR 60580, 75 FR 72007, and 75 FR 72010 through 72012), the supervisory responsibility is more than the mere capacity to respond to an emergency. It also includes being available to reassess the patient and potentially modify treatment as needed on a nonemergency basis. The supervisory practitioner must have, within his or her State scope of practice and hospital-granted privileges, the knowledge, skills, ability, and privileges to perform the service or procedure. Specially trained ancillary staff and technicians are the primary operators of some specialized diagnostic or therapeutic equipment, and while in such cases CMS does not expect the supervisory practitioner to operate this equipment instead of a technician, CMS does expect the practitioner that supervises provision of the service to be knowledgeable about the test and clinically appropriate to furnish the test. The supervisory responsibility includes the ability to furnish assistance and direction throughout the performance of a procedure and, as appropriate to the supervisory practitioner and the patient, to change a procedure or the course of care for a particular patient. CMS would not expect that the supervisory practitioner would make all decisions unilaterally without consulting the patient's treating physician or NPP. The supervisory practitioner should have the training and knowledge to clinically redirect the service or provide additional orders.

We proposed that, in the event there has been a previous consideration and decision on the supervision standard for a service, we would consider the request and, as warranted, forward the request to the APC Panel for its review. We proposed to require the requestor to submit new evidence to support a change in policy, for example, evidence of a change in clinical practice patterns due to new techniques or new technology. We proposed that if sufficient new information was provided with the request, CMS would send the request to the APC Panel, and the Panel would reconsider the service and make another recommendation to CMS, which could be the same or a different level of supervision than the current level for the service.

Finally, we stated that we anticipated extending through CY 2012 the notice of nonenforcement of the requirement for direct supervision in CAHs and small rural hospitals as defined by the notice (available on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS/01_overview.asp*). This extension would allow these facilities time to meet the appropriate supervision standard and allow us to complete supervision policy decisions on many key services during 2012.

Comment: Commenters largely supported the proposed four clinical criteria. One commenter requested that CMS expand these criteria to allow exceptions based on changes in technology.

Response: We believe that a change in technology or practice patterns that affects a procedure's level of safety is an appropriate additional criterion. Therefore, as part of our final policy, we are adding a fifth criterion, ''Recent changes in technology or practice patterns that affect a procedure's safety.'' This criterion is similar to the criteria CMS will use to determine whether there is a need for reconsideration of a particular service as discussed below.

Comment: Several commenters continued to request that CMS establish a default supervision standard of general supervision for all hospital outpatient therapeutic services, and assign direct supervision only as recommended by the review entity. The commenters reiterated public comments on prior rules, stating that the review entity and CMS should not consider services for assignment of personal supervision because many services that might qualify for personal supervision are already personally performed by a physician or NPP. They again noted that certain services are not furnished personally by these practitioners and instead are furnished personally by auxiliary personnel such as technicians or RNs. However, the commenters maintained that hospitals currently furnish adequate supervision of those services by higher level practitioners. Further, they requested that any evaluation for personal supervision be based on clinical evidence and evidence of a current deficiency in the quality of care. In contrast, one commenter suggested that, to shorten the list of services that need consideration, CMS assign personal supervision to all services that require the practitioner to personally furnish the service and limit the Panel's scope to consideration of any remaining services. One commenter requested that the Panel be permitted to advise the agency on ''alternative'' forms of supervision such as satellite offices and telemedicine.

Response: In the CY 2012 OPPS/ASC proposed rule and the CY 2011 OPPS/ASC final rule with comment period (76 FR 42281 and 75 FR 72006, respectively), we expressed our belief that direct supervision is the most appropriate level of supervision for most hospital outpatient therapeutic services due to the ''incident to'' nature of most hospital outpatient therapeutic services. We discussed how our requirements for physician (or NPP) orders and direct physician involvement in patient care stem from our interpretation of the nature of incident to physicians' services under the law. We reviewed our regulations and other guidance over the years which reflect these beliefs and interpretations (75 FR 71999 and 72005).

We stated in the proposed rule and continue to believe that, while the statute does not explicitly mandate direct supervision, direct supervision is the most appropriate level of supervision for most hospital outpatient services that are authorized for payment as ''incident to'' physicians' services. We believe that the ''incident to'' nature of hospital outpatient therapeutic services under the law permits us to recognize specific circumstances in which general supervision is appropriate, as we have for extended duration services, and that CMS has authority to accept a recommendation by the review entity of general supervision for a given service. However, we continue to believe that direct supervision is the most appropriate level of supervision for the majority of hospital outpatient therapeutic services and, as such, it is the default supervision standard.

In the course of evaluating a stakeholder request for review of the supervision level required for a given service, the APC Panel may recommend that personal supervision is the most

appropriate level of supervision for that service. It may also be appropriate for the Panel to recommend personal supervision for certain services to ensure that auxiliary personnel or personnel in training (such as medical students) are adequately supervised. As we indicated in last year's final rule with comment period, our supervision policy is designed to preserve both the quality and safety of the hospital outpatient services that are paid for by Medicare. Accordingly, we believe that the APC Panel should have authority to recommend personal supervision for a service if, in the course of its evaluation, it believes that personal supervision is most appropriate and safe. Therefore, we are finalizing our proposal that the Panel shall recommend general, direct or personal supervision for a service.

For situations where the supervisory practitioner is not available in person, but only by ''telemedicine'' or in a location such as a ''satellite office,'' the Panel shall apply the definitions of direct, general and personal supervision in accordance with the regulations. For example, if a supervisory practitioner is only available via telemedicine, meaning telephone or Internet, and is not able to be immediately physically present, the supervisory practitioner would be furnishing general supervision. If a supervisory practitioner is present in a satellite office such as an off-campus PBD and is able to be immediately physically present but is not present in the room where the service is being furnished, he or she would be furnishing direct supervision. As we previously noted in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72008), with regard to recognizing availability by phone or modes other than in-person, we believe that the requirement for physical presence distinguishes direct supervision from general supervision because the regulations define general supervision as ''the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure'' (§ 410.32(b)(3)(i)). We believe that it would be out of the APC Panel's scope of activities for it to deliberate on the underlying definitions of direct, general or personal supervision, or for it to consider recommending yet another type of supervision based on a supervisory practitioner's location. Any changes to the definitions would be proposed and finalized through the notice and comment rulemaking process.

The APC Panel must base its recommendations on the available clinical evidence. It shall also take into consideration any known impacts of the level of supervision on the quality of care. As we have previously noted (75 FR 72005), while literature or clinical opinions may exist on the risk of adverse outcomes and susceptibility to medical error associated with the provision of specific hospital outpatient procedures when a physician is not present, we do not know of any analyses that have directly examined levels of supervision and patient outcomes in the hospital outpatient setting. This may be an area for future study.

Comment: With respect to a starting agenda, several commenters continued to request that the Panel begin by evaluating all therapeutic services with a work RVU < 1.0 under the MPFS, which includes many extended duration services. Many commenters requested that the Panel review surgical procedures and the surgical recovery period, chemotherapy administration, and blood transfusions. A few commenters also requested that the Panel evaluate therapies that accompany chemotherapy administration such as hydration and anti-emetics. One commenter asked how stakeholders could request evaluation of services that are not defined by CPT codes, notably the surgical recovery period. The commenter requested that CMS allow general supervision after ''phase 1'' of the recovery period as designated by the American Anesthesiology Association (ASA), and asked that CMS synchronize its supervision requirements for the recovery period with the phases established by the ASA. Another commenter requested that CMS place on the agenda services that are high volume or of high priority for CAHs and small rural hospitals.

Response: In considering our final policy for the appropriate unit of service evaluation, we noted that the HCPCS code is a broader unit of service than the CPT code, and concluded that it would be more appropriate for use to identify services that do not have an assigned CPT code. Therefore, we will consider requests, and forward them to the APC Panel for evaluation as described above, for service(s) that are identified by either a HCPCS code or a CPT code.

With regard to setting an agenda, we noted in the proposed rule that we may receive more requests for evaluation than can be addressed at a given Panel meeting. We did not receive any public comments regarding criteria for prioritizing requests and services to be reviewed at each meeting. Therefore, we will prioritize requests based on service volume, total expenditures for the service, and frequency of requests. As proposed, we will also give priority to services that the public has requested for evaluation in the CY 2010 through CY 2012 OPPS/ASC rules. In addition, we will give priority to services that have not previously been evaluated by the Panel. As we proposed, requests must include justification for the change in supervision level that is sought, supported to the extent possible with clinical evidence. In prioritizing services for review, we also will take these justifications into consideration.

We did not receive any public comments on our proposal that the agency would retain the independent discretion to request that the Panel evaluate supervision levels for one or more services. Therefore, we are finalizing that provision.

Comment: Several commenters requested that CMS explicitly include the place of service as an evaluation criterion, especially when the service is furnished in a CAH or rural facility. However, several other commenters recommended that supervision requirements should be applied based on service type and safety requirements, irrespective of location.

Response: We continue to believe that the overall patient experience for a given encounter may differ significantly by facility depending on physician practice patterns, the facility's patient and payer mix, Medicare payment structure for the facility, applicable regulations, quality of care, available resources and practitioners, and many other factors. In recent years, researchers have noted an undesirable amount of variation in the care that is furnished to Medicare patients in both metropolitan and nonmetropolitan areas of the country (MedPAC Report to the Congress: Regional Variation in Medicare Service Use, January 2011, available at: *http://www.medpac.gov/documents/Jan11_RegionalVariation_report.pdf*). In addition, according to a recent study, the quality of care that is furnished in CAHs appears to be worse in comparison to small rural hospitals (Joynt K, Harris Y, *et al.*: Quality of Care and Patient Outcomes in Critical Access Rural Hospitals, JAMA. 2011; 306(1):45–52). Joynt *et al.* found significant differences between CAHs and non-CAH small rural hospitals in resources, quality of care, and outcomes. In public comments to date, there has not been consensus on whether or not CMS should set supervision levels for individual services that are unique to CAHs or rural facilities. Many commenters opposed the agency's requirement of direct supervision of

outpatient chemotherapy administration in rural areas, citing access concerns and potentially lengthy patient commutes for care. However, as we discussed above, published safety standards appear to recommend direct supervision of chemotherapy administration.

We continue to believe that in making its recommendations, the Panel should consider the context in which care is furnished and that CMS should seek balanced input from various groups on these issues, and this belief is reflected in our proposed charge to the Panel. To emphasize this point, in our final policy, we are incorporating the clinical setting as a specific evaluation criterion, thereby instructing the Panel to consider the clinical context in which the service is delivered when making recommendations on supervision levels.

Comment: One commenter recommended that, to ensure consistency among settings, the Panel should be allowed to set supervision requirements no higher than the supervision requirements for a given service under the MPFS. Several commenters recommended that CMS require the same supervision levels in the hospital outpatient setting and ASCs, or among the hospital outpatient setting, ASCs, and physician offices.

Response: We disagree with this commenter. We do not believe that supervision requirements should necessarily be the same in the hospital outpatient setting and the physician office setting for therapeutic services. Various factors contribute to the appropriate level of supervision that is needed in different settings, for example, differences in patient populations. Patients receiving treatment in a hospital are generally sicker that patients treated in physician offices. Therefore, in some cases the appropriate level of supervision would be higher in the hospital than in a physician office setting.

Comment: One commenter suggested that CMS allow reconsideration requests. One commenter requested that CMS expand its proposed criteria to include unique circumstances generally, rather than limiting the criteria for conducting another evaluation to changes in technology or practice patterns.

Response: As we indicated in the proposed rule, conducting evaluations of services that the Panel has previously considered without new evidence supporting a change in the supervision level could become burdensome and consume a disproportionate amount of the Agency's and the Panel's resources. As our final policy, we are providing that the Panel may consider requests for re-review of a service that has already been evaluated. The public may request reconsideration of a service if new information indicates recent changes in technology or practice patterns that affect a procedure's safety. Such a request must be substantiated with new information such as a change in clinical practice patterns due to new techniques or new technology. If CMS believes that another evaluation is warranted, the Panel shall review the service again using the same process that it uses to evaluate new requests, and shall make another recommendation to CMS that could be the same or a different level of supervision.

Comment: Most commenters supported extending through CY 2012 the notice of nonenforcement of the requirement for direct supervision of hospital outpatient therapeutic services in CAHs and small rural hospitals with 100 or fewer beds.

Response: Because we will not complete supervision policy decisions on many key services until sometime in CY 2012, we are extending the notice of nonenforcement for CAHs and small rural hospitals with 100 or fewer beds as defined in the notice another year, through CY 2012. The purpose of the nonenforcement extension is to allow these facilities time to meet the appropriate supervision standard, and to give us an opportunity to use the new APC Panel review process to consider certain changes in required supervision levels. We will post a notice of the extension on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS/01_overview.asp*.

We noted in the proposed rule that we have not yet defined the terms ''personal supervision'' or ''general supervision'' for the hospital outpatient setting, except, as explained above, for general supervision in relation to extended duration services in § 410.27(a)(1)(v)(A). Because we proposed to allow the independent review entity to recommend that CMS assign either personal or general supervision to hospital outpatient therapeutic services, we proposed to define these terms in the regulations. We proposed to use the definitions established for purposes of the MPFS as specified at § 410.32(b)(3). Specifically, we proposed that ''personal supervision'' would have the same meaning as the definition specified at § 410.32(b)(3)(iii) and ''general supervision'' would have the same meaning as the definition specified in § 410.32(b)(3)(i), which is the definition that we established for the general supervision portion of an extended duration service.

We did not receive any public comments on this proposal. Therefore, in § 410.27(a)(1)(iv)(B), we are finalizing our proposed definitions of ''personal supervision'' for hospital outpatient therapeutic services to mean the definition specified at § 410.32(b)(3)(iii), and ''general supervision'' for hospital outpatient therapeutic services to mean the definition specified in § 410.32(b)(3)(i). In addition, we are revising the language in § 410.27(a)(1)(iv)(C) to clarify that the NPPs that are authorized in this section to furnish direct supervision may also furnish general or personal supervision (as required by CMS). Specifically, we are removing the word ''directly'' and inserting ''the required'' to provide that ''nonphysician practitioners may provide the required supervision of services that they may personally furnish in accordance with State law and all additional requirements, including those specified in §§ 410.71, 410.73, 410.74, 410.75, 410.76, and 410.77.''

Comment: One commenter raised an issue that CMS has discussed in recent OPPS rules, namely that under the CAH CoP at § 485.618 governing standards for emergency personnel, in most areas, a physician or NPP with training or experience in emergency care must be on call and immediately available only by telephone or radio contact, and available on site within 30 minutes. The commenter suggested that hospitals are only required to adhere to the CoPs in order to submit a claim; therefore, they are not required to follow the more strict direct supervision rule for payment of services. The commenter also recommended that CMS require the same level of supervision for payment as the level that is required under the CAH CoP.

Response: We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72000 through 72010) for a more detailed discussion of this issue. We continue to believe that the supervision rules are a condition of payment for CAH services, irrespective of their CoP staffing standard. In the CY 2011 final rule, we also discussed our position that the CoP is a general condition of the CAH's participation in the Medicare program, while the supervision standards apply to particular individual services furnished by the CAH. The CoP and the supervision requirements serve different purposes and are not inconsistent with each other. As such, there is no need to reconcile them.

2. Conditions of Payment and Hospital Outpatient Therapeutic Services Described by Different Benefit Categories

Another issue that we addressed in the CY 2012 OPPS/ASC proposed rule (76 FR 42277 through 42285) is the applicability of the payment conditions for hospital outpatient therapeutic services in § 410.27 to services described in paragraphs or subparagraphs of section 1861(s) of the Act other than section 1861(s)(2)(B) of the Act, which describes outpatient hospital services incident to physicians' services. Over the years, and particularly in recent months, we have received inquiries asking that we explain or clarify our application of the payment conditions under our regulation at § 410.27, which explicitly applies to ''hospital services and supplies furnished incident to a physician service to outpatients,'' to outpatient therapeutic services other than those specified under section 1861(s)(2)(B) of the Act. For example, we have received inquiries as to whether it is permissible for hospitals to furnish radiation therapy (described under section 1861(s)(4) of the Act) or ambulatory surgical center services (described under section 1832(a)(2)(F)(i) of the Act) under arrangement in locations that are not provider-based. Some inquirers have suggested that the language in § 410.27 is not applicable to services described by benefit categories in section 1861(s) of the Act other than section 1861(s)(2)(B) of the Act because § 410.27 only refers to ''incident to'' services.

In the proposed rule, we acknowledged that the language of § 410.27 could be read as limited to services and supplies described under section 1861(s)(2)(B) of the Act, hospital services incident to physicians' services furnished to outpatients. However, we noted that CMS has not interpreted the regulation so narrowly. For instance, in the CY 2010 OPPS/ASC final rule with comment period, we noted that, long before the OPPS, we required that hospital services and supplies furnished to outpatients incident to a physician's service must be furnished ''on a physician's order by hospital personnel and under a physician's supervision'' (section 3112.4 of the Medicare Intermediary Manual). We also clearly treated all nondiagnostic services that are furnished to hospital outpatients as ''incident to services'' (sections 3112 and 3112.4 of the Medicare Intermediary Manual; Section 20.5, Chapter 6, of the Medicare Benefit Policy Manual (Pub. 100–02)). While we have not delineated this position as clearly in the regulations, and while the regulation text of § 410.27 only explicitly refers to ''incident to'' services, we noted that our policy is longstanding and, in fact, predates the OPPS. In longstanding manual guidance, we have expressed our view that direct supervision is required for hospital outpatient therapeutic services, and suggested that this requirement stems from the ''incident to'' nature of those services. In the CY 2010 OPPS/ASC final rule with comment period, we stated, ''Therapeutic services and supplies which hospitals provide on an outpatient basis are those services and supplies (including the use of hospital facilities) which are incident to the services of physicians and practitioners in the treatment of patients'' (74 FR 60584 through 60585). We indicated that outpatient therapeutic services and supplies must be furnished under the order of a physician or other appropriate NPP, and by hospital personnel under the direct supervision of a physician or appropriate NPP.

Thus, we have long maintained that all hospital outpatient therapeutic services are, according to our policy, furnished ''incident to'' a physician's service even when described by benefit categories other than the specific ''incident to'' provision in section 1861(s)(2)(B) of the Act. Because hospital outpatient therapeutic services are furnished ''incident to'' a physician's professional service, we believe the conditions for payment, including the direct supervision standard, should apply to all hospital outpatient therapeutic services. As discussed above, because the statute includes specific requirements for physician supervision of PR, CR, and ICR, we believe that those statutory specifications take precedence over the agency's general requirements.

In the CY 2012 OPPS/ASC proposed rule, we proposed to amend our regulations to clarify our policy as follows. Therapeutic services and supplies described by benefit categories other than the hospital outpatient ''incident to'' services under section 1861(s)(2)(B) of the Act are subject to the conditions of payment in § 410.27 when they are furnished to hospital outpatients and paid under the OPPS or to CAHs under section 1834(g) of the Act.

We stated our belief that this clarification could most readily be accomplished by more specifically defining the services and supplies described in the regulation text to which the requirements at § 410.27 apply. Accordingly, we proposed to revise the description of the services and supplies addressed in § 410.27(a) by adding the term ''therapeutic'' so that paragraph (a) would read, ''Medicare Part B pays for therapeutic hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service'' to outpatients. We proposed to define these services, similar to the way they are currently defined in Section 20.5, Chapter 6, of the Medicare Benefit Policy Manual, to mean ''all services and supplies furnished to hospital outpatients that are not diagnostic services and that aid the physician or practitioner in the treatment of the patient.'' We also proposed to add the term ''therapeutic'' to the title of § 410.27 so that it would read, ''Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service: Conditions.''

Comment: Several commenters requested that CMS clarify that certain services which are not paid under the OPPS are excluded from the requirements of § 410.27 and thus from our proposed clarification, especially physical therapy (PT), speech language pathology (SLP) and occupational therapy (OT); diabetes self management training (DSMT); medical nutrition therapy; end-stage renal disease (ESRD) services; and services paid under the MPFS or the Clinical Laboratory Fee Schedule (CLFS).

Response: The requirements of § 410.27 must be met for payment of the facility component of hospital outpatient therapeutic services. They do not apply to the professional component of the services or to services that are paid under other fee schedules such as the CLFS.

Comment: One commenter noted that because CAHs are paid based on reasonable cost and not under the OPPS or the MPFS for outpatient PT/SLP/OT services, under the proposed clarification, the supervision and other requirements of § 410.27 would apply to CAHs but not to hospitals that are paid for those services under the MPFS. They expressed concern that CAHs will be disproportionately affected by CMS' clarification regarding the applicability of the requirements of § 410.27 to outpatient therapeutic services furnished in CAHs.

Response: CAHs have long been paid at reasonable cost rather than under the MPFS for PT/SLP/OT services, and, as discussed above, CAHs and other hospitals have long been subject to the requirements of § 410.27. We are not imposing any new requirements on CAHs through this clarification. We are finalizing our proposed amendment to

our regulations to clarify our policy as follows. Hospital outpatient therapeutic services and supplies, including those services described by benefit categories other than the hospital outpatient ''incident to'' category under section 1861(s)(2)(B) of the Act, are subject to the conditions of payment in § 410.27 when they are paid under the OPPS or paid to CAHs under section 1834(g) of the Act.

We proposed to define more specifically in the regulation text the services and supplies to which the requirements at § 410.27 apply. Accordingly, we are finalizing our proposed revision of the description of the services and supplies addressed in § 410.27(a) by adding the term ''therapeutic'' so that paragraph (a) reads, ''Medicare Part B pays for therapeutic hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service'' to outpatients. We are defining these services, similar to the way they are defined in Section 20.5, Chapter 6, of the Medicare Benefit Policy Manual, to mean ''all services and supplies furnished to hospital outpatients that are not diagnostic services and that aid the physician or practitioner in the treatment of the patient.'' Also, as we proposed, we are adding the term ''therapeutic'' to the title of § 410.27 so that it reads, ''Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service: Conditions.''

3. Technical Corrections to the Supervision Standards for Hospital Outpatient Therapeutic Services Furnished in Hospitals or CAHs

In the proposed rule, we noted that CAHs are not specifically named in the definition of nonsurgical extended duration therapeutic services at § 410.27(a)(1)(v). We proposed to make a technical correction to insert the words ''or CAH'' after ''hospital'' in this paragraph. This is the same technical correction that we made throughout § 410.27 in the CY 2010 OPPS/ASC final rule with comment period, discussed above. We did not receive any public comments on this proposal. Therefore, we are inserting the words ''or CAH'' after ''hospital'' in revised § 410.27(a)(1)(iv)(E) to clarify that CAHs are subject to all of the requirements of § 410.27 in the same manner as other types of hospitals.

As we discussed in the proposed rule (76 FR 42284 through 42285), we recently noted that the text of § 410.27(b) and (c) includes cross-references to section § 410.168 of the regulations, which is obsolete. We believe that § 410.27(b) refers to § 410.168 in error and should instead reference § 410.29 (Limitations on drugs and biologicals). We proposed to correct § 410.27(b) so that it cross-references § 410.29. It would then read, ''Drugs and biological are also subject to the limitations specified in § 410.29.'' In addition, we proposed to update § 410.27(c) to cross-reference the sections of the regulation that have replaced § 410.168, that is, Part 424, Subparts G and H. For this update, we proposed to revise paragraph (c) to read, ''Rules on emergency services furnished to outpatients by nonparticipating hospitals are specified in subpart G of Part 424 of this chapter'' and to add a new paragraph (d) to read, ''Rules on emergency services furnished to outpatients in a foreign country are specified in subpart H of Part 424 of this chapter''. Accordingly, we proposed to redesignate the existing paragraphs (d) through (f) of § 410.27 as paragraphs (e) through (g), respectively.

We did not receive any public comments on this proposal. Therefore, we are finalizing our proposal to correct § 410.27(b) so that it cross-references § 410.29 rather than § 410.168 and now reads, ''Drugs and biological are also subject to the limitations specified in § 410.29.'' In addition, we are updating § 410.27(c) to cross-reference the sections of the regulation that have replaced § 410.168, that is, Part 424, Subparts G and H. For this update, as we proposed, we are revising paragraph (c) to read, ''Rules on emergency services furnished to outpatients by nonparticipating hospitals are specified in subpart G of Part 424 of this chapter'' and are adding a new paragraph (d) to read, ''Rules on emergency services furnished to outpatients in a foreign country are specified in subpart H of Part 424 of this chapter''. Accordingly, as we proposed, we are redesignating the existing paragraphs (d) through (f) of § 410.27 as paragraphs (e) through (g), respectively.

C. Summary of CY 2012 Final Policies on Supervision Standards for Outpatient Therapeutic Services in Hospitals and CAHs

As we have indicated earlier in this section, after consideration of the public comments we received, we are finalizing the following policies.

1. Independent Review Process

We are designating the APC Panel as the body that will review and advise the agency regarding the appropriate level of supervision for individual hospital outpatient therapeutic services. We will amend the Panel Charter to add the appropriate statutory authority and to allow representatives of CAHs to serve on the Panel for purposes of the supervision deliberations. We will add 4 voting seats to the Panel (for a current total of 19), and will designate two of these seats for representatives of CAHs and two for representatives of small rural PPS hospitals. ''Small rural PPS hospital'' means the definition of small rural hospital that is used by the Congress for purposes of TOPs, and that is used in CMS' notice of nonenforcement of direct supervision of outpatient therapeutic services in CAHs and small rural hospitals. With respect to supervision policy, the scope of the Panel's activity is limited to recommending to CMS the appropriate level of supervision (general, direct, or personal) for individual hospital outpatient therapeutic services.

We will issue agency decisions based on Panel recommendations through a subregulatory process. We will post our preliminary decisions on the OPPS Web site for a 30-day period of public review and comment. After consideration of any public comments that we receive, we will issue our final decisions which will be effective either in July or January following the most recent APC Panel meeting.

The Panel will be charged with recommending to CMS a supervision level (general, direct, or personal) that will ensure an appropriate level of quality and safety for delivery of a given service, as defined by a HCPCS or CPT code. In recommending a supervision level to CMS, the Panel will assess whether there is a significant likelihood that the supervisory practitioner would need to reassess the patient and modify treatment during or immediately following the therapeutic intervention, or provide guidance or advice to the individual who provides the service. In answering that question, the Panel will consider the following factors but may also consider others as appropriate:

- Complexity of the service.
- Acuity of the patients receiving the service.
- Probability of unexpected or adverse patient event.
- Expectation of rapid clinical changes during the therapeutic service or procedure.
- Recent changes in technology or practice patterns that affect a procedure's safety.
- The clinical context in which the service is delivered.

As we have discussed above, these criteria include, but extend well beyond, the likelihood of the need to manage medical emergencies during or

after the provision of the service. The supervisory responsibility is more than the mere capacity to respond to an emergency, and includes being available to reassess the patient and potentially modify treatment as needed on a nonemergency basis. We will prioritize stakeholder requests for APC Panel review of specific services based upon service volume, total expenditures for the service and frequency of requests. We also will give priority to services that the public has requested we evaluate in the CY 2010 through CY 2012 OPPS/ASC rules, and to services that have not been previously evaluated by the Panel. All requests must include justification for the change in supervision level that is sought, supported to the extent possible with clinical evidence. In prioritizing services for the agenda, we also will take these justifications into consideration.

We may ask the Panel to consider requests for review of a service that has already been evaluated. If there has been a previous consideration and decision on the supervision standard for a service, the requestor should submit new evidence to support a change in policy. For example, the public could request another review of a previously reviewed service if new information indicates recent changes in technology or practice patterns that affect a procedure's safety. Such a request must be substantiated with new information such as a change in clinical practice patterns due to new techniques or new technology. If CMS believes that another evaluation is warranted, the agency will ask the APC Panel to review the service again using the same process that it uses to evaluate new requests. The Panel will then make another recommendation to CMS that could be the same or a different level of supervision than the previous recommendation.

Because the agency will not complete APC Panel review or consideration of changes to supervision levels for many key services until sometime in CY 2012, we are extending the notice of nonenforcement of the requirement for direct supervision of outpatient therapeutic services in CAHs and small rural hospitals as defined by the notice (available on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS/01_overview.asp*) another year, through CY 2012. The purpose of this nonenforcement extension is to allow these facilities time to meet the appropriate supervision standard, and to allow us time to complete our review of supervision levels for at least some services.

Because the APC Panel may recommend that CMS assign either personal or general supervision to services, we are defining these terms for hospital outpatient therapeutic services in the regulations at new § 410.27(a)(1)(iv)(B). We are revising the language in § 410.27(a)(1)(iv)(C) to provide that the NPPs that are authorized in this section to furnish direct supervision may also furnish general or personal supervision as required by CMS.

2. Conditions of Payment and Hospital Outpatient Therapeutic Services Described by Different Benefit Categories

We are finalizing our clarification that therapeutic services and supplies described by benefit categories other than the hospital outpatient ''incident to'' services under section 1861(s)(2)(B) of the Act are subject to the conditions of payment in § 410.27 when they are furnished to hospital outpatients and paid under the OPPS or paid to CAHs under section 1834(g) of the Act. To that end, we are redefining the services described in § 410.27 to clarify the nature and scope of the included services.

3. Technical Corrections

We are correcting § 410.27(b) so that it cross-references § 410.29 rather than § 410.168 and now reads, ''Drugs and biological are also subject to the limitations specified in § 410.29.'' In addition, we are updating § 410.27(c) to cross-reference the sections of the regulation that have replaced § 410.168, that is, Part 424, Subparts G and H. For this update, we are revising paragraph (c) to read, ''Rules on emergency services furnished to outpatients by nonparticipating hospitals are specified in subpart G of Part 424 of this chapter'' and are adding a new paragraph (d) to read, ''Rules on emergency services furnished to outpatients in a foreign country are specified in subpart H of Part 424 of this chapter''. Accordingly, we are redesignating the existing paragraphs (d) through (f) of § 410.27 as paragraphs (e) through (g), respectively.

We are inserting the words ''or CAH'' after ''hospital'' in the revised § 410.27(a)(1)(iv)(E) to clarify that CAHs are subject to the requirements of § 410.27 in the same manner as other types of hospitals.

XI. Final CY 2012 OPPS Payment Status and Comment Indicators

A. Final CY 2012 OPPS Payment Status Indicator Definitions

Payment status indicators (SIs) that we assign to HCPCS codes and APCs play an important role in determining payment for services under the OPPS. They indicate whether a service represented by a HCPCS code is payable under the OPPS or another payment system and also whether particular OPPS policies apply to the code. The CY 2012 status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS.* We note that, in the past, a majority of the Addenda referred to throughout the preamble of our OPPS/ASC proposed and final rules appeared in the printed version of the **Federal Register** as part of the annual rulemakings. However, beginning with the CY 2012 proposed rule, the Addenda will no longer appear in the printed version of the OPPS/ASC rules that are found in the **Federal Register**. Instead, these Addenda will be published and available only via the Internet on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS*.

As we proposed in the CY 2012 OPPS/ASC proposed rule (76 FR 42285 through 42287), for CY 2012, we are not making any changes to the definitions of status indicators that were listed in Addendum D1 of the CY 2011 OPPS/ASC final rule with comment period. The final CY 2012 status indicators and their definitions are listed in the tables under sections XI.A.1., 2., 3., and 4. of this final rule with comment period.

1. Payment Status Indicators To Designate Services That Are Paid Under the OPPS

BILLING CODE 4120–01–P

Indicator	Item/Code/Service	OPPS Payment Status
G	Pass-Through Drugs and Biologicals	Paid under OPPS; separate APC payment.
H	Pass-Through Device Categories	Separate cost-based pass-through payment; not subject to copayment.
K	Nonpass-Through Drugs and Nonimplantable Biologicals, including Therapeutic Radiopharmaceuticals	Paid under OPPS; separate APC payment.
N	Items and Services Packaged into APC Rates	Paid under OPPS; payment is packaged into payment for other services. Therefore, there is no separate APC payment.
P	Partial Hospitalization	Paid under OPPS; per diem APC payment.
Q1	STVX-Packaged Codes	Paid under OPPS; Addendum B displays APC assignments when services are separately payable. (1) Packaged APC payment if billed on the same date of service as a HCPCS code assigned status indicator "S," "T," "V," or "X." (2) In all other circumstances, payment is made through a separate APC payment.
Q2	T-Packaged Codes	Paid under OPPS; Addendum B displays APC assignments when services are separately payable. (1) Packaged APC payment if billed on the same date of service as a HCPCS code assigned status indicator "T." (2) In all other circumstances, payment is made through a separate APC payment.

Indicator	Item/Code/Service	OPPS Payment Status
Q3	Codes that may be paid through a composite APC	Paid under OPPS; Addendum B displays APC assignments when services are separately payable. Addendum M displays composite APC assignments when codes are paid through a composite APC. (1) Composite APC payment based on OPPS composite-specific payment criteria. Payment is packaged into a single payment for specific combinations of services. (2) In all other circumstances, payment is made through a separate APC payment or packaged into payment for other services.
R	Blood and Blood Products	Paid under OPPS; separate APC payment.
S	Significant Procedure, Not Discounted When Multiple	Paid under OPPS; separate APC payment.
T	Significant Procedure, Multiple Reduction Applies	Paid under OPPS; separate APC payment.
U	Brachytherapy Sources	Paid under OPPS; separate APC payment.
V	Clinic or Emergency Department Visit	Paid under OPPS; separate APC payment.
X	Ancillary Services	Paid under OPPS; separate APC payment.

BILLING CODE 4120–01–C

We did not receive any public comments related to the definitions of payment status indicators to designate services that are paid under OPPS. We continue to believe that the proposed definitions of the OPPS status indicators continue to be appropriate, and therefore, we are finalizing, without modification, our CY 2012 proposal. The final CY 2012 status indicators and their definitions are displayed in both the table above and in Addendum D1 on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS.*

2. Payment Status Indicators To Designate Services That Are Paid Under a Payment System Other Than the OPPS

In the CY 2012 OPPS/ASC proposed rule (76 FR 42286), we did not propose to make any changes to the definitions of status indicators listed below for the CY 2012 OPPS.

Indicator	Item/Code/Service	OPPS Payment Status
A	Services furnished to a hospital outpatient that are paid under a fee schedule or payment system other than OPPS, for example:	Not paid under OPPS. Paid by fiscal intermediaries/MACs under a fee schedule or payment system other than OPPS. Services are subject to the deductible and coinsurance unless indicated otherwise.
	• Ambulance Services	
	• Clinical Diagnostic Laboratory Services	Not subject to deductible or coinsurance.
	• Non-Implantable Prosthetic and Orthotic Devices	
	• EPO for ESRD Patients	
	• Physical, Occupational, and Speech Therapy	
	• Routine Dialysis Services for ESRD Patients Provided in a Certified Dialysis Unit of a Hospital	
	• Diagnostic Mammography	
	• Screening Mammography	Not subject to deductible or coinsurance.
C	Inpatient Procedures	Not paid under OPPS. Admit patient. Bill as inpatient.
F	Corneal Tissue Acquisition; Certain CRNA Services; and Hepatitis B Vaccines	Not paid under OPPS. Paid at reasonable cost.
L	Influenza Vaccine; Pneumococcal Pneumonia Vaccine	Not paid under OPPS. Paid at reasonable cost; not subject to deductible or coinsurance.
M	Items and Services Not Billable to the Fiscal Intermediary/MAC	Not paid under OPPS.
Y	Non-Implantable Durable Medical Equipment	Not paid under OPPS. All institutional providers other than home health agencies bill to DMERC.

We did not receive any public comments regarding the definitions of payment status indicators that designate services that are not recognized under the OPPS but that may be recognized by other institutional providers. We continue to believe that the proposed definitions of the OPPS status indicators continue to be appropriate, and therefore, we are finalizing, without modification, our CY 2012 proposal. The final CY 2012 status indicators and their definitions displayed in the table above are also displayed in Addendum D1 on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS.*

3. Payment Status Indicators To Designate Services That Are Not Recognized Under the OPPS But That May Be Recognized by Other Institutional Providers

In the CY 2012 OPPS/ASC proposed rule (76 FR 42286 through 42287), we did not propose to make changes to the definitions of status indicators listed below for the CY 2012 OPPS.

Indicator	Item/Code/Service	OPPS Payment Status
B	Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and13x)	Not paid under OPPS.
		● May be paid by fiscal intermediaries/MACs when submitted on a different bill type, for example, 75x (CORF), but not paid under OPPS.
		● An alternate code that is recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x) may be available.

We did not receive any public comments related to the definitions of payment status indicators that designate services that are paid under a payment system other than the OPPS. We continue to believe that the proposed definitions of the OPPS status indicators continue to be appropriate, and therefore, we are finalizing, without modification, our proposal for CY 2012. The final status indicators and their definitions listed in the table above are also displayed in Addendum D1 on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS.*

4. Payment Status Indicators To Designate Services That Are Not Payable by Medicare on Outpatient Claims

In the CY 2012 OPPS/ASC proposed rule (76 FR 42287), we did not propose to make changes to the definitions of payment status indicators listed below for the CY 2012 OPPS.

Indicator	Item/Code/Service	OPPS Payment Status
D	Discontinued Codes	Not paid under OPPS or any other Medicare payment system.
E	Items, Codes, and Services:	Not paid by Medicare when submitted on outpatient claims (any outpatient bill type).
	• That are not covered by any Medicare outpatient benefit based on statutory exclusion	
	• That are not covered by any Medicare outpatient benefit for reasons other than statutory exclusion.	
	• That are not recognized by Medicare for outpatient claims; alternate code for the same item or service may be available	
	• For which separate payment is not provided on outpatient claims	

We did not receive any public comments related to the definitions of payment status indicators that designate services that are not payable by Medicare on outpatient claims. We continue to believe that the proposed definitions of the OPPS status indicators continue to be appropriate, and therefore, we are finalizing, without modification, our proposal for CY 2012. The final CY 2012 payment status indicators and their definitions listed in the table above are also displayed in Addendum D1 on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS*.

B. Final CY 2012 Comment Indicator Definitions

As we proposed in the CY 2012 OPPS/ASC proposed rule (76 FR 42287 through 42288), for the CY 2012 OPPS, we are using the same two comment indicators that are in effect for the CY 2011 OPPS.

• ''CH''—Active HCPCS codes in current and next calendar year; status indicator and/or APC assignment have changed or active HCPCS code that will be discontinued at the end of the current calendar year.

• ''NI''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.

We proposed in the CY 2012 OPPS/ASC proposed rule (76 FR 42287) to use the ''CH'' comment indicator in this CY 2012 OPPS/ASC final rule with comment period to indicate HCPCS codes for which the status indicator or APC assignment, or both, will change in CY 2012 compared to their assignment as of December 31, 2011. We believe that using the ''CH'' indicator in this CY 2012 OPPS/ASC final rule with comment period will facilitate the public's review of the changes that we are making for CY 2012. The use of the comment indicator ''CH'' in association with a composite APC indicates that the configuration of the composite APC is changed in this CY 2012 OPPS/ASC final rule with comment period.

We did not proposed any changes to our current policy regarding the use of comment indicator ''NI.''

Any existing HCPCS code numbers with substantial revisions to the code descriptors for CY 2012 compared to the CY 2011 descriptors is labeled with comment indicator ''NI'' in Addendum B to this CY 2012 OPPS/ASC final rule with comment period. However, in order to receive the comment indicator ''NI,'' the CY 2012 revision to the code descriptor (compared to the CY 2011 descriptor) must be significant such that the new code descriptor describes a new service or procedure for which the OPPS treatment may change. We use comment indicator ''NI'' to indicate that these HCPCS codes are open to comment on this CY 2012 OPPS/ASC final rule with comment period. Like all codes labeled with comment indicator ''NI,'' we will respond to public comments and finalize their OPPS treatment in the CY 2013 OPPS/ASC final rule with comment period.

In accordance with our usual practice, CPT and Level II HCPCS code numbers that are new for CY 2012 are also labeled with comment indicator ''NI'' in Addendum B to this CY 2012 OPPS/ASC final rule with comment period.

Only HCPCS codes with comment indicator ''NI'' in this CY 2012 OPPS/ASC final rule with comment period are subject to comment. HCPCS codes that do not appear with comment indicator ''NI'' in this CY 2012 OPPS/ASC final rule with comment period are not open to public comment, unless we

specifically request additional comments elsewhere in this final rule with comment period. The CY 2012 treatment of HCPCS codes that appear in this CY 2012 OPPS/ASC final rule with comment period to which comment indicator ''NI'' is not appended were open to public comment during the comment period for the proposed rule, and we are responding to those comments in this CY 2012 OPPS/ASC final rule with comment period.

We did not receive any public comments on the proposed comment indicators. We continue to believe that the proposed definitions of the OPPS status indicators continue to be appropriate, and therefore, we are finalizing, without modification, our CY 2012 proposal and are continuing to use comment indicators ''CH'' and ''NI'' for CY 2012. Their final definitions are listed in Addendum D2 on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS*.

XII. OPPS Policy and Payment Recommendations

A. MedPAC Recommendations

MedPAC was established under section 1805 of the Act to advise the U.S. Congress on issues affecting the Medicare program. As required under the statute, MedPAC submits reports to Congress not later than March and June of each year that contain its Medicare payment policy recommendations. This section describes recent recommendations relevant to the OPPS that have been made by MedPAC.

The March 1, 2011 MedPAC ''Report to Congress: Medicare Payment Policy'' included the following recommendation relating to the Medicare hospital IPPS and, in part, to the Medicare hospital OPPS:

Recommendation 3: ''The Congress should increase payment rates for the acute care hospital inpatient and outpatient prospective payment systems in 2012 by 1 percent. The Congress should also require the Secretary of Health and Human Services to make adjustments to inpatient payment rates in future years to fully recover all overpayments due to documentation and coding improvements.'' (page 60)

MedPAC further stated that: ''For outpatient hospital services, the Commission is concerned that significant payment disparities among Medicare's ambulatory care settings (hospital outpatient departments, ambulatory surgical centers, and physician offices) for similar services are fostering undesirable financial incentives. Physician practices and ambulatory surgical centers are being reorganized as hospital outpatient entities in part to receive higher reimbursements. The Commission believes that Medicare should seek to pay similar amounts for similar services, taking into account differences in quality of care and in the relative risks of the patient populations. The Commission is concerned by the trend to reorganize for higher reimbursement and will examine this issue. However, in the interim, the modest update of 1 percent is warranted in the hospital outpatient setting to slow the growing payment rate disparities among ambulatory care settings.'' (page 61)

CMS Response: We note that MedPAC's recommendation is for the Congress to increase IPPS and OPPS payment rates by 1 percent in 2012. Absent action by Congress, we are following the statutory requirements that govern the amount of the annual OPD fee schedule increase factor to the OPPS for CY 2012. We discuss the CY 2012 OPD fee schedule increase factor in section II.B. of this final rule with comment period.

We look forward to reviewing the results of MedPAC's examination of what it perceives as a trend towards reorganization of ambulatory surgical centers and physician offices as hospital outpatient departments to maximize program payment.

The full March 2011 MedPAC report can be downloaded from MedPAC's Web site at: *http://www.medpac.gov/documents/Mar11_EntireReport.pdf*.

On June 15, 2011, MedPAC released a report to Congress entitled ''Medicare and the Health Care Delivery System.'' The report did not contain recommendations with regard to payment under the OPPS or the ASC payment system. The full report can be downloaded from MedPAC's Web site at: *http://www.medpac.gov/documents/Jun11_EntireReport.pdf*.

On August 30, 2011, MedPAC submitted comments to CMS on the CY 2012 OPPS/ASC proposed rule. MedPAC submitted comments on the following topics, each of which is discussed in the indicated section of this final rule with comment period.

- Adjustment to payments for dedicated cancer hospitals (section II.F. of this final rule with comment period)
- Payment for pharmacy overhead (section V.B. of this final rule with comment period)
- Hospital wage index policy (section II.C. of this final rule with comment period)
- Composite APC 8009 cardiac resynchronization therapy (section II.A.2.e.(6) of this final rule with comment period)
- Hospital outpatient quality reporting measures (section X.G. of this final rule with comment period)
- Ambulatory surgical center quality reporting measures (section X.K. of this final rule with comment period)
- Hospital inpatient value based purchasing (section XVI. of this final rule with comment period)

B. APC Panel Recommendations

Recommendations made by the APC Panel meeting held on February 28 and March 1, 2011 and August 10–12, 2011 are discussed in the sections of this final rule with comment period that correspond to topics addressed by the APC Panel. The reports and recommendations from the APC Panel's February 28 and March 1, 2011 and August 10–12, 2011 meetings regarding payment under the OPPS for CY 2012 are available on the CMS Web site at: *http://www.cms.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp*.

C. OIG Recommendations

The mission of the Office of the Inspector General (OIG), as mandated by Public Law 95–452, as amended, is to protect the integrity of the U.S. Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections.

On October 22, 2010, the OIG published a memorandum report entitled ''Payment for Drugs under the Hospital Outpatient Prospective Payment System'' (OIG–03–09–00420). The report may be viewed on the Web site at: *http://oig.hhs.gov/oei/reports/oei-03-09-00420.pdf*. The OIG did not make any recommendations to CMS regarding Medicare payment for drugs and biologicals under the OPPS.

CMS Response: We appreciate the work of the OIG regarding the payment for drugs under the OPPS, and we have taken the findings in its report into consideration in the development of our final payment policy for CY 2012.

XIII. Updates to the Ambulatory Surgical Center (ASC) Payment System

A. Background

1. Legislative Authority for the ASC Payment System

Section 1832(a)(2)(F)(i) of the Act provides that benefits under Medicare Part B include payment for facility services furnished in connection with surgical procedures specified by the Secretary that are performed in an

Ambulatory Surgical Center (ASC). To participate in the Medicare program as an ASC, a facility must meet the standards specified in section 1832(a)(2)(F)(i) of the Act, which are set forth in 42 CFR Part 416, Subpart B and Subpart C of our regulations. The regulations at 42 CFR Part 416, Subpart B describe the general conditions and requirements for ASCs, and the regulations at Subpart C explain the specific conditions for coverage for ASCs.

Section 141(b) of the Social Security Act Amendments of 1994, Public Law 103–432, required establishment of a process for reviewing the appropriateness of the payment amount provided under section 1833(i)(2)(A)(iii) of the Act for intraocular lenses (IOLs) that belong to a class of new technology intraocular lenses (NTIOLs). That process was the subject of a final rule entitled ''Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers,'' published on June 16, 1999, in the **Federal Register** (64 FR 32198).

Section 626(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Public Law 108–173, added subparagraph (D) to section 1833(i)(2) of the Act, which required the Secretary to implement a revised ASC payment system to be effective not later than January 1, 2008. Section 626(c) of the MMA amended section 1833(a)(1) of the Act by adding new subparagraph (G), which requires that, beginning with implementation of the revised ASC payment system, payment for surgical procedures furnished in ASCs shall be 80 percent of the lesser of the actual charge for the services or the amount determined by the Secretary under the revised payment system.

Section 109(b) of the Medicare Improvements and Extension Act of 2006 of the Tax Relief and Health Care Act of 2006 (MIEA–TRHCA), Public Law 109–432, amended section 1833(i) of the Act by redesignating clause (iv) as clause (v) and adding a new clause (iv) to paragraph (2)(D) and by adding new paragraph (7).

Section 1833(i)(2)(D)(iv) of the Act authorizes, but does not require, the Secretary to implement the revised ASC payment system ''in a manner so as to provide for a reduction in any annual update for failure to report on quality measures in accordance with paragraph (7).'' Section 1833(i)(7)(A) of the Act states that the Secretary may provide that any ASC that does not submit quality measures to the Secretary in accordance with paragraph (7) will incur a 2.0 percentage point reduction to any annual increase provided under the revised ASC payment system for such year.

Section 1833(i)(7)(B) of the Act provides that, ''[e]xcept as the Secretary may otherwise provide,'' the hospital outpatient quality data provisions of subparagraphs (B) through (E) of section 1833(t)(17) of the Act, added by section 109(a) of the MIEA–TRHCA, shall apply to ASCs in a similar manner to the manner in which they apply under these paragraphs to hospitals under the Hospital OQR Program.

Sections 4104 and 10406 of the Affordable Care Act, Pub. L. 111–148, amended section 1833(a)(1) and (b)(1) of the Act to waive the coinsurance and the Part B deductible for those preventive services under section 1861(ddd)(3)(A) of the Act as described in section 1861(ww)(2) of the Act (excluding electrocardiograms) that are recommended by the United States Preventive Services Task Force (USPSTF) with a grade of A or B for any indication or population and that are appropriate for the individual. Section 4104(c) of the Affordable Care Act amended section 1833(b)(1) of the Act to waive the Part B deductible for colorectal cancer screening tests that become diagnostic. These provisions apply to these items and services furnished in an ASC on or after January 1, 2011.

Section 3401(k) of the Affordable Care Act amended section 1833(i)(2)(D) of the Act to require that, effective for CY 2011 and subsequent years, any annual update under the ASC payment system be reduced by a productivity adjustment, which is equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period). Application of this productivity adjustment to the ASC payment system may result in the update to the ASC payment system being less than zero for a year and may result in payment rates under the ASC payment system for a year being less than such payment rates for the preceding year.

For a detailed discussion of the legislative history related to ASCs, we refer readers to the June 12, 1998 proposed rule (63 FR 32291 through 32292).

2. Prior Rulemaking

On August 2, 2007, we published in the **Federal Register** (72 FR 42470) the final rule for the revised ASC payment system, effective January 1, 2008 (the ''August 2, 2007 final rule''). In that final rule, we revised our criteria for identifying surgical procedures that are eligible for Medicare payment when furnished in ASCs and adopted the method we would use to set payment rates for ASC covered surgical procedures and covered ancillary services furnished in association with those covered surgical procedures beginning in CY 2008. We also established a policy for treating new and revised Healthcare Common Procedure Coding System (HCPCS) and Current Procedural Terminology (CPT) codes under the ASC payment system. This policy is consistent with the OPPS to the extent possible (72 FR 42533).

In addition, we established a standard ASC ratesetting methodology that bases payment for most services on the list of ASC covered surgical procedures on the OPPS relative payment weight multiplied by the ASC conversion factor. We also established modifications to this methodology for subsets of services, such as device-intensive services (where the estimated device portion of the ASC payment is the same as that paid under the OPPS) and services that are predominantly performed in the office setting and covered ancillary radiology services (where ASC payment may be based on the MPFS nonfacility practice expense (PE) Relative Value Units (RVUs)). Additionally, we established a policy for updating the conversion factor, the relative payment weights, and the ASC payment rates on an annual basis. We also annually update the list of procedures for which Medicare does not make an ASC payment.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66827), we updated and finalized the CY 2008 ASC rates and lists of covered surgical procedures and covered ancillary services. We also made regulatory changes to 42 CFR Parts 411, 414, and 416 related to our final policies to provide payments to physicians who perform non-covered ASC procedures in ASCs based on the facility PE RVUs, to exclude covered ancillary radiology services and covered ancillary drugs and biologicals from the categories of designated health services (DHS) that are subject to the physician self-referral prohibition, and to reduce ASC payments for surgical procedures when the ASC receives full or partial credit toward the cost of the implantable device.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68722), we updated and finalized the CY 2009 ASC rates and lists of covered surgical

procedures and covered ancillary services.

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60596), we updated and finalized the CY 2010 ASC rates and lists of covered surgical procedures and covered ancillary services. We also corrected some of those ASC rates in a correction notice published in the **Federal Register** on December 31, 2009 (74 FR 69502). In that correction notice, we revised the ASC rates to reflect changes in the MPFS conversion factor and PE RVUs listed for some CPT codes in Addendum B to the CY 2010 MPFS final rule with comment period (74 FR 62017), which were incorrect due to methodological errors and were subsequently corrected in a correction notice to that final rule with comment period (74 FR 65449). We also published a second correction notice in the **Federal Register** to address changes to the ASC rates resulting from corrections to the PE RVUs identified subsequent to publication of the December 31, 2009 correction notice (75 FR 45700). Finally, we published a notice in the **Federal Register** to reflect changes to CY 2010 ASC payment rates for certain ASC services due to changes to the OPPS and MPFS under the Affordable Care Act and to reflect technical changes to the ASC payment rates announced in prior correction notices (75 FR 45769).

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71800), we updated and finalized the CY 2011 ASC rates and lists of covered surgical procedures and covered ancillary services. We corrected some of the ASC rates that were published in Addenda AA and BB, as well as errors in the preamble text, in a correction notice published in the **Federal Register** on March 11, 2011 (76 FR 13292). The corrections to the ASC Addenda were primarily due to changes to the MPFS conversion factor and PE RVUs listed for some CPT codes in Addendum B and Addendum C to the MPFS for CY 2011 which, in turn, affected office-based and ancillary radiology payment under the ASC payment system. Following legislative changes to the MPFS for CY 2011 associated with passage of section 101 of the Medicare and Medicaid Extenders Act of 2010 that occurred after publication of the CY 2011 OPPS/ASC and MPFS final rules with comment periods, we posted revised ASC Addenda on our Web site to reflect associated changes to office-based and ancillary radiology payment under the ASC payment system.

3. Policies Governing Changes to the Lists of Codes and Payment Rates for ASC Covered Surgical Procedures and Covered Ancillary Services

The August 2, 2007 final rule established our policies for determining which procedures are ASC covered surgical procedures and covered ancillary services. Under § 416.2 and § 416.166 of the regulations, subject to certain exclusions, covered surgical procedures are surgical procedures that are separately paid under the OPPS, that would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and that would not be expected to require active medical monitoring and care at midnight following the procedure (''overnight stay''). We adopted this standard for defining which surgical procedures are covered surgical procedures under the ASC payment system as an indicator of the complexity of the procedure and its appropriateness for Medicare payment in ASCs. We use this standard only for purposes of evaluating procedures to determine whether or not they are appropriate for Medicare beneficiaries in ASCs. We define surgical procedures as those described by Category I CPT codes in the surgical range from 10000 through 69999, as well as those Category III CPT codes and Level II HCPCS codes that crosswalk or are clinically similar to ASC covered surgical procedures (72 FR 42478). We note that we added over 800 surgical procedures to the list of covered surgical procedures for ASC payment in CY 2008, the first year of the revised ASC payment system, based on the criteria for payment that we adopted in the August 2, 2007 final rule as described above in this section.

In the August 2, 2007 final rule, we also established our policy to make separate ASC payments for the following ancillary items and services when they are provided integral to ASC covered surgical procedures: Brachytherapy sources; certain implantable items that have pass-through status under the OPPS; certain items and services that we designate as contractor-priced, including, but not limited to, procurement of corneal tissue; certain drugs and biologicals for which separate payment is allowed under the OPPS; and certain radiology services for which separate payment is allowed under the OPPS. These covered ancillary services are specified in § 416.164(b) and, as stated previously, are eligible for separate ASC payment (72 FR 42495). Payment for ancillary items and services that are not paid separately under the ASC payment system is packaged into the ASC payment for the covered surgical procedure.

We update the lists of, and payment rates for, covered surgical procedures and covered ancillary services in conjunction with the annual proposed and final rulemaking process to update the OPPS and the ASC payment system (§ 416.173; 72 FR 42535). In addition, as discussed in detail in section XIII.B. of the proposed rule and this final rule with comment period, because we base ASC payment policies for covered surgical procedures, drugs, biologicals, and certain other covered ancillary services on the OPPS payment policies, we also provide quarterly updates for ASC services throughout the year (January, April, July, and October). The updates are to implement newly created Level II HCPCS and Category III CPT codes for ASC payment and to update the payment rates for separately paid drugs and biologicals based on the most recently submitted ASP data. New Category I CPT codes, except vaccine codes, are released only once a year and, therefore, are implemented through the January quarterly update. New Category I CPT vaccine codes are released twice a year and thus are implemented through the January and July quarterly updates.

In our annual updates to the ASC list of, and payment rates for, covered surgical procedures and covered ancillary services, we undertake a review of excluded surgical procedures (including all procedures newly proposed for removal from the OPPS inpatient list), new procedures, and procedures for which there is revised coding, to identify any that we believe meet the criteria for designation as ASC covered surgical procedures or covered ancillary services. Updating the lists of covered surgical procedures and covered ancillary services, as well as their payment rates, in association with the annual OPPS rulemaking cycle is particularly important because the OPPS relative payment weights and, in some cases, payment rates, are used as the basis for the payment of covered surgical procedures and covered ancillary services under the revised ASC payment system. This joint update process ensures that the ASC updates occur in a regular, predictable, and timely manner.

Comment: Several commenters provided a number of general suggestions related to the ASC list of covered surgical procedures. The commenters contended that CMS should not restrict which procedures are payable in ASCs any more than CMS restricts which procedures are payable

in HOPDs. According to the commenters, when CMS declines to add a service to the ASC list that can be performed in hospitals and physician offices, CMS should articulate a clinical rationale for why the procedure should be excluded from the ASC setting. Commenters also stated that the frequency that a surgical procedure is performed in an office setting should be included as one of the criteria for inclusion on the ASC list of covered surgical procedures. Some commenters urged CMS to eliminate unlisted codes from the exclusionary criteria at § 416.166(c), and other commenters requested that ASCs be allowed to use unlisted codes to bill for procedures that are from anatomic sites that could not possibly pose a potential risk to beneficiary safety. The commenters reported that unlisted codes enable surgeons to utilize innovative techniques or new technologies and are paid under the OPPS and by commercial insurers.

Response: We appreciate the commenters' suggestions related to our decisions about which procedures are excluded from the ASC list of covered surgical procedures. However, as we explained in the August 2, 2007 final rule (72 FR 42479), we do not believe that all procedures that are appropriate for performance in HOPDs are appropriate in ASCs. HOPDs are able to provide much higher acuity care than ASCs. ASCs have neither patient safety standards consistent with those in place for hospitals, nor are they required to have the trained staff and equipment needed to provide the breadth and intensity of care that hospitals are required to maintain. Therefore, there are some procedures that we believe may be appropriately provided in the HOPD setting that are unsafe for performance in ASCs. Thus, we are not modifying our policy and will continue to exclude certain procedures for which payment is made in HOPDs from the ASC list of covered surgical procedures.

We do not agree with the commenters' request that we provide specific reasons for our decisions to exclude each procedure from the ASC list of covered surgical procedures that can be performed in hospitals and physician offices. Our decisions to exclude procedures from the ASC list are based on a number of the criteria listed at § 416.166 of the regulations, and we believe that it would be unnecessary and overly burdensome to list each reason for those decisions. As we have stated in the past (74 FR 60598), we continue to believe that these reasons are sufficiently specific to enable the public to provide meaningful comments on our decisions to exclude procedures from the list of covered surgical procedures.

We believe that we should not use the frequency that a procedure is performed in the office setting as one of our criteria for additions to the ASC list of covered surgical procedures. Because a surgical procedure is performed in significant volume in the office setting does not automatically mean that the procedure would not be expected to pose a significant risk to beneficiary safety when performed in an ASC or would not be expected to require active medical monitoring and care at midnight following the procedure. We believe that such procedures still need to be evaluated using the criteria listed at § 416.166 of the regulations.

We also do not agree with the commenters' recommendation that we include unlisted codes or unlisted codes for procedures from certain anatomic sites on the list of covered surgical procedures. Even though it may be highly unlikely that procedures reported by unlisted codes or by unlisted codes for procedures from certain anatomic sites would be expected to pose a risk to beneficiary safety when performed in an ASC or would be expected to require an overnight stay, we cannot know exactly what surgical procedure is being reported by an unlisted code. Therefore, as we have explained in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72026 and 72027), because we cannot evaluate any such procedure, we continue to believe that we must exclude unlisted codes as a group from the list of covered surgical procedures.

After consideration of the public comments we received, we are continuing our established policies without modification for determining which procedures are ASC covered surgical procedures and covered ancillary services.

B. Treatment of New Codes

1. Process for Recognizing New Category I and Category III CPT Codes and Level II HCPCS Codes

CPT and Level II HCPCS codes are used to report procedures, services, items, and supplies under the ASC payment system. Specifically, we recognize the following codes on ASC claims: (1) Category I CPT codes, which describe medical services and procedures; (2) Category III CPT codes, which describe new and emerging technologies, services, and procedures; and (3) Level II HCPCS codes, which are used primarily to identify products, supplies, temporary procedures, and services not described by CPT codes. CPT codes are established by the American Medical Association (AMA) and the Level II HCPCS codes are established by the CMS HCPCS Workgroup. These codes are updated and changed throughout the year. CPT and HCPCS code changes that affect ASCs are addressed both through the ASC quarterly update Change Requests (CRs) and through the annual rulemaking cycle. CMS releases new Level II HCPCS codes to the public or recognizes the release of new CPT codes by the AMA and makes these codes effective (that is, the codes are recognized on Medicare claims) outside of the formal rulemaking process via ASC quarterly update CRs. This quarterly process offers ASCs access to codes that may more accurately describe items or services furnished and/or provides payment or more accurate payment for these items or services in a more timely manner than if we waited for the annual rulemaking process. We solicit comments on the new codes recognized for ASC payment and finalize our proposals related to these codes through our annual rulemaking process.

We finalized a policy in the August 2, 2007 final rule to evaluate each year all new Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to make preliminary determinations in the annual OPPS/ASC final rule with comment period regarding whether or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether they are office-based procedures (72 FR 42533 through 42535). In addition, we identify new codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system.

In Table 41 of the CY 2012 OPPS/ASC proposed rule (76 FR 42291), we summarized our process for updating the HCPCS codes recognized under the ASC payment system.

This process is discussed in detail below. We have separated our discussion into two sections based on whether we proposed to solicit public comments in the CY 2012 OPPS/ASC proposed rule (and respond to those comments in this CY 2012 OPPS/ASC final rule with comment period) or whether we are soliciting public comments in this CY 2012 OPPS/ASC final rule with comment period (and responding to those comments in the CY 2013 OPPS/ASC final rule with comment period). We note that we sought public comment in the CY 2011 OPPS/ASC final rule with comment

period on the new CPT and Level II HCPCS codes that were effective January 1, 2011. We also sought public comments in the CY 2011 OPPS/ASC final rule with comment period on the new Level II HCPCS codes effective October 1, 2010. These new codes, with an effective date of October 1, 2010, or January 1, 2011, were flagged with comment indicator ''N1'' in Addenda AA and BB to the CY2011 OPPS/ASC final rule with comment period to indicate that we were assigning them an interim payment status and payment rate, if applicable, which were subject to public comment following publication of the CY 2011 OPPS/ASC final rule with comment period. We stated that we would respond to public comments and finalize our proposed ASC treatment of these codes in this CY 2012 OPPS/ASC final rule with comment period.

We did not receive any public comments regarding our process for recognizing new HCPCS codes under the ASC payment system and are implementing our proposed policy as final, without modification, for CY 2012.

2. Treatment of New Level II HCPCS Codes and Category III CPT Codes Implemented in April and July 2011 for Which We Solicited Public Comments in the CY 2012 OPPS/ASC Proposed Rule

In the April and July CRs, we made effective for April 1 or July 1, 2011, a total of 13 new Level II HCPCS codes and 6 new Category III CPT codes that were not addressed in the CY 2011 OPPS/ASC final rule with comment period. The 13 new Level II HCPCS codes describe covered ancillary services.

In the April 2011 ASC quarterly update (Transmittal 2185, CR 7343, dated March 25, 2011), we added four new drug and biological Level II HCPCS codes to the list of covered ancillary services. Specifically, as displayed in Table 42 of the CY 2012 OPPS/ASC proposed rule (76 FR 42292), these included HCPCS codes C9280 (Injection, eribulin mesylate, 1 mg), C9281 (Injection, pegloticase, 1 mg), C9282 (Injection, ceftaroline fosamil, 10 mg), and Q2040 (Injection, incobotulinumtoxin A, 1 unit). We note that HCPCS code Q2040 replaced HCPCS code C9278 (Injection, incobotulinumtoxin A, 1 unit) beginning April 1, 2011. HCPCS code C9278 was effective January 1, 2011, and deleted for dates of service April 1, 2011 and forward, because it was replaced with HCPCS code Q2040.

In the July 2011 quarterly update (Transmittal 2235, Change Request 7445, dated June 03, 2011), we added nine new drug and biological Level II HCPCS codes to the list of covered ancillary services. Specifically, as displayed in Table 43 of the CY 2012 OPPS/ASC proposed rule (76 FR 42292), we provided separate payment for HCPCS codes C9283 (Injection, acetaminophen, 10 mg), C9284 (Injection, ipilimumab, 1 mg), C9285 (Lidocaine 70 mg/tetracaine 70 mg, per patch), C9365 (Oasis Ultra Tri-Layer matrix, per square centimeter), C9406 (Iodine I–123 ioflupane, diagnostic, per study dose, up to 5 millicuries), Q2041 (Injection, von willebrand factor complex (human), Wilate, 1 i.u. vwf:rco), Q2042 (Injection, hydroxyprogesterone caproate, 1 mg), Q2043 (Sipuleucel-t, minimum of 50 million autologous cd54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion), and Q2044 (Injection, belimumab, 10 mg). We note that HCPCS code Q2041 replaced HCPCS code J7184 and HCPCS code Q2043 replaced HCPCS code C9273 beginning July 1, 2011.

We assigned payment indicator ''K2'' (Drugs and biologicals paid separately when provided integral to a surgical procedure on the ASC list; payment based on OPPS rate) to these 13 new Level II HCPCS codes to indicate that they are separately paid when provided in ASCs. In the CY 2012 OPPS/ASC proposed rule, we solicited public comment on the proposed CY 2012 ASC payment indicators and payment rates for the drugs and biologicals, as listed in Tables 42 and 43 of the CY 2012 OPPS/ASC proposed rule (76 FR 42292). Those HCPCS codes became payable in ASCs, beginning in April or July 2011, and are paid at the ASC rates posted for the appropriate calendar quarter on the CMS Web site at *http://www.cms.gov/ASCPayment/*.

The HCPCS codes listed in Table 42 were included in Addendum BB to the CY 2012 OPPS/ASC proposed rule. We note that all ASC addenda were only available via the Internet on the CMS Web site. Because HCPCS codes that became effective for July (listed in Table 43 of the CY 2012 OPPS/ASC proposed rule) were not available to us in time for incorporation into the Addenda to the OPPS/ASC proposed rule, our policy is to include these HCPCS codes and their proposed payment indicators and payment rates in the preamble to the proposed rule but not in the Addenda to the proposed rule. These codes and their final payment indicators and rates are included in the appropriate Addendum to this CY 2012 OPPS/ASC final rule with comment period. Thus, the codes implemented by the July 2011 ASC quarterly update CR and their proposed CY 2012 payment rates (based on July 2011 ASP data) that are displayed in Table 43 of the CY 2012 OPPS/ASC proposed rule were not included in Addendum BB to that proposed rule. The final list of covered ancillary services and the associated payment weights and payment indicators is included in Addendum BB to this CY 2012 OPPS/ASC final rule with comment period, consistent with our annual update policy.

We did not receive any public comments regarding our proposals. We are continuing our established policy for recognizing new mid-year HCPCS codes. We also are adopting as final for CY 2012 the ASC payment indicators for the ancillary services described by the new Level II HCPCS codes implemented in April and July 2011 through the quarterly update CRs as shown below, in Tables 48 and 49, respectively. These new HCPCS codes also are displayed in Addendum BB to this final rule with comment period. We note that after publication of the CY 2012 OPPS/ASC proposed rule, the CMS HCPCS Workgroup created permanent HCPCS J-codes for CY 2012 to replace certain temporary HCPCS C-codes made effective for CY 2011. These permanent CY 2012 HCPCS J-codes are listed alongside the temporary CY 2011 HCPCS C-codes in Tables 48 and 49 below.

TABLE 48.—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES IMPLEMENTED IN APRIL 2011

CY 2012 HCPCS Code	CY 2011 HCPCS Code	CY 2012 Long Descriptor	Final CY 2012 Payment Indicator
J9179	C9280	Injection, eribulin mesylate, 1 mg	K2
J2507	C9281	Injection, pegloticase, 1 mg	K2
J0712	C9282	Injection, ceftaroline fosamil, 10 mg	K2
J0588	Q2040*	Injection, incobotulinumtoxin A, 1 unit	K2

*Level II HCPCS code C9278 was deleted March 31, 2011, and replaced with HCPCS code Q2040 effective April 1, 2011

TABLE 49.—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES IMPLEMENTED IN JULY 2011

CY 2012 HCPCS Code	CY 2011 HCPCS Code	CY 2012 Long Descriptor	Final CY 2012 Payment Indicator
J0131	C9283	Injection, acetaminophen, 10 mg	K2
J9288	C9284	Injection, ipilimumab, 1 mg	K2
C9285	C9285	Lidocaine 70 mg/tetracaine 70mg, per patch	K2
Q4124	C9365	Oasis Ultra Tri-Layer matrix, per square centimeter	K2
A9584	C9406	Iodine I-123 ioflupane, diagnostic, per study dose, up to 5 millicuries	K2
J7183	Q2041*	Injection, von willebrand factor complex (human), Wilate, 1 i.u. vwf:rco	K2
J1725	Q2042	Injection, hydroxyprogesterone caproate, 1 mg	K2
Q2043	Q2043*	Sipuleucel-t, minimum of 50 million autologous cd54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion	K2
J0490	Q2044	Injection, belimumab, 10 mg	K2

*Level II HCPCS codes J7184 and C9273 were deleted June 30, 2011 and were replaced with HCPCS codes Q2041 and Q2043, respectively, effective July 1, 2011

Through the July 2011 quarterly update CR, we also implemented ASC payment for six new Category III CPT codes as ASC covered surgical procedures, effective July 1, 2011. These codes were listed in Table 44 of the CY 2012 OPPS/ASC proposed rule (76 FR 42292 and 42293), along with their proposed payment indicators and proposed payment rates for CY 2012. Because new Category III CPT and Level II HCPCS codes that became effective for July were not available to us in time for incorporation into the Addenda to the OPPS/ASC proposed rule, our policy is to include the codes, their proposed payment indicators, and proposed payment rates in the preamble to the proposed rule but not in the Addenda to the proposed rule. These codes and their final payment indicators and rates are included in Addendum AA to this CY 2012 OPPS/ASC final rule with comment period. We proposed to assign payment indicator ''G2'' (Non-office-based surgical procedure added in CY 2008 or later; payment based on OPPS

relative payment weight) to all six of the new Category III CPT codes to be implemented in July 2011. We believe that these procedures would not pose a significant safety risk to Medicare beneficiaries or would not require an overnight stay if performed in ASCs. We solicited public comment on these proposed payment indicators and the payment rates for the new Category III CPT codes that were newly recognized as ASC covered surgical procedures in July 2011 through the quarterly update CR, as listed in Table 44 of the CY 2012 OPPS/ASC proposed rule (76 FR 42292 and 42293). We proposed to finalize their payment indicators and their payment rates in this CY 2012 OPPS/ASC final rule with comment period.

We did not receive any public comments regarding this proposal. We are continuing our established policy for recognizing new mid-year CPT codes for CY 2012. We also are adopting as final for CY 2012 the ASC payment indicators for the covered surgical procedures described by the new Category III CPT codes implemented in the July 2011 CR as shown below in Table 50. The new CPT codes implemented in July 2011 are also displayed in Addendum AA to this final rule with comment period (which is available via the Internet on the CMS Web site).

TABLE 50.—NEW CATEGORY III CPT CODES IMPLEMENTED IN JULY 2011 AS ASC COVERED SURGICAL PROCEDURES

CY 2012 CPT Code	CY 2012 Long Descriptor	Final CY 2012 Payment Indicator
0263T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure including unilateral or bilateral bone marrow harvest	G2
0264T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure excluding bone marrow harvest	G2
0265T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; unilateral or bilateral bone marrow harvest only for intramuscular autologous bone marrow cell therapy	G2
0269T	Revision or removal of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)	G2
0270T	Revision or removal of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)	G2
0271T	Revision or removal of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)	G2

3. Process for New Level II HCPCS Codes and Category I and III CPT Codes for Which We Are Soliciting Public Comments in This CY 2012 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new Category I and Category III CPT codes and new Level II HCPCS codes that are effective January 1 in the final rule with comment period updating the ASC payment system for the following calendar year. These codes are released to the public via the CMS HCPCS (for Level II HCPCS codes) and AMA Web sites (for CPT codes), and also through the January ASC quarterly update CRs. In the past, we also have released new Level II HCPCS codes that are effective October 1 through the October ASC quarterly update CRs and incorporated these new codes in the final rule with comment period updating the ASC payment system for the following calendar year. All of these codes are flagged with comment indicator ''NI'' in Addenda AA and BB to the OPPS/ASC final rule with comment period to indicate that we are assigning them an interim payment status which is subject to public comment. The payment indicator and payment rate, if applicable, for all such codes flagged with comment indicator ''NI'' are open to public comment in the OPPS/ASC final rule with comment period, and we respond to these comments in the final rule with comment period for the next calendar year's OPPS/ASC update. In the CY 2012 OPPS/ASC proposed rule (76 FR 42293), we proposed to continue this process for CY 2012. Specifically, for CY 2012, we proposed to include in Addenda AA and BB to the CY 2012 OPPS/ASC final rule with comment period the new Category I and III CPT codes effective January 1, 2012 that would be incorporated in the January 2012 ASC quarterly update CR and the new Level II HCPCS codes, effective October 1, 2011 or January 1, 2012, that would be released by CMS in its October 2011 and January 2012 ASC quarterly update CRs. We stated that these codes would be flagged with comment indicator ''NI'' in Addenda AA and BB to this CY 2012 OPPS/ASC final rule with comment period to indicate that we have assigned them an interim payment status. We also stated that their payment indicators and payment rates, if applicable, would be open to public comment in the CY 2012 OPPS/ASC final rule with comment period and would be finalized in the CY 2013 OPPS/ASC final rule with comment period.

We did not receive any public comments regarding this proposed process. For CY 2012, we are finalizing our proposal, without modification, to continue our established process for recognizing and soliciting public comments on new Level II HCPCS codes and Category I and III CPT codes that become effective for the following year, as described above.

C. Update to the Lists of ASC Covered Surgical Procedures and Covered Ancillary Services

1. Covered Surgical Procedures

a. Additions to the List of ASC Covered Surgical Procedures

We conducted a review of all HCPCS codes that currently are paid under the OPPS, but not included on the ASC list of covered surgical procedures, to determine if changes in technology and/or medical practice changed the clinical appropriateness of these procedures for the ASC setting. Upon review, we did not identify any procedures that are currently excluded from the ASC list of procedures that met the definition of a covered surgical procedure based on our expectation that they would not pose a significant safety risk to Medicare beneficiaries or would require an overnight stay if performed in ASCs. Therefore, in the CY 2012 OPPS/ASC proposed rule (76 FR 42293) we did not propose additions to the list of ASC covered surgical procedures for CY 2012.

Comment: Commenters requested that CMS add the procedures described by the 232 CPT codes displayed in Table 51 below to the list of ASC covered surgical procedures as well as several CPT unlisted codes. The commenters argued that these procedures are less complex and/or as safe as procedures already paid for when performed in the ASC setting.

BILLING CODE 4120–01–P

TABLE 51.—SURGICAL PROCEDURES REQUESTED FOR ADDITION TO THE CY 2012 ASC LIST OF COVERED SURGICAL PROCEDURES

CY 2012 CPT/HCPCS Code	CY 2012 CPT/HCPCS Long Descriptor
19260	Excision of chest wall tumor including ribs
19307	Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle
20100	Exploration of penetrating wound (separate procedure); neck
20101	Exploration of penetrating wound (separate procedure); chest
20102	Exploration of penetrating wound (separate procedure); abdomen/flank/back
20660	Application of cranial tongs, caliper, or stereotactic frame, including removal (separate procedure)
21049	Excision of benign tumor or cyst of maxilla; requiring extra-oral osteotomy and partial maxillectomy (eg, locally aggressive or destructive lesion(s))
21089	Unlisted maxillofacial prosthetic procedure
21141	Reconstruction midface, lefort i; single piece, segment movement in any direction (eg, for long face syndrome), without bone graft
21142	Reconstruction midface, lefort i; two pieces, segment movement in any direction, without bone graft
21143	Reconstruction midface, lefort i; three or more pieces, segment movement in any direction, without bone graft
21145	Reconstruction midface, lefort i; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)
21146	Reconstruction midface, lefort i; two pieces, segment movement in any direction, requiring bone grafts (includes obtaining autografts) (eg, ungrafted unilateral alveolar cleft)
21147	Reconstruction midface, lefort i; three or more pieces, segment movement in any direction, requiring bone grafts (includes obtaining autografts) (eg, ungrafted bilateral alveolar cleft or multiple osteotomies)
21151	Reconstruction midface, lefort ii; any direction, requiring bone grafts (includes obtaining autografts)
21172	Reconstruction superior-lateral orbital rim and lower forehead, advancement or alteration, with or without grafts (includes obtaining

CY 2012 CPT/HCPCS Code	CY 2012 CPT/HCPCS Long Descriptor
	autografts)
21188	Reconstruction midface, osteotomies (other than lefort type) and bone grafts (includes obtaining autografts)
21193	Reconstruction of mandibular rami, horizontal, vertical, c, or l osteotomy; without bone graft
21194	Reconstruction of mandibular rami, horizontal, vertical, c, or l osteotomy; with bone graft (includes obtaining graft)
21195	Reconstruction of mandibular rami and/or body, sagittal split; without internal rigid fixation
21196	Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation
21247	Reconstruction of mandibular condyle with bone and cartilage autografts (includes obtaining grafts) (eg, for hemifacial microsomia)
21256	Reconstruction of orbit with osteotomies (extracranial) and with bone grafts (includes obtaining autografts) (eg, micro-ophthalmia)
21343	Open treatment of depressed frontal sinus fracture
21346	Open treatment of nasomaxillary complex fracture (lefort ii type); with wiring and/or local fixation
21365	Open treatment of complicated (eg, comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with internal fixation and multiple surgical approaches
21385	Open treatment of orbital floor blowout fracture; transantral approach (caldwell-luc type operation)
21386	Open treatment of orbital floor blowout fracture; periorbital approach
21387	Open treatment of orbital floor blowout fracture; combined approach
21395	Open treatment of orbital floor blowout fracture; periorbital approach with bone graft (includes obtaining graft)
21408	Open treatment of fracture of orbit, except blowout; with bone grafting (includes obtaining graft)
21422	Open treatment of palatal or maxillary fracture (lefort i type);
21423	Open treatment of palatal or maxillary fracture (lefort i type); complicated (comminuted or involving cranial nerve foramina), multiple approaches
21431	Closed treatment of craniofacial separation (lefort iii type) using

CY 2012 CPT/HCPCS Code	CY 2012 CPT/HCPCS Long Descriptor
	interdental wire fixation of denture or splint
21470	Open treatment of complicated mandibular fracture by multiple surgical approaches including internal fixation, interdental fixation, and/or wiring of dentures or splints
22100	Partial excision of posterior vertebral component (eg, spinous process, lamina or facet) for intrinsic bony lesion, single vertebral segment; cervical
22222	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; thoracic
22612	Arthrodesis, posterior or posterolateral technique, single level; lumbar (with or without lateral transverse technique)
22614	Arthrodesis, posterior or posterolateral technique, single level; each additional vertebral segment (list separately in addition to code for primary procedure)
22851	Application of intervertebral biomechanical device(s) (eg, synthetic cage(s), methylmethacrylate) to vertebral defect or interspace (list separately in addition to code for primary procedure)
23470	Arthroplasty, glenohumeral joint; hemiarthroplasty
23929	Unlisted procedure, shoulder
27006	Tenotomy, abductors and/or extensor(s) of hip, open (separate procedure)
27027	Decompression fasciotomy(ies), pelvic (buttock) compartment(s) (eg, gluteus medius-minimus, gluteus maximus, iliopsoas, and/or tensor fascia lata muscle), unilateral
27035	Denervation, hip joint, intrapelvic or extrapelvic intra-articular branches of sciatic, femoral, or obturator nerves
27524	Open treatment of patellar fracture, with internal fixation and/or partial or complete patellectomy and soft tissue repair
28805	Amputation, foot; transmetatarsal
31292	Nasal/sinus endoscopy, surgical; with medial or inferior orbital wall decompression
31600	Tracheostomy, planned (separate procedure);
31610	Tracheostomy, fenestration procedure with skin flaps
31785	Excision of tracheal tumor or carcinoma; cervical

CY 2012 CPT/HCPCS Code	CY 2012 CPT/HCPCS Long Descriptor
32201	Pneumonostomy; with percutaneous drainage of abscess or cyst
32551	Tube thoracostomy with or without water seal (eg, for abscess, hemothorax, empyema) (separate procedure)
32560	Chemical pleurodesis (eg, for recurrent or persistent pneumothorax)
32601	Thoracoscopy, diagnostic (separate procedure); lungs, pericardial sac, mediastinal or pleural space, without biopsy
32602	Thoracoscopy, diagnostic (separate procedure); lungs and pleural space, with biopsy
32606	Thoracoscopy, diagnostic (separate procedure); mediastinal space, with biopsy
33244	Removal of single or dual chamber pacing cardioverter-defibrillator electrode(s); by transvenous extraction
34101	Embolectomy or thrombectomy, with or without catheter; axillary, brachial, innominate, subclavian artery, by arm incision
34111	Embolectomy or thrombectomy, with or without catheter; radial or ulnar artery, by arm incision
34201	Embolectomy or thrombectomy, with or without catheter; femoropopliteal, aortoiliac artery, by leg incision
34203	Embolectomy or thrombectomy, with or without catheter; popliteal-tibio-peroneal artery, by leg incision
34421	Thrombectomy, direct or with catheter; vena cava, iliac, femoropopliteal vein, by leg incision
34501	Valvuloplasty, femoral vein
34520	Cross-over vein graft to venous system
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
35180	Repair, congenital arteriovenous fistula; head and neck
35184	Repair, congenital arteriovenous fistula; extremities
35190	Repair, acquired or traumatic arteriovenous fistula; extremities
35206	Repair blood vessel, direct; upper extremity
35226	Repair blood vessel, direct; lower extremity
35231	Repair blood vessel with vein graft; neck
35236	Repair blood vessel with vein graft; upper extremity

CY 2012 CPT/HCPCS Code	CY 2012 CPT/HCPCS Long Descriptor
35256	Repair blood vessel with vein graft; lower extremity
35266	Repair blood vessel with graft other than vein; upper extremity
35286	Repair blood vessel with graft other than vein; lower extremity
35321	Thromboendarterectomy, including patch graft, if performed; axillary-brachial
35458	Transluminal balloon angioplasty, open; brachiocephalic trunk or branches, each vessel
35471	Transluminal balloon angioplasty, percutaneous; renal or visceral artery
35472	Transluminal balloon angioplasty, percutaneous; aortic
35494	Transluminal peripheral atherectomy, percutaneous; brachiocephalic trunk or branches, each vessel
35500	Harvest of upper extremity vein, one segment, for lower extremity or coronary artery bypass procedure (list separately in addition to code for primary procedure)
35686	Creation of distal arteriovenous fistula during lower extremity bypass surgery (non-hemodialysis) (list separately in addition to code for primary procedure)
35860	Exploration for postoperative hemorrhage, thrombosis or infection; extremity
35879	Revision, lower extremity arterial bypass, without thrombectomy, open; with vein patch angioplasty
35881	Revision, lower extremity arterial bypass, without thrombectomy, open; with segmental vein interposition
35884	Revision, femoral anastomosis of synthetic arterial bypass graft in groin, open; with autogenous vein patch graft
35903	Excision of infected graft; extremity
36838	Distal revascularization and interval ligation (dril), upper extremity hemodialysis access (steal syndrome)
37183	Revision of transvenous intrahepatic portosystemic shunt(s) (tips) (includes venous access, hepatic and portal vein catheterization, portography with hemodynamic evaluation, intrahepatic tract recanulization/ dilatation, stent placement and all associated
37195	Thrombolysis, cerebral, by intravenous infusion
37201	Transcatheter therapy, infusion for thrombolysis other than coronary

CY 2012 CPT/HCPCS Code	CY 2012 CPT/HCPCS Long Descriptor
37202	Transcatheter therapy, infusion other than for thrombolysis, any type (eg, spasmolytic, vasoconstrictive)
37205	Transcatheter placement of an intravascular stent(s) (except coronary, carotid, and vertebral vessel), percutaneous; initial vessel
37206	Transcatheter placement of an intravascular stent(s) (except coronary, carotid, and vertebral vessel), percutaneous; each additional vessel (List separately in addition to code for primary procedure)
37207	Transcatheter placement of an intravascular stent(s) (non-coronary vessel other than iliac and lower extremity arteries), open; initial vessel
37208	Transcatheter placement of an intravascular stent(s) (non-coronary vessel other than iliac and lower extremity arteries), open; each additional vessel (List separately in addition to code for primary procedure)
37209	Exchange of a previously placed intravascular catheter during thrombolytic therapy
37224	Revascularization, endovascular, open or percutaneous, femoral/popliteal artery(s), unilateral; with transluminal angioplasty
37225	Revascularization, endovascular, open or percutaneous, femoral/popliteal artery(s), unilateral; with atherectomy, includes angioplasty within the same vessel, when performed
37226	Revascularization, endovascular, open or percutaneous, femoral/popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed
37227	Revascularization, endovascular, open or percutaneous, femoral/popliteal artery(s), unilateral; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed
37228	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, initial vessel; with transluminal angioplasty
37229	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, initial vessel; with atherectomy, includes angioplasty within the same vessel, when performed
37230	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, initial vessel; with transluminal stent placement(s),

CY 2012 CPT/HCPCS Code	CY 2012 CPT/HCPCS Long Descriptor
	includes angioplasty within the same vessel, when performed
37231	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, initial vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed
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)
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)
37235	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)
37501	Unlisted vascular endoscopy procedure
37605	Ligation; internal or common carotid artery
37615	Ligation, major artery (eg, post-traumatic, rupture); neck
37620	Interruption, partial or complete, of inferior vena cava by suture, ligation, plication, clip, extravascular, intravascular (umbrella device)
38120	Laparoscopy, surgical, splenectomy
38240	Bone marrow or blood-derived peripheral stem cell transplantation; allogenic
38720	Cervical lymphadenectomy (complete)
39400	Mediastinoscopy, with biopsy(ies), when performed
42842	Radical resection of tonsil, tonsillar pillars, and/or retromolar trigone; without closure
42844	Radical resection of tonsil, tonsillar pillars, and/or retromolar trigone;

CY 2012 CPT/HCPCS Code	CY 2012 CPT/HCPCS Long Descriptor
	closure with local flap (eg, tongue, buccal)
43280	Laparoscopy, surgical, esophagogastric fundoplasty (eg, nissen, toupet procedures)
43420	Closure of esophagostomy or fistula; cervical approach
43510	Gastrotomy; with esophageal dilation and insertion of permanent intraluminal tube (eg, celestin or mousseaux-barbin)
43659	Unlisted laparoscopy procedure, stomach
43830	Gastrostomy, open; without construction of gastric tube (eg, stamm procedure) (separate procedure)
44180	Laparoscopy, surgical, enterolysis (freeing of intestinal adhesion) (separate procedure)
44186	Laparoscopy, surgical; jejunostomy (eg, for decompression or feeding)
44206	Laparoscopy, surgical; colectomy, partial, with end colostomy and closure of distal segment (hartmann type procedure)
44207	Laparoscopy, surgical; colectomy, partial, with anastomosis, with coloproctostomy (low pelvic anastomosis)
44208	Laparoscopy, surgical; colectomy, partial, with anastomosis, with coloproctostomy (low pelvic anastomosis) with colostomy
44213	Laparoscopy, surgical, mobilization (take-down) of splenic flexure performed in conjunction with partial colectomy (list separately in addition to primary procedure)
44238	Unlisted laparoscopy procedure, intestine (except rectum)
44901	Incision and drainage of appendiceal abscess; percutaneous
44950	Appendectomy;
44955	Appendectomy; when done for indicated purpose at time of other major procedure (not as separate procedure) (list separately in addition to code for primary procedure)
44970	Laparoscopy, surgical, appendectomy
47011	Hepatotomy; for percutaneous drainage of abscess or cyst, one or two stages
47371	Laparoscopy, surgical, ablation of one or more liver tumor(s); cryosurgical
47379	Unlisted laparoscopic procedure, liver
47490	Cholecystostomy, percutaneous, complete procedure, including

CY 2012 CPT/HCPCS Code	CY 2012 CPT/HCPCS Long Descriptor
	imaging guidance, catheter placement, cholecystogram when performed, and radiological supervision and interpretation
47579	Unlisted laparoscopy procedure, biliary tract
48511	External drainage, pseudocyst of pancreas; percutaneous
49021	Drainage of peritoneal abscess or localized peritonitis, exclusive of appendiceal abscess; percutaneous
49041	Drainage of subdiaphragmatic or subphrenic abscess; percutaneous
49061	Drainage of retroperitoneal abscess; percutaneous
49323	Laparoscopy, surgical; with drainage of lymphocele to peritoneal cavity
49329	Unlisted laparoscopy procedure, abdomen, peritoneum and omentum
49659	Unlisted laparoscopy procedure, hernioplasty, herniorrhaphy, herniotomy
50020	Drainage of perirenal or renal abscess; open
50021	Drainage of perirenal or renal abscess; percutaneous
50542	Laparoscopy, surgical; ablation of renal mass lesion(s), including intraoperative ultrasound guidance and monitoring, when performed
50543	Laparoscopy, surgical; partial nephrectomy
50544	Laparoscopy, surgical; pyeloplasty
50945	Laparoscopy, surgical; ureterolithotomy
50949	Unlisted laparoscopy procedure, ureter
51845	Abdomino-vaginal vesical neck suspension, with or without endoscopic control (eg, stamey, raz, modified pereyra)
51860	Cystorrhaphy, suture of bladder wound, injury or rupture; simple
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 (Do not report 52649 with 52000, 52276, 52281, 52601, 52647, 52648, 53020, 55250)
53500	Urethrolysis, transvaginal, secondary, open, including cystourethroscopy (eg, postsurgical obstruction, scarring)
54332	One stage proximal penile or penoscrotal hypospadias repair requiring extensive dissection to correct chordee and urethroplasty by use of skin graft tube and/or island flap

CY 2012 CPT/HCPCS Code	CY 2012 CPT/HCPCS Long Descriptor
54336	One stage perineal hypospadias repair requiring extensive dissection to correct chordee and urethroplasty by use of skin graft tube and/or island flap
54411	Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue
54417	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue
54535	Orchiectomy, radical, for tumor; with abdominal exploration
54650	Orchiopexy, abdominal approach, for intra-abdominal testis (eg, fowler-stephens)
57106	Vaginectomy, partial removal of vaginal wall;
57107	Vaginectomy, partial removal of vaginal wall; with removal of paravaginal tissue (radical vaginectomy)
57120	Colpocleisis (le fort type)
57282	Colpopexy, vaginal; extra-peritoneal approach (sacrospinous, iliococcygeus)
57283	Colpopexy, vaginal; intra-peritoneal approach (uterosacral, levator myorrhaphy)
57284	Paravaginal defect repair (including repair of cystocele, stress urinary incontinence, and/or incomplete vaginal prolapse if performed); open abdominal approach (do not report 57284 in conjunction with 51840, 51841, 51990, 57240, 57260, 57265, 58152, 58267)
57285	Paravaginal defect repair (including repair of cystocele, stress urinary incontinence, and/or incomplete vaginal prolapse if performed); vaginal approach (do not report 57285 in conjunction with 51990, 57240, 57260, 57265, 58267)
57310	Closure of urethrovaginal fistula;
57330	Closure of vesicovaginal fistula; transvesical and vaginal approach
57423	Paravaginal defect repair (including repair of cystocele, if performed), laparoscopic approach (do not report 57423 in conjunction with 49320, 51840, 51841, 51990, 57240, 57260, 58152, 58267)

CY 2012 CPT/HCPCS Code	CY 2012 CPT/HCPCS Long Descriptor
57425	Laparoscopy, surgical, colpopexy (suspension of vaginal apex)
58260	Vaginal hysterectomy, for uterus 250 g or less;
58262	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)
58263	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s), with repair of enterocele
58270	Vaginal hysterectomy, for uterus 250 g or less; with repair of enterocele
58291	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58541	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less;
58542	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58553	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g;
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58570	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less;
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58578	Unlisted laparoscopy procedure, uterus
58770	Salpingostomy (salpingoneostomy)
58823	Drainage of pelvic abscess, transvaginal or transrectal approach, percutaneous (eg, ovarian, pericolic)
58925	Ovarian cystectomy, unilateral or bilateral
59074	Fetal fluid drainage (eg, vesicocentesis, thoracocentesis, paracentesis), including ultrasound guidance
59409	Vaginal delivery only (with or without episiotomy and/or forceps);
60240	Thyroidectomy, total or complete
60252	Thyroidectomy, total or subtotal for malignancy; with limited neck dissection

CY 2012 CPT/HCPCS Code	CY 2012 CPT/HCPCS Long Descriptor
60260	Thyroidectomy, removal of all remaining thyroid tissue following previous removal of a portion of thyroid
60271	Thyroidectomy, including substernal thyroid; cervical approach
60500	Parathyroidectomy or exploration of parathyroid(s);
60512	Parathyroid autotransplantation (list separately in addition to code for primary procedure)
61623	Endovascular temporary balloon arterial occlusion, head or neck (extracranial/intracranial) including selective catheterization of vessel to be occluded, positioning and inflation of occlusion balloon, concomitant neurological monitoring, and radiologic supervision and interpretation of all angiography required for balloon occlusion and to exclude vascualr injury post occlusion
61626	Transcatheter permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method; non-central nervous system, head or neck (extracranial, brachiocephalic branch)
61720	Creation of lesion by stereotactic method, including burr hole(s) and localizing and recording techniques, single or multiple stages; globus pallidus or thalamus
62000	Elevation of depressed skull fracture; simple, extradural
62351	Implantation, revision or repositioning of tunneled intrathecal or epidural catheter, for long-term medication administration via an external pump or implantable reservoir/infusion pump; with laminectomy
63001	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy, (eg, spinal stenosis), one or two vertebral segments; cervical
63003	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy, (eg, spinal stenosis), one or two vertebral segments; thoracic
63005	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy, (eg, spinal stenosis), one or two vertebral segments;

CY 2012 CPT/HCPCS Code	CY 2012 CPT/HCPCS Long Descriptor
	lumbar, except for spondylolisthesis
63011	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy, (eg, spinal stenosis), one or two vertebral segments; sacral
63012	Laminectomy with removal of abnormal facets and/or pars inter-articularis with decompression of cauda equina and nerve roots for spondylolisthesis, lumbar (gill type procedure)
63015	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy, (eg, spinal stenosis), more than 2 vertebral segments; cervical
63016	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy, (eg, spinal stenosis), more than 2 vertebral segments; thoracic
63017	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy, (eg, spinal stenosis), more than 2 vertebral segments; lumbar
63020	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, including open and endoscopically-assisted approaches; 1 interspace, cervical
63030	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, including open and endoscopically-assisted approaches; 1 interspace, lumbar
63035	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, including open and endoscopically-assisted approaches; each additional interspace, cervical or lumbar (List separately in addition to code for primary procedure)
63040	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; cervical

CY 2012 CPT/HCPCS Code	CY 2012 CPT/HCPCS Long Descriptor
63042	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; lumbar
63045	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root(s), (eg, spinal or lateral recess stenosis)), single vertebral segment; cervical
63046	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root(s), (eg, spinal or lateral recess stenosis)), single vertebral segment; thoracic
63047	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root(s), (eg, spinal or lateral recess stenosis)), single vertebral segment; lumbar
63048	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root(s), (eg, spinal or lateral recess stenosis)), single vertebral segment; each additional segment, cervical, thoracic, or lumbar (list separately in addition to code for primary procedure) (Use 63048 with 63045-63047)
63055	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (eg, herniated intervertebral disc), single segment; thoracic
63056	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (eg, herniated intervertebral disc), single segment; lumbar (including transfacet, or lateral extraforaminal approach) (eg, far lateral herniated intervertebral disc)
63057	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (eg, herniated intervertebral disc), single segment; each additional segment, thoracic or lumbar (list separately in addition to code for primary procedure)
63075	Discectomy, anterior, with decompression of spinal cord and/ or nerve root(s), including osteophytectomy; cervical, single interspace
63076	Discectomy, anterior, with decompression of spinal cord and/ or nerve root(s), including osteophytectomy; cervical, each additional interspace (list separately in addition to code for primary procedure)
69970	Removal of tumor, temporal bone
0171T	Insertion of posterior spinous process distraction device (including

CY 2012 CPT/HCPCS Code	CY 2012 CPT/HCPCS Long Descriptor
	necessary removal of bone or ligament for insertion and imaging guidance), lumbar; single level
0172T	Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; each additional level (list separately in addition to code for primary procedure)
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)
G0413	Percutaneous skeletal fixation of posterior pelvic bone fracture and/or dislocation, for fracture patterns which disrupt the pelvic ring, unilateral or bilateral, (includes ilium, sacroiliac joint and/or sacrum)

BILLING CODE 4120–01–C

Response: We reviewed all of the surgical procedures that commenters requested be added to the ASC list of covered surgical procedures. We did not review any of the procedures that may be reported by the CPT unlisted codes because those codes are not eligible for addition to the ASC list, consistent with our final policy which is discussed in detail in the August 2, 2007 final rule (72 FR 42484 through 42486). We do not agree that most of the procedures recommended by the commenters are appropriate for provision to Medicare beneficiaries in ASCs. Although the commenters asserted that the procedures they were requesting for addition to the list are less complex than and as safe as procedures already on the list, our review did not support those assertions. We exclude from ASC payment any procedure for which standard medical practice dictates that the beneficiary who undergoes the procedure would typically be expected to require active medical monitoring and care at midnight following the procedure (overnight stay) as well as all surgical procedures that our medical advisors determine may be expected to pose a significant safety risk to Medicare beneficiaries when performed in an ASC. The criteria used under the revised ASC payment system to identify procedures that would be expected to pose a significant safety risk when performed in an ASC include, but are not limited to, those procedures that: generally result in extensive blood loss; require major or prolonged invasion of body cavities; directly involve major blood vessels; are emergent or life threatening in nature; commonly require systemic thrombolytic therapy; are designated as requiring inpatient care under § 419.22(n); can only be reported using a CPT unlisted surgical procedure code; or are otherwise excluded under § 411.15 (we refer readers to § 416.166).

In our review of the procedures listed in Table 51, we found that most of the procedures either may be expected to pose a threat to beneficiary safety or require active medical monitoring at midnight following the procedure. Specifically, we found that prevailing medical practice called for inpatient hospital stays for beneficiaries undergoing many of the procedures and that some of the procedures directly involve major blood vessels and/or may result in extensive blood loss. However, we do agree with commenters that the procedures described by CPT codes 37201, 37202, 37207, 37208, 59074, and HCPCS code G0365 meet the criteria under § 416.166 and would be safely performed in the ASC setting and would not require overnight stays. We are adding these CPT/HCPCS codes to the ASC list of covered surgical procedures for CY 2012.

After consideration of the public comments we received, we are adding six of the procedures requested by the commenters to the CY 2012 ASC list of covered surgical procedures. The procedures, their descriptors, and payment indicators are displayed in Table 52 below.

BILLING CODE 4120–01–P

TABLE 52.—NEW ASC COVERED SURGICAL PROCEDURES FOR CY 2012

CY 2012 CPT/HCPCS Code	CY 2012 Long Descriptor	CY 2012 ASC Payment Indicator
37201	Transcatheter therapy, infusion for thrombolysis other than coronary	G2
37202	Transcatheter therapy, infusion other than for thrombolysis, any type (eg, spasmolytic, vasoconstrictive)	G2
37207	Transcatheter placement of an intravascular stent(s) (non-coronary vessel other than iliac and lower extremity arteries), open; initial vessel	G2
37208	Transcatheter placement of an intravascular stent(s) (non-coronary vessel other than iliac and lower extremity arteries), open; each additional vessel (List separately in addition to code for primary procedure)	G2
59074	Fetal fluid drainage (eg, vesicocentesis, thoracocentesis, paracentesis), including ultrasound guidance	G2
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)	G2

BILLING CODE 4120–01–C

b. Covered Surgical Procedures Designated as Office-Based

(1) Background

In the August 2, 2007 ASC final rule, we finalized our policy to designate as ''office-based'' those procedures that are added to the ASC list of covered surgical procedures in CY 2008 or later years that we determine are performed predominantly (more than 50 percent of the time) in physicians' offices based on consideration of the most recent available volume and utilization data for each individual procedure code and/or, if appropriate, the clinical characteristics, utilization, and volume of related codes. In that rule, we also finalized our policy to exempt all procedures on the CY 2007 ASC list from application of the office-based classification (72 FR 42512). The procedures that were added to the ASC list of covered surgical procedures beginning in CY 2008 that we determined were office-based were identified in Addendum AA to that rule by payment indicator ''P2'' (Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight); ''P3'' (Office-based surgical procedures added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs); or ''R2'' (Office-based surgical procedure added to ASC list in CY 2008 or later without MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight), depending on whether we estimated it would be paid according to the standard ASC payment methodology based on its OPPS relative payment weight or at the MPFS nonfacility PE RVU-based amount.

Consistent with our final policy to annually review and update the list of surgical procedures eligible for payment in ASCs, each year we identify surgical procedures as either temporarily office-based, permanently office-based, or non-office-based, after taking into account updated volume and utilization data.

(2) Changes for CY 2012 to Covered Surgical Procedures Designated as Office-Based

In developing the CY 2012 OPPS/ASC proposed rule (76 FR 42293 through 42296), we followed our policy to annually review and update the surgical procedures for which ASC payment is made and to identify new procedures that may be appropriate for ASC payment, including their potential designation as office-based. We

reviewed CY 2010 volume and utilization data and the clinical characteristics for all surgical procedures that are assigned payment indicator ''G2'' in CY 2011, as well as for those procedures assigned one of the temporary office-based payment indicators, specifically ''P2*,'' ''P3*,'' or ''R2*'' in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72033 through 72038).

In the CY 2012 OPPS/ASC proposed rule (76 FR 42294), we stated that our review of the CY 2010 volume and utilization data resulted in our identification of 10 surgical procedures that we believe meet the criteria for designation as office-based. We stated that the data indicated that the procedures are performed more than 50 percent of the time in physicians' offices, and that our medical advisors believed the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices. The 10 CPT codes we proposed to permanently designate as office-based are listed in Table 45 of the CY 2012 OPPS/ASC proposed rule (76 FR 42294), and are listed in Table 53 below.

Comment: Some commenters expressed their continued disagreement with the policy to make payment at the lower of the ASC rate or the MPFS nonfacility PE RVU payment amount for procedures we identify as office-based and requested that these services be subject to the same payment methodology as all other Medicare covered ASC procedures. Commenters also recommended that CMS establish a minimum volume threshold before designating a procedure office-based and use multiple years of data in the calculation in order to ensure that the data used to apply this policy are reliable.

Response: We have responded to this comment in the past and we continue to believe that our policy of identifying low complexity procedures that are usually provided in physicians' offices and limiting their payment in ASCs to the physician's office payment amount is necessary and valid. We believe this is the most appropriate approach to preventing the creation of payment incentives for services to move from physicians' offices to ASCs for the many newly covered low complexity procedures on the ASC list. We refer readers to our response to this comment in final rules with comment period from prior years: 74 FR 60605 through 60606 and 75 FR 72034 through 72035.

After consideration of the public comments we received, we are finalizing our CY 2012 proposal to designate the procedures displayed in Table 53 below as permanently office-based for CY 2012.

BILLING CODE 4120–01–P

TABLE 53.—ASC COVERED SURGICAL PROCEDURES NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2012

CY 2012 CPT Code	CY 2012 Long Descriptor	CY 2011 ASC Payment Indicator	Proposed CY 2012 ASC Payment Indicator	Final CY 2012 ASC Payment Indicator*
0213T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; single level	G2	R2	R2
0214T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; second level (list separately in addition to code for primary procedure)	G2	R2	R2
0215T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; third and any additional level(s) (list separately in addition to code for primary procedure)	G2	R2	R2

CY 2012 CPT Code	CY 2012 Long Descriptor	CY 2011 ASC Payment Indicator	Proposed CY 2012 ASC Payment Indicator	Final CY 2012 ASC Payment Indicator*
0216T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; single level	G2	R2	R2
0217T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; second level (list separately in addition to code for primary procedure)	G2	R2	R2
0218T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; third and any additional level(s) (list separately in addition to code for primary procedure)	G2	R2	R2
35475	Transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel	G2	P3	P3

CY 2012 CPT Code	CY 2012 Long Descriptor	CY 2011 ASC Payment Indicator	Proposed CY 2012 ASC Payment Indicator	Final CY 2012 ASC Payment Indicator*
35476	Transluminal balloon angioplasty, percutaneous; venous	G2	P3	P3
41530	Submucosal ablation of the tongue base, radiofrequency, one or more sites, per session	G2	P2	P2
69801	Labyrinthotomy, with or without cryosurgery including other nonexcisional destructive procedures or perfusion of vestibuloactive drugs (single or multiple perfusions); transcanal	G2	P3	P3

*Payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the MPFS final rates. At the time this final rule with comment period is being finalized for publication, current law authorizes a negative update to the MPFS payment rates for CY 2012. Therefore, this final rule with comment period reflects a negative update to the MPFS payment rates for CY 2012. If Congress revises the MPFS update for CY 2012, we will recalculate the ASC payment rates using the revised update factor in the January 2012 payment rate files issued to contractors.

BILLING CODE 4120–01–C

We also reviewed CY 2010 volume and utilization data and other information for the 23 procedures finalized for temporary office-based status in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72036 through 72038). Among these 23 procedures, there were very few claims data for eight procedures: CPT code 0099T (Implantation of intrastromal corneal ring segments); CPT code 0124T (Conjunctival incision with posterior extrascleral placement of pharmacological agent (does not include supply of medication)); CPT code 0226T (Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); diagnostic, including collection of specimen(s) by brushing or washing when performed); CPT code 0227T (Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); with biopsy(ies)); CPT code 0232T (Injection(s), platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed); CPT code C9800 (Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies); CPT code 37761 (Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg); and CPT code 67229 (Treatment of extensive or progressive retinopathy, one or more sessions; preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (eg, retinopathy of prematurity), photocoagulation or cryotherapy). Consequently, we proposed in the CY 2012 OPPS/ASC proposed rule (76 FR 42294) to maintain their temporary office-based designations for CY 2012.

As a result of our review of the remaining 15 procedures that have temporary office-based designations for CY 2011 for which we do have claims data, we proposed that none of the procedures be designated as office-based in CY 2012. The 15 surgical procedure codes are:

- CPT code 21015 (Radical resection of tumor (eg, malignant neoplasm), soft tissue of face or scalp; less than 2 cm);
- CPT code 21555 (Excision, tumor, soft tissue of neck or anterior thorax, subcutaneous; less than 3 cm);
- CPT code 21930 (Excision, tumor, soft tissue of back or flank, subcutaneous; less than 3 cm);
- CPT code 23075 (Excision, tumor, soft tissue of shoulder area, subcutaneous; less than 3 cm);
- CPT code 24075 (Excision, tumor, soft tissue of upper arm or elbow area, subcutaneous; less than 3 cm);
- CPT code 25075 (Excision, tumor, soft tissue of forearm and/or wrist area, subcutaneous; less than 3 cm);
- CPT code 26115 (Excision, tumor or vascular malformation, soft tissue of hand or finger, subcutaneous; less than 1.5 cm);

- CPT code 27047 (Excision, tumor, soft tissue of pelvis and hip area, subcutaneous; less than 3 cm);
- CPT code 27327 (Excision, tumor, soft tissue of thigh or knee area, subcutaneous; less than 3 cm);
- CPT code 27618 (Excision, tumor, soft tissue of leg or ankle area, subcutaneous; less than 3 cm);
- CPT code 28039 (Excision, tumor, soft tissue of foot or toe, subcutaneous; 1.5 cm or greater);
- CPT code 28041 (Excision, tumor, soft tissue of foot or toe, subfascial (eg, intramuscular); 1.5 cm or greater);
- CPT code 28043 (Excision, tumor, soft tissue of foot or toe, subcutaneous; less than 1.5 cm);
- CPT code 28045 (Excision, tumor, soft tissue of foot or toe, subfascial (eg, intramuscular); less than 1.5 cm); and
- CPT code 28046 (Radical resection of tumor (eg, malignant neoplasm), soft tissue of foot or toe; less than 3 cm).

The volume and utilization data for these CPT codes are sufficient to indicate that these procedures are not performed predominantly in physicians' offices and, therefore, should not be assigned an office-based payment indicator in CY 2012.

The CY 2012 payment indicator designations that we proposed for the 23 procedures that were temporarily designated as office-based in CY 2011 were displayed in Table 46 of the CY 2012 OPPS/ASC proposed rule (76 FR 42295). The procedures for which the proposed office-based designations for CY 2012 are temporary also were indicated by asterisks in Addendum AA to the proposed rule (which was available via the Internet on the CMS Web site).

We did not receive any public comments that addressed our proposal to continue to designate the eight procedures listed in Table 46 of the CY 2012 OPPS/ASC proposed rule (76 FR 42294) as temporarily office-based for CY 2012. Therefore, we are finalizing our proposal to designate the eight procedures listed in Table 46 of the CY 2012 OPPS/ASC proposed rule and restated in Table 54 below, which were designated as temporarily office-based for CY 2011, as temporarily office-based for CY 2012. In addition, we did not receive any public comments that addressed our proposal to not designate any of the remaining 15 procedures as office-based for CY 2012 that were listed in Table 46 of the CY 2012 OPPS/ASC proposed rule (76 FR 42295) and designated as temporarily office-based in CY 2011. Therefore, we are finalizing our proposal to not provide an office-based designation to the 15 procedures listed in Table 46 of the CY 2012 OPPS/ASC proposed rule, and restated below in Table 54, which were designated as temporarily office-based for CY 2011.

BILLING CODE 4120–01–P

TABLE 54.—CY 2012 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2011 OPPS/ASC FINAL RULE WITH COMMENT PERIOD

CY 2012 CPT Code	CY 2012 Long Descriptor	CY 2011 ASC Payment Indicator	CY 2012 ASC Payment Indicator**
21015	Radical resection of tumor (eg, malignant neoplasm), soft tissue of face or scalp; less than 2 cm)	R2*	G2
21555	Excision, tumor, soft tissue of neck or anterior thorax, subcutaneous; less than 3 cm	P3*	G2
21930	Excision, tumor, soft tissue of back or flank, subcutaneous; less than 3 cm	P3*	G2
23075	Excision, tumor, soft tissue of shoulder area, subcutaneous; less than 3 cm	P3*	G2
24075	Excision, tumor, soft tissue of upper arm or elbow area, subcutaneous; less than 3 cm	P3*	G2
25075	Excision, tumor, soft tissue of forearm and/or wrist area, subcutaneous; less than 3 cm	P3*	G2
26115	Excision, tumor or vascular malformation, soft tissue of hand or finger, subcutaneous; less than 1.5 cm	P3*	G2
27047	Excision, tumor, soft tissue of pelvis and hip area, subcutaneous; less than 3 cm	P3*	G2
27327	Excision, tumor, soft tissue of thigh or knee area, subcutaneous; less than 3 cm	P3*	G2
27618	Excision, tumor, soft tissue of leg or ankle area, subcutaneous; less than 3 cm	P3*	G2
28039	Excision, tumor, soft tissue of foot or toe, subcutaneous; 1.5 cm or greater	P3*	G2
28041	Excision, tumor, soft tissue of foot or toe, subfascial (eg, intramuscular); 1.5 cm or greater	R2*	G2
28043	Excision, tumor, soft tissue of foot or toe,	P3*	G2

CY 2012 CPT Code	CY 2012 Long Descriptor	CY 2011 ASC Payment Indicator	CY 2012 ASC Payment Indicator**
	subcutaneous; less than 1.5 cm		
28045	Excision, tumor, soft tissue of foot or toe, subfascial (eg, intramuscular); less than 1.5 cm	P3*	G2
28046	Radical resection of tumor (eg, malignant neoplasm), soft tissue of foot or toe; less than 3 cm	R2*	G2
37761	Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg	R2*	R2*
67229	Treatment of extensive or progressive retinopathy, one or more sessions; preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (eg, retinopathy of prematurity), photocoagulation or cryotherapy	R2*	R2*
0099T	Implantation of intrastromal corneal ring segments	R2*	R2*
0124T	Conjunctival incision with posterior extrascleral placement of pharmacological agent (does not include supply of medication)	R2*	R2*
0226T	Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); diagnostic, including collection of specimen(s) by brushing or washing when performed	R2*	R2*
0227T	Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); with biopsy(ies)	R2*	R2*
0232T	Injection(s), platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed	R2*	R2*

CY 2012 CPT Code	CY 2012 Long Descriptor	CY 2011 ASC Payment Indicator	CY 2012 ASC Payment Indicator**
C9800	Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies	R2*	R2*

* If designation is temporary.

**Payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the MPFS final rates. At the time this final rule with comment period is being finalized for publication, current law authorizes a negative update to the MPFS payment rates for CY 2012. Therefore, this final rule with comment period reflects a negative update to the MPFS payment rates for CY 2012. If Congress revises the MPFS update for CY 2012, we will recalculate the ASC payment rates using the revised update factor in the January 2012 payment rate files issued to contractors.

BILLING CODE 4120–01–C

c. ASC Covered Surgical Procedures Designated as Device-Intensive

(1) Background

As discussed in the August 2, 2007 final rule (72 FR 42503 through 42508), we adopted a modified payment methodology for calculating the ASC payment rates for covered surgical procedures that are assigned to the subset of OPPS device-dependent APCs with a device offset percentage greater than 50 percent of the APC cost under the OPPS, in order to ensure that payment for the procedure is adequate to provide packaged payment for the high-cost implantable devices used in those procedures. We assigned payment indicators ''H8'' (Device-intensive procedure on ASC list in CY 2007; paid at adjusted rate) and ''J8'' (Device-intensive procedure added to ASC list in CY 2008 or later; paid at adjusted rate) to identify the procedures that were eligible for ASC payment calculated according to the modified methodology, depending on whether the procedure was included on the ASC list of covered surgical procedures prior to CY 2008 and, therefore, subject to transitional payment as discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68739 through 68742).

As discussed in section XIII.F.2. of the CY 2012 OPPS/ASC proposed rule (76 FR 42309 and 42310), because the 4-year transition to the ASC payment rates under the standard methodology is complete and, therefore, identification of device-intensive procedures that are subject to transitional payment methodology is no longer necessary, we proposed to delete payment indicator ''H8'' (Device-intensive procedure on ASC list in CY 2007; paid at adjusted rate). We proposed that the device-intensive procedures for which the device-intensive payment methodology would apply in CY 2012 or later would be assigned payment indicator ''J8'' (Device-intensive procedure; paid at adjusted rate).

(2) Changes to List of Covered Surgical Procedures Designated as Device-Intensive for CY 2012

In the CY 2012 OPPS/ASC proposed rule (76 FR 42296), we proposed to update the ASC list of covered surgical procedures that are eligible for payment according to the device-intensive procedure payment methodology for CY 2012, consistent with the proposed OPPS device-dependent APC update, reflecting the proposed APC assignments of procedures, designation of APCs as device-dependent, and APC device offset percentages based on the CY 2010 OPPS claims and cost report data available for the proposed rule. The OPPS device-dependent APCs were discussed further in section II.A.2.d.(1) of the proposed rule (76 FR 42190 through 42191).

The ASC covered surgical procedures that we proposed to designate as device-intensive and that would be subject to the device-intensive procedure payment methodology for CY 2012 were listed in Table 47 of the CY 2012 OPPS/ASC proposed rule (76 FR 42296 through 42297). The CPT code, the CPT code short descriptor, the proposed CY 2012 ASC payment indicator, the proposed CY 2012 OPPS APC assignment and title, and the proposed CY 2012 OPPS APC device offset percentage were also listed in Table 47 of the proposed rule. All of these procedures were included in Addendum AA to the proposed rule (which was available via the Internet on the CMS Web site).

We invited public comments on these proposals.

Comment: Some commenters expressed the same general concerns made in prior rulemakings—that is concerns regarding the sufficiency of ASC payment for device-related services and recommended modifications to the ASC device-intensive payment methodology. The commenters argued that CMS should not apply the ASC conversion factor to the device-related portion of the payment for all procedures for which CMS can establish a median device cost, regardless of whether they are designated as device-intensive under the established methodology. In a related suggestion, the commenters urged CMS to lower the threshold used to determine device-intensive procedures stating that the designation of a device-intensive procedure based on whether the device portion of the cost is greater than 50 percent of the APC median cost excludes too many procedures from a reasonable modification to the standard ASC payment methodology. Commenters suggested that APCs with a device offset percentage greater than 23 percent of the APC median cost under the OPPS may be a more appropriate threshold to determine device-intensive procedures in ASCs. The commenters also made the same argument as made

in prior rulemakings—that CMS should not adjust the device portion of the ASC payment for device-intensive procedures by the wage index. According to the commenters, the acquisition of devices occurs on a national market, and the price is the same regardless of the location of the ASC. Commenters also suggested that application of device-intensive status should supersede the office-based designation. Commenters believed that CMS has misapplied its policy in a limited number of cases by designating a device-intensive procedure as office-based and setting the payment for the procedure at the physician fee schedule rate.

Response: In the August 2, 2007 final rule (72 FR 42504), we established that the modified payment methodology for calculating ASC payment rates for device-intensive procedures shall apply to ASC covered surgical procedures that are assigned to device-dependent APCs under the OPPS for the same calendar year, where those APCs have a device cost of greater than 50 percent of the APC cost (that is, the device offset percentage is greater than 50). We continue to believe these criteria ensure that ASC payment rates are adequate to provide packaged payment for high cost implantable devices and ensure Medicare beneficiaries have access to these procedures in all appropriate settings of care.

As we have stated in the past, we do not agree that we should change our criteria and treat device-intensive services that are assigned to APCs for which the device offset percentage is less than 50 percent or ASC services that are not assigned to device-dependent APCs and we continue to believe that when device costs comprise less than 50 percent of total procedure costs, those costs are less likely to be as predictable across sites-of-service. Accordingly, we believe that it is possible for ASCs to achieve efficiencies relative to HOPDs when providing those procedures, and that the application of the ASC conversion factor to the entire ASC payment weight is appropriate. We refer readers to our response to this comment in final rules with comment period from prior years: 74 FR 60608 and 60609; 75 FR 72039.

We also continue to believe it would not be appropriate to vary the portion of the national payment that is wage adjusted for different services, such as applying the wage index only to the service portion of the ASC payment for device-intensive procedures, as the commenters requested. Consistent with the OPPS, we apply the ASC geographic wage adjustment to the entire ASC payment rate for device-intensive procedures. We refer readers to our response to this comment in final rules with comment period from prior years: 73 FR 68735; 74 FR 60608 and 60609; 75 FR 72039.

As we have noted in the past (73 FR 68735; 74 FR 60609; 75 FR 72039), MedPAC has indicated its intent to evaluate CMS' method for adjusting payments for variations in labor costs in light of differences in labor-related costs for device-implantation services. We look forward to reviewing the results of its evaluation, as well as any recommendations it may provide, regarding the OPPS or ASC wage adjustment policy.

Although the commenter suggested that CMS has applied the office-based payment methodology to procedures that have been designated as device-intensive, the commenter did not provide examples where this situation has occurred. If a device-intensive procedure were to meet the criteria for the office-based payment methodology, we note that the designation of a procedure as device-intensive does supersede the office-based designation when setting the ASC payment rates. We have reviewed all procedures that are on the ASC list of covered services, are in device-dependent APCs, and have device offset percentages greater than 50 percent and have ensured that all of these device-intensive procedures have a payment indicator of ''J8.''

Comment: One commenter expressed appreciation for the proposed increase in payment rates calculated according to the ASC device-intensive payment methodology for procedures involving auditory osseointegrated devices. However, the commenter indicated that the proposed payment rates remain insufficient for covering ASCs' costs for providing the procedures and requested that CMS further increase these rates for CY 2012. The commenter believed that the rates might have a negative impact on the availability of these services in an ASC setting and therefore might limit patient access.

Response: We appreciate the commenter's support of the proposed payment rates for procedures involving auditory osseointegrated devices, but we disagree with the commenters' assertion that we should increase payment rates for these procedures further in order to maintain beneficiary access. We believe that the final CY 2012 ASC payment rates for these procedures, calculated according to the ASC device-intensive ratesetting methodology, are appropriate and adequate to cover costs for providing the procedures and to ensure beneficiaries have access to these procedures in the ASC setting.

After consideration of the public comments we received, we are designating the ASC covered surgical procedures displayed in Table 55 below as device-intensive for CY 2012. The CPT code, the CPT code short descriptor, the final CY 2012 ASC payment indicator, the final CY 2012 OPPS APC assignment, the CY 2012 OPPS APC Title, and the final CY 2012 device-dependent APC offset percentage are listed in Table 55. As we discuss in section XIII.B.3. of the CY 2012 OPPS/ASC proposed rule (76 FR 42293) and this final rule with comment period, we incorporate new Category I and Category III CPT codes and new Level II HCPCS codes that are effective October 1, 2011 and January 1, 2012 in this final rule with comment period. Because these codes were not available to us until after the CY 2012 OPPS/ASC proposed rule was published, these codes were not included in that rule. We have reviewed these new codes and have added twelve of these CPT codes to Table 55 because they are ASC covered surgical procedures and are assigned to device-dependent APCs that meet the ASC device-intensive criteria. It is also our standard methodology to review deleted CPT codes annually and remove them from all relevant tables in the OPPS/ASC final rule with comment period. Therefore, we have also removed CPT codes 64560 (percutaneous implantation of neurostimulator electrodes; autonomic nerve) and 64577 (Incision for implantation of neurostimulator electrodes; autonomic nerve) because these CPT codes have been deleted for CY 2012. Each device-intensive procedure is assigned payment indicator ''J8.'' All of these procedures are included in Addendum AA to this final rule with comment period (which is available via the Internet on the CMS Web site). The OPPS device-dependent APCs are discussed further in section II.A.2.d.(1) of this final rule with comment period.

BILLING CODE 4120–01–P

TABLE 55.—ASC COVERED SURGICAL PROCEDURES DESIGNATED AS DEVICE-INTENSIVE FOR CY 2012

CPT Code	Short Descriptor	Final CY 2012 ASC Payment Indicator	Final CY 2012 OPPS APC	CY 2012 OPPS APC Title	Final CY 2012 Device-Dependent APC Offset Percentage
0282T	Periph field stimul trial	J8	0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes	55%
0283T	Periph field stimul perm	J8	0318	Implantation of Cranial Neurostimulator Pulse Generator and Electrode	86%
24361	Reconstruct elbow joint	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	61%
24363	Replace elbow joint	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	61%
24366	Reconstruct head of radius	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	61%
25441	Reconstruct wrist joint	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	61%
25442	Reconstruct wrist joint	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	61%
25446	Wrist replacement	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	61%
27446	Revision of knee joint	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	61%

CPT Code	Short Descriptor	Final CY 2012 ASC Payment Indicator	Final CY 2012 OPPS APC	CY 2012 OPPS APC Title	Final CY 2012 Device-Dependent APC Offset Percentage
33206	Insertion of heart pacemaker	J8	0089	Insertion/Replacement of Permanent Pacemaker and Electrodes	71%
33207	Insertion of heart pacemaker	J8	0089	Insertion/Replacement of Permanent Pacemaker and Electrodes	71%
33208	Insertion of heart pacemaker	J8	0655	Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing Electrode	74%
33212	Insertion of pulse generator	J8	0090	Insertion/Replacement of Pacemaker Pulse Generator	73%
33213	Insertion of pulse generator	J8	0654	Insertion/Replacement of a Permanent Dual Chamber Pacemaker	75%
33214	Upgrade of pacemaker system	J8	0655	Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing Electrode	74%
33221	Insert pulse gen mult leads	J8	0654	Level II Insertion/Replacement of Permanent Pacemaker	75%
33224	Insert pacing lead & connect	J8	0655	Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing Electrode	74%
33225	Lventric pacing lead add-on	J8	0655	Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing Electrode	74%

CPT Code	Short Descriptor	Final CY 2012 ASC Payment Indicator	Final CY 2012 OPPS APC	CY 2012 OPPS APC Title	Final CY 2012 Device-Dependent APC Offset Percentage
33227	Remove&replace pm gen singl	J8	0090	Insertion/Replacement of Pacemaker Pulse Generator	73%
33228	Remv&repl c pm gen dual lead	J8	0654	Level II Insertion/Replacement of Permanent Pacemaker	75%
33229	Remv&repl c pm gen mult leads	J8	0654	Level II Insertion/Replacement of Permanent Pacemaker	75%
33230	Insrt pulse gen w/dual leads	J8	0107	Insertion of Cardioverter-Defibrillator Pulse Generator	89%
33231	Insrt pulse gen w/dual leads	J8	0107	Insertion of Cardioverter-Defibrillator Pulse Generator	89%
33240	Insert pulse generator	J8	0107	Insertion of Cardioverter-Defibrillator	89%
33249	Eltrd/insert pace-defib	J8	0108	Insertion/Replacement/Repair of AICD Leads, Generator, and Pacing Electrodes	87%
33262	Remv&repl c cvd gen sing lead	J8	0107	Insertion of Cardioverter-Defibrillator Pulse Generator	89%
33263	Remv&repl c cvd gen dual lead	J8	0107	Insertion of Cardioverter-Defibrillator Pulse Generator	89%
33264	Remv&repl c cvd gen mult lead	J8	0107	Insertion of Cardioverter-Defibrillator Pulse Generator	89%

CPT Code	Short Descriptor	Final CY 2012 ASC Payment Indicator	Final CY 2012 OPPS APC	CY 2012 OPPS APC Title	Final CY 2012 Device-Dependent APC Offset Percentage
33282	Implant pat-active ht record	J8	0680	Insertion of Patient Activated Event Recorders	73%
53440	Male sling procedure	J8	0385	Level I Prosthetic Urological Procedures	61%
53444	Insert tandem cuff	J8	0385	Level I Prosthetic Urological Procedures	61%
53445	Insert uro/ves nck sphincter	J8	0386	Level II Prosthetic Urological Procedures	71%
53447	Remove/replace ur sphincter	J8	0386	Level II Prosthetic Urological Procedures	71%
54400	Insert semi-rigid prosthesis	J8	0385	Level I Prosthetic Urological Procedures	61%
54401	Insert self-contd prosthesis	J8	0386	Level II Prosthetic Urological Procedures	71%
54405	Insert multi-comp penis pros	J8	0386	Level II Prosthetic Urological Procedures	71%
54410	Remove/replace penis prosth	J8	0386	Level II Prosthetic Urological Procedures	71%
54416	Remv/repl penis contain pros	J8	0386	Level II Prosthetic Urological Procedures	71%
55873	Cryoablate prostate	J8	0674	Prostate Cryoablation	59%

CPT Code	Short Descriptor	Final CY 2012 ASC Payment Indicator	Final CY 2012 OPPS APC	CY 2012 OPPS APC Title	Final CY 2012 Device-Dependent APC Offset Percentage
61885	Insrt/redo neurostim 1 array	J8	0039	Level I Implantation of Neurostimulator Generator	86%
61886	Implant neurostim arrays	J8	0315	Level II Implantation of Neurostimulator Generator	88%
62361	Implant spine infusion pump	J8	0227	Implantation of Drug Infusion Device	81%
62362	Implant spine infusion pump	J8	0227	Implantation of Drug Infusion Device	81%
63650	Implant neuroelectrodes	J8	0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes	55%
63655	Implant neuro-electrodes	J8	0061	Level II Implantation/Revision/Replacement of Neurostimulator Electrodes	64%
63663	Revise spine eltrd perq aray	J8	0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes	55%
63664	Revise spine eltrd plate	J8	0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes	55%

CPT Code	Short Descriptor	Final CY 2012 ASC Payment Indicator	Final CY 2012 OPPS APC	CY 2012 OPPS APC Title	Final CY 2012 Device-Dependent APC Offset Percentage
63685	Insrt/redo spine n generator	J8	0039	Level I Implantation of Neurostimulator Generator	86%
64553	Implant neuro-electrodes	J8	0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes	55%
64555	Implant neuro-electrodes	J8	0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes	55%
64561	Implant neuro-electrodes	J8	0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes	55%
64565	Implant neuro-electrodes	J8	0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes	55%
64568	Implant neuro-electrodes	J8	0318	Implantation of Cranial Neurostimulator Pulse Generator and Electrode	86%
64575	Implant neuro-electrodes	J8	0061	Level II Implantation/Revision/Replacement of Neurostimulator Electrodes	64%
64580	Implant neuro-electrodes	J8	0061	Level II Implantation/Revision/Replacement of Neurostimulator Electrodes	64%

CPT Code	Short Descriptor	Final CY 2012 ASC Payment Indicator	Final CY 2012 OPPS APC	CY 2012 OPPS APC Title	Final CY 2012 Device-Dependent APC Offset Percentage
64581	Implant neuro-electrodes	J8	0061	Level II Implantation/Revision/Replacement of Neurostimulator Electrodes	64%
64590	Insrt/redo pn/gastr stimul	J8	0039	Level I Implantation of Neurostimulator Generator	85%
65770	Revise cornea with implant	J8	0293	Level VI Anterior Segment Eye Procedures	66%
69714	Implant temple bone w/stimul	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	61%
69715	Temple bne implnt w/stimulat	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	61%
69717	Temple bone implant revision	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	61%
69718	Revise temple bone implant	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	61%
69930	Implant cochlear device	J8	0259	Level VII ENT Procedures	84%
G0448	Place perm pacing cardiovert	J8	0108	Insertion/Replacement/Repair of AICD Leads, Generator, and Pacing Electrodes	87%

BILLING CODE 4120–01–C

d. ASC Treatment of Surgical Procedures Removed From the OPPS Inpatient List for CY 2012

As we discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68724), we adopted a policy to include in our annual evaluation of the ASC list of covered surgical procedures, a review of the procedures that are being proposed for removal from the OPPS inpatient list for possible inclusion on the ASC list of covered surgical procedures. For the CY 2012 OPPS/ASC proposed rule, we evaluated each of the three procedures we proposed to remove from the OPPS inpatient list for CY 2012 according to the criteria for exclusion from the list of covered ASC surgical procedures (76 FR

42298). We stated in the CY 2012 OPPS/ASC proposed rule (76 FR 42298) that we believe that these three procedures should continue to be excluded from the ASC list of covered surgical procedures for CY 2012 because they would be expected to pose a significant risk to beneficiary safety or to require an overnight stay in ASCs. A full discussion about the APC Panel's recommendations regarding the procedures we proposed to remove from the OPPS inpatient list for CY 2012 may be found in section IX.B. of the CY 2012 OPPS/ASC proposed rule (76 FR 42276 and 42277). The CPT codes for these three procedures and their long descriptors were listed in Table 48 of the CY 2012 OPPS/ASC proposed rule (76 FR 42298).

We did not receive any public comments regarding the procedures proposed for exclusion from the ASC list of covered procedures for CY 2012, that were proposed for removal from the CY 2012 OPPS inpatient list. Therefore, we are finalizing our proposal, without modification, to continue to exclude the procedures described by the CPT codes listed in Table 48 of the CY 2012 OPPS/ASC proposed rule, and restated in Table 56 below, from the ASC list of covered surgical procedures.

TABLE 56.—PROCEDURES EXCLUDED FROM THE ASC LIST OF COVERED PROCEDURES FOR CY 2012 THAT WERE REMOVED FROM THE CY 2012 OPPS INPATIENT LIST

CPT Code	Long Descriptor
21346	Open treatment of nasomaxillary complex fracture (Lefort II type); with wiring and/or local fixation
35045	Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for aneurysm, pseudoaneurysm, and associated occlusive disease, radial or ulnar artery
54650	Orchiopexy, abdominal approach, for intra-abdominal testis (eg, Fowler-Stephens)

2. Covered Ancillary Services

Consistent with the established ASC payment system policy, in the CY 2012 OPPS/ASC proposed rule (76 FR 42298), we proposed to update the ASC list of covered ancillary services to reflect the proposed payment status for the services under the CY 2012 OPPS. Maintaining consistency with the OPPS may result in proposed changes to ASC payment indicators for some covered ancillary items and services because of changes that are being proposed under the OPPS for CY 2012. For example, a covered ancillary service that was separately paid under the revised ASC payment system in CY 2011 may be proposed for packaged status under the CY 2012 OPPS and, therefore, also under the ASC payment system for CY 2012. Comment indicator ''CH,'' discussed in section XIII.F. of the CY 2012 OPPS/ASC proposed rule (76 FR 42309), was used in Addendum BB to that proposed rule (which is available via the Internet on the CMS Web site) to indicate covered ancillary services for which we proposed a change in the ASC payment indicator to reflect a proposed change in the OPPS treatment of the service for CY 2012.

Except for the Level II HCPCS codes listed in Table 43 of the CY 2012 OPPS/ASC proposed rule (76 FR 42292), all ASC covered ancillary services and their proposed payment indicators for CY 2012 were included in Addendum BB to that proposed rule.

We did not receive any public comments on our proposal. Therefore, we are finalizing, without modification, our proposal to update the ASC list of covered ancillary services to reflect the payment status for the services under the OPPS. All CY 2012 ASC covered ancillary services and their final payment indicators are included in Addendum BB to this final rule with comment period (which is available via the Internet on the CMS Web site).

D. ASC Payment for Covered Surgical Procedures and Covered Ancillary Services

1. Payment for Covered Surgical Procedures

a. Background

Our ASC payment policies for covered surgical procedures under the revised ASC payment system are fully described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831). Under our established policy for the revised ASC payment system, the ASC standard ratesetting methodology of multiplying the ASC relative payment weight for the procedure by the ASC conversion factor for that same year is used to calculate the national unadjusted payment rates for procedures with payment indicator ''G2.'' For procedures assigned payment indicator ''A2,'' our final policy established blended rates to be used during the transitional period and, beginning in CY 2011, ASC rates calculated according to the ASC standard ratesetting methodology. The rate calculation established for device-intensive procedures (payment indicator ''J8'') is structured so that the packaged device payment amount is the same as under the OPPS, and only the service portion of the rate is subject to the ASC standard ratesetting methodology. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72024 through 72064), we updated the CY 2010 ASC payment rates for ASC covered surgical procedures with payment indicators of ''A2,'' ''G2,'' ''H8,'' and ''J8'' using CY 2009 data, consistent with the CY 2011 OPPS update. Payment rates for device-intensive procedures also were updated to incorporate the CY 2011 OPPS device

offset percentages. Because transitional payments were no longer required in CY 2011, we calculated CY 2011 payments for procedures formerly subject to the transitional payment methodology (payment indicators ''A2'' and ''H8'') using the standard rate setting methodology, incorporating the device-intensive methodology, as appropriate.

Payment rates for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') are the lower of the MPFS nonfacility PE RVU-based amount (we refer readers to the CY 2012 MPFS final rule with comment period) or the amount calculated using the ASC standard ratesetting methodology for the procedure. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72024 through 72064), we updated the payment amounts for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') using the most recent available MPFS and OPPS data. We compared the estimated CY 2011 rate for each of the office-based procedures, calculated according to the ASC standard ratesetting methodology, to the MPFS nonfacility PE RVU-based amount to determine which was lower and, therefore, would be the CY 2011 payment rate for the procedure according to the final policy of the revised ASC payment system (§ 416.171(d)).

b. Update to ASC-Covered Surgical Procedure Payment Rates for CY 2012

In the CY 2012 OPPS/ASC proposed rule (76 FR 42298 and 42299), we proposed to update ASC payment rates for CY 2012 using the established rate calculation methodologies under § 416.171. Under § 416.171(c)(4), the transitional payment rates are no longer used for CY 2011 and subsequent calendar years for a covered surgical procedure designated in accordance with § 416.166. Thus, we proposed to calculate CY 2012 payments for procedures formerly subject to the transitional payment methodology (payment indicators ''A2'' and ''H8'') using the proposed CY 2012 ASC rate calculated according to the ASC standard ratesetting methodology, incorporating the device-intensive procedure methodology, as appropriate. We proposed to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicator ''G2.'' We proposed to modify or delete the payment indicators for procedures that were subject to transitional payment prior to CY 2011 (we refer readers to our discussion in section XIII.F.2. of the proposed rule (76 FR 42309 through 42310).

We proposed that payment rates for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') and device-intensive procedures that were not subject to transitional payment (payment indicator ''J8'') be calculated according to our established policies, incorporating the device-intensive procedure methodology as appropriate. Thus, we proposed to update the payment amounts for device-intensive procedures based on the CY 2012 OPPS proposal that reflects updated OPPS device offset percentages, and to make payment for office-based procedures at the lesser of the proposed CY 2012 MPFS nonfacility PE RVU-based amount or the proposed CY 2012 ASC payment amount calculated according to the standard ratesetting methodology.

We did not receive any comments on our proposal to calculate CY 2012 payment rates for ASC-covered surgical procedures according to our established methodologies. Therefore, we are finalizing our CY 2012 proposal, without modification, to calculate the CY 2012 final ASC payment rates for ASC-covered surgical procedures according to our established methodologies.

c. Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

Our ASC policy with regard to payment for costly devices implanted in ASCs at no cost/full credit or partial credit as set forth in § 416.179 is consistent with the OPPS policy. The proposed CY 2012 OPPS APCs and devices subject to the adjustment policy are discussed in section IV.B.2. of the proposed rule and this final rule with comment period. The established ASC policy includes adoption of the OPPS policy for reduced payment to providers when a specified device is furnished without cost/full credit or partial credit for the cost of the device for those ASC covered surgical procedures that are assigned to APCs under the OPPS to which this policy applies. We refer readers to the CY 2009 OPPS/ASC final rule with comment period for a full discussion of the ASC payment adjustment policy for no cost/full credit and partial credit devices (73 FR 68742 through 68745).

In the CY 2012 OPPS/ASC proposed rule (76 FR 42299 through 42301), consistent with the OPPS, we proposed to update the list of ASC covered device-intensive procedures and devices that would be subject to the no cost/full credit and partial credit device adjustment policy for CY 2012. Table 49 of the CY 2012 OPPS/ASC proposed rule (76 FR 42299 through 42301) displayed the ASC covered device-intensive procedures that we proposed would be subject to the no cost/full credit or partial credit device adjustment policy for CY 2012. Specifically, when a procedure that is listed in Table 49 is performed to implant a device that is listed in Table 50 of the CY 2012 OPPS/ASC proposed rule (76 FR 42301), where that device is furnished at no cost or with full credit from the manufacturer, the ASC would append the HCPCS ''FB'' modifier on the line with the procedure to implant the device. The contractor would reduce payment to the ASC by the device offset amount that we estimate represents the cost of the device when the necessary device is furnished without cost to the ASC or with full credit. We would provide the same amount of payment reduction based on the device offset amount in ASCs that would apply under the OPPS under the same circumstances. We stated in the CY 2012 OPPS/ASC proposed rule (76 FR 42299) that we continue to believe that the reduction of ASC payment in these circumstances is necessary to pay appropriately for the covered surgical procedure being furnished by the ASC.

We also proposed to reduce the payment for implantation procedures listed in Table 49 of the CY 2012 OPPS/ASC proposed rule (76 FR 42299 through 42301) by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more of the cost of the new device. The ASC would append the HCPCS ''FC'' modifier to the HCPCS code for a surgical procedure listed in Table 49 when the facility receives a partial credit of 50 percent or more of the cost of a device listed in Table 50 of the proposed rule (76 FR 42301). In order to report that they received a partial credit of 50 percent or more of the cost of a new device, ASCs would have the option of either: (1) Submitting the claim for the device replacement procedure to their Medicare contractor after the procedure's performance but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment once the credit determination is made; or (2) holding the claim for the device implantation procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the ''FC'' modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more of the cost of the replacement device. Beneficiary

coinsurance would continue to be based on the reduced payment amount.

We did not receive any comments on our CY 2012 proposal to continue the no cost/full credit and partial credit device adjustment policy for ASCs. For CY 2012, as we proposed, we will reduce the payment for the device implantation procedures listed in Table 57, below, by the full device offset amount for no cost/full credit cases. ASCs must append the modifier ''FB'' to the HCPCS procedure code when the device furnished without cost or with full credit is listed in Table 58, below, and the associated implantation procedure code is listed in Table 57. In addition, for CY 2012, we will reduce the payment for implantation procedures listed in Table 57 by one half of the device offset amount if a device is provided with partial credit, if the credit to the ASC is 50 percent or more of the device cost. If the ASC receives a partial credit of 50 percent or more of the cost of a device listed in Table 58, the ASC must append the modifier ''FC'' to the associated implantation procedure code if the procedure is listed in Table 57.

As we discuss in section XIII.B.3. of the CY 2012 OPPS/ASC proposed rule (76 FR 42293) and this final rule with comment period, we incorporate new Category I and Category III CPT codes and new Level II HCPCS codes that are effective October 1, 2011 and January 1, 2012 in this final rule with comment period. Because these codes were not available to us until after the CY 2012 OPPS/ASC proposed rule was published, these codes were not included in that rule. We have reviewed these new codes and have added eleven of these CPT codes to Table 57 because they are ASC covered surgical procedures that are assigned to APCs under the OPPS to which the no cost/full credit and partial credit device adjustment policy applies. It is also our standard methodology to review deleted CPT codes annually and remove them from all relevant tables in the OPPS/ASC final rule with comment period. Therefore, we have also removed CPT codes 64560 (Percutaneous implantation of neurostimulator electrodes; autonomic nerve) and 64577 (Incision for implantation of neurostimulator electrodes; autonomic nerve) because these CPT codes have been deleted for CY 2012. We also have added two device HCPCS codes to Table 58, C1777 (Lead, cardioverter-defibrillator, endocardial single coil (implantable)) and C1895 (Lead, cardioverter-defibrillator, endocardial dual coil (implantable)) because these devices are now associated with CPT code 33249 (Insertion or replacement of permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber) due to a descriptor change effective January 1, 2012.

BILLING CODE 4120–01–P

TABLE 57.—CY 2012 PROCEDURES TO WHICH THE NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE ADJUSTMENT POLICY APPLIES

CPT Code	Short Descriptor	Final CY 2012 ASC Payment Indicator	Final CY 2012 OPPS APC	OPPS APC Title	Final CY 2012 OPPS Full APC Offset Percentage	Final CY 2012 OPPS Partial APC Offset Percentage
0282T	Periph field stimul trial	J8	0040	Level I Implantation/Revision/ Replacement of Neurostimulator Electrodes	55%	28%
0283T	Periph field stimul perm	J8	0318	Implantation of Cranial Neurostimulator Pulse Generator and Electrode	86%	43%
24361	Reconstruct elbow joint	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	61%	31%
24363	Replace elbow joint	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	61%	31%
24366	Reconstruct head of radius	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	61%	31%
25441	Reconstruct wrist joint	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	61%	31%
25442	Reconstruct wrist joint	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	61%	31%
25446	Wrist replacement	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	61%	31%
27446	Revision of knee joint	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	61%	31%
33206	Insertion of heart pacemaker	J8	0089	Insertion/Replacement of Permanent Pacemaker and Electrodes	71%	36%

CPT Code	Short Descriptor	Final CY 2012 ASC Payment Indicator	Final CY 2012 OPPS APC	OPPS APC Title	Final CY 2012 OPPS Full APC Offset Percentage	Final CY 2012 OPPS Partial APC Offset Percentage
33207	Insertion of heart pacemaker	J8	0089	Insertion/Replacement of Permanent Pacemaker and Electrodes	71%	36%
33208	Insertion of heart pacemaker	J8	0655	Insertion/Replacement /Conversion of a Permanent Dual Chamber Pacemaker or Pacing Electrode	74%	37%
33212	Insertion of pulse generator	J8	0090	Insertion/Replacement of Pacemaker Pulse Generator	73%	37%
33213	Insertion of pulse generator	J8	0654	Level II Insertion/Replacement of Permanent Pacemaker	75%	37%
33214	Upgrade of pacemaker system	J8	0655	Insertion/Replacement /Conversion of a Permanent Dual Chamber Pacemaker or Pacing Electrode	73%	37%
33221	Insert pulse gen mult leads	J8	0654	Level II Insertion/Replacement of Permanent Pacemaker	75%	37%
33224	Insert pacing lead & connect	J8	0655	Insertion/Replacement /Conversion of a Permanent Dual Chamber Pacemaker or Pacing Electrode	73%	37%
33225	Lventric pacing lead add-on	J8	0655	Insertion/Replacement /Conversion of a Permanent Dual Chamber Pacemaker or Pacing Electrode	73%	37%
33227	Remove&repla ce pm gen singl	J8	0090	Insertion/Replacement of Pacemaker Pulse Generator	73%	37%

CPT Code	Short Descriptor	Final CY 2012 ASC Payment Indicator	Final CY 2012 OPPS APC	OPPS APC Title	Final CY 2012 OPPS Full APC Offset Percentage	Final CY 2012 OPPS Partial APC Offset Percentage
33228	Remv&replc pm gen dual lead	J8	0654	Level II Insertion/Replacement of Permanent Pacemaker	75%	37%
33229	Remv&replc pm gen mult leads	J8	0654	Level II Insertion/Replacement of Permanent Pacemaker	75%	37%
33230	Insrt pulse gen w/dual leads	J8	0107	Insertion of Cardioverter-Defibrillator Pulse Generator	89%	45%
33231	Insrt pulse gen w/mult leads	J8	0107	Insertion of Cardioverter-Defibrillator Pulse Generator	89%	45%
33240	Insert pulse generator	J8	0107	Insertion of Cardioverter-Defibrillator Pulse Generator	89%	45%
33249	Eltrd/insert pace-defib	J8	0108	Insertion/Replacement /Repair of AICD Leads, Generator, and Pacing Electrodes	87%	43%
33262	Remv&replc cvd gen sing lead	J8	0107	Insertion of Cardioverter-Defibrillator Pulse Generator	89%	45%
33263	Remv&replc cvd gen dual lead	J8	0107	Insertion of Cardioverter-Defibrillator Pulse Generator	89%	45%
33264	Remv&replc cvd gen mult lead	J8	0107	Insertion of Cardioverter-Defibrillator Pulse Generator	89%	45%
33282	Implant pat-active ht record	J8	0680	Insertion of Patient Activated Event Recorders	73%	36%

CPT Code	Short Descriptor	Final CY 2012 ASC Payment Indicator	Final CY 2012 OPPS APC	OPPS APC Title	Final CY 2012 OPPS Full APC Offset Percentage	Final CY 2012 OPPS Partial APC Offset Percentage
53440	Male sling procedure	J8	0385	Level I Prosthetic Urological Procedures	61%	31%
53444	Insert tandem cuff	J8	0385	Level I Prosthetic Urological Procedures	61%	31%
53445	Insert uro/ves nck sphincter	J8	0386	Level II Prosthetic Urological Procedures	71%	35%
53447	Remove/replac e ur sphincter	J8	0386	Level II Prosthetic Urological Procedures	71%	35%
54400	Insert semi-rigid prosthesis	J8	0385	Level I Prosthetic Urological Procedures	61%	31%
54401	Insert self-contd prosthesis	J8	0386	Level II Prosthetic Urological Procedures	71%	35%
54405	Insert multi-comp penis pros	J8	0386	Level II Prosthetic Urological Procedures	71%	35%
54410	Remove/replac e penis prosth	J8	0386	Level II Prosthetic Urological Procedures	71%	35%
54416	Remv/repl penis contain pros	J8	0386	Level II Prosthetic Urological Procedures	71%	35%
61885	Insrt/redo neurostim 1 array	J8	0039	Level I Implantation of Neurostimulator Generator	86%	43%
61886	Implant neurostim arrays	J8	0315	Level II Implantation of Neurostimulator Generator	88%	44%
62361	Implant spine infusion pump	J8	0227	Implantation of Drug Infusion Device	81%	41%
62362	Implant spine infusion pump	J8	0227	Implantation of Drug Infusion Device	81%	41%
63650	Implant neuroelectrodes	J8	0040	Level I Implantation/Revision/ Replacement of Neurostimulator Electrodes	55%	28%

CPT Code	Short Descriptor	Final CY 2012 ASC Payment Indicator	Final CY 2012 OPPS APC	OPPS APC Title	Final CY 2012 OPPS Full APC Offset Percentage	Final CY 2012 OPPS Partial APC Offset Percentage
63655	Implant neuroelectrodes	J8	0061	Level II Implantation/Revision/ Replacement of Neurostimulator Electrodes	64%	32%
63663	Revise spine eltrd perq aray	J8	0040	Level I Implantation/Revision/ Replacement of Neurostimulator Electrodes	55%	28%
63664	Revise spine eltrd plate	J8	0040	Level I Implantation/Revision/ Replacement of Neurostimulator Electrodes	55%	28%
63685	Insrt/redo spine n generator	J8	0039	Level I Implantation of Neurostimulator Generator	86%	43%
64553	Implant neuroelectrodes	J8	0040	Level I Implantation/Revision/ Replacement of Neurostimulator Electrodes	55%	28%
64555	Implant neuroelectrodes	J8	0040	Level I Implantation/Revision/ Replacement of Neurostimulator Electrodes	55%	28%
64561	Implant neuroelectrodes	J8	0040	Level I Implantation/Revision/ Replacement of Neurostimulator Electrodes	55%	28%
64565	Implant neuroelectrodes	J8	0040	Level I Implantation/Revision/ Replacement of Neurostimulator Electrodes	55%	28%

CPT Code	Short Descriptor	Final CY 2012 ASC Payment Indicator	Final CY 2012 OPPS APC	OPPS APC Title	Final CY 2012 OPPS Full APC Offset Percentage	Final CY 2012 OPPS Partial APC Offset Percentage
64568	Implant neuroelectrodes	J8	0318	Implantation of Cranial Neurostimulator Pulse Generator and Electrode	86%	43%
64575	Implant neuroelectrodes	J8	0061	Level II Implantation/Revision/ Replacement of Neurostimulator Electrodes	64%	32%
64580	Implant neuroelectrodes	J8	0061	Level II Implantation/Revision/ Replacement of Neurostimulator Electrodes	64%	32%
64581	Implant neuroelectrodes	J8	0061	Level II Implantation/Revision/ Replacement of Neurostimulator Electrodes	64%	32%
64590	Insrt/redo pn/gastr stimul	J8	0039	Level I Implantation of Neurostimulator Generator	86%	43%
69714	Implant temple bone w/stimul	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	61%	31%
69715	Temple bne implnt w/stimulat	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	61%	31%
69717	Temple bone implant revision	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	61%	31%
69718	Revise temple bone implant	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	61%	31%
69930	Implant cochlear device	J8	0259	Level VII ENT Procedures	84%	42%

TABLE 58.—DEVICES FOR WHICH THE "FB" OR "FC" MODIFIER MUST BE REPORTED WITH THE PROCEDURE CODE IN CY 2012 WHEN FURNISHED AT NO COST OR WITH FULL OR PARTIAL CREDIT

CY 2012 Device HCPCS Code	CY 2012 Short Descriptor
C1721	AICD, dual chamber
C1722	AICD, single chamber
C1762	Conn tiss, human(inc fascia)
C1763	Conn tiss, non-human
C1764	Event recorder, cardiac
C1767	Generator, neurostim, imp
C1771	Rep dev, urinary, w/sling
C1772	Infusion pump, programmable
C1776	Joint device (implantable)
C1777	Stent, non-coat/cov w/o del
C1778	Lead, neurostimulator
C1779	Lead, pmkr, transvenous VDD
C1781	Mesh (implantable)
C1785	Pmkr, dual, rate-resp
C1786	Pmkr, single, rate-resp
C1813	Prosthesis, penile, inflatab
C1815	Pros, urinary sph, imp
C1820	Generator, neuro rechg bat sys
C1881	Dialysis access system
C1882	AICD, other than sing/dual
C1891	Infusion pump, non-prog, perm
C1895	Lead, AICD, endo dual coil
C1897	Lead, neurostim, test kit
C1898	Lead, pmkr, other than trans
C1900	Lead coronary venous
C2618	Probe, cryoablation
C2619	Pmkr, dual, non rate-resp
C2620	Pmkr, single, non rate-resp
C2621	Pmkr, other than sing/dual
C2622	Prosthesis, penile, non-inf
C2626	Infusion pump, non-prog, temp
C2631	Rep dev, urinary, w/o sling

CY 2012 Device HCPCS Code	CY 2012 Short Descriptor
L8614	Cochlear device/system
L8680	Implt neurostim elctr each
L8685	Implt nrostm pls gen sng rec
L8686	Implt nrostm pls gen sng non
L8687	Implt nrostm pls gen dua rec
L8688	Implt nrostm pls gen dua non
L8690	Aud osseo dev, int/ext comp

BILLING CODE 4120–01–C

d. Waiver of Coinsurance and Deductible for Certain Preventive Services

As discussed in the CY 2012 OPPS/ASC proposed rule (76 FR 42301), sections 1833(a)(1) and (b)(1) of the Act waives the coinsurance and the Part B deductible for those preventive services under section 1861(ddd)(3)(A) of the Act as described in section 1861(ww)(2) of the Act (excluding electrocardiograms) that are recommended by the United States Preventive Services Task Force (USPSTF) with a grade of A or B for any indication or population and that are appropriate for the individual. Section 1833(b) of the Act also waives the Part B deductible for colorectal cancer screening tests that become diagnostic. In the CY 2011 OPPS/ASC final rule with comment period, we finalized our policies with respect to these provisions and identified the ASC covered surgical and ancillary services that are preventive services that are recommended by the USPSTF with a grade of A or B for which the coinsurance and the deductible are waived. For a complete discussion of our policies and identified services, we refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72047 through 72049). We did not propose any changes to our policies or the list of services in the CY 2012 OPPS/ASC proposed rule. We identify these services with a double asterisk in Addenda AA and BB to this CY 2012 OPPS/ASC final rule with comment period.

e. Payment for the Cardiac Resynchronization Therapy Composite

Cardiac resynchronization therapy (CRT) uses electronic devices to sequentially pace both sides of the heart to improve its output. CRT utilizes a pacing electrode implanted in combination with either a pacemaker or an implantable cardioverter defibrillator (ICD). CRT performed by the implantation of an ICD along with a pacing electrode is referred to as ''CRT–D.'' As detailed in section II.A.2.e.(6) of the CY 2012 OPPS/ASC proposed rule (76 FR 42203 through 42206), we proposed to create an OPPS composite APC (Composite APC 8009 (Cardiac Resynchronization Therapy—ICD Pulse Generator and Leads)) which would be used when CPT code 33225 (Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of pacing cardioverter-defibrillator or pacemaker pulse generator (including upgrade to dual chamber system)) and CPT code 33249 (Insertion or repositioning of electrode lead(s) for single or dual chamber pacing cardioverter-defibrillator and insertion of pulse generator) are performed on the same date of service. We also proposed to cap the OPPS payment rate for composite APC 8009 at the most comparable Medicare severity diagnosis-related group (MS–DRG) payment rate established under the IPPS that would be provided to acute care hospitals for providing CRT–D services to hospital inpatients. In other words, we proposed to pay APC 8009 at the lesser of the APC 8009 median cost or the IPPS standardized payment rate for MS–DRG 227 (Cardiac Defibrillator Implant without Cardiac Catheterization without Major Complication or Comorbidity). This would ensure appropriate and equitable payment to hospitals and that we do not create an inappropriate payment incentive to provide CRT–D services in one setting of care over another by paying more for CRT–D services in the outpatient setting compared to the inpatient setting.

Because CPT code 33225 and CPT code 33249 are on the list of ASC covered surgical procedures, in the proposed rule (76 FR 42302), we proposed to establish an ASC payment rate that is based on the OPPS payment rate applicable to APC 8009 when these procedures are performed on the same date of service in an ASC. Again, we do not want to create an inappropriate payment incentive to provide CRT–D services in one setting of care over another by paying more for CRT–D services furnished in ASCs compared to those furnished in the hospital outpatient setting. Because CPT codes 33225 and 33249 are on the proposed list of device-intensive procedures for CY 2012, we proposed to apply the usual device-intensive methodology based on the OPPS payment rate applicable to APC 8009 (which is the lesser of the APC 8009 median cost that we will calculate for the CY 2012 OPPS/ASC final rule with comment period or the FY 2012 IPPS standardized payment rate for MS–DRG 227). We also proposed to create a HCPCS Level II G-code so that ASCs can properly report when the procedures described by CPT codes 33225 and 33249 are performed on the same date of service and, therefore, receive the appropriate payment amount for CRT–D services performed in an ASC.

In a related issue, as detailed in section III.D.6 of the CY 2012 OPPS/ASC proposed rule (76 FR 42241 through 42242), CPT codes 33225 and 33249 are the only procedures proposed for inclusion in APC 0108. We proposed that these codes would be paid under APC 0108 only if they are not reported on the same date of service. Further, we proposed to pay the OPPS payment rate for services that are assigned to APC 0108 at the lesser of the APC 0108 median cost or the IPPS standardized payment rate for MS–DRG 227. For ASC payment in CY 2012, we proposed to apply the device-intensive methodology to calculate payment for CPT codes 33225 and 33249 based on the OPPS payment rate applicable to APC 0108

(which is the lesser of the APC 0108 median cost that we would calculate for this CY 2012 OPPS/ASC final rule with comment period or the FY 2012 IPPS standardized payment rate for MS–DRG 227).

We did not receive any public comments on our CY 2012 proposal to establish an ASC payment rate for CRT–D services, using the device-intensive methodology, based on the OPPS payment rate applicable to composite APC 8009 when procedures described by CPT codes 33225 and 33249 are performed on the same date of service in an ASC. However, as detailed in section II.A.2.e.(6) of this final rule with comment period, after consideration public comments regarding OPPS payment for CRT–D services, we are not finalizing our proposal to implement a payment cap for CRT–D services and ICD implantation procedures performed in a hospital outpatient department based upon the payment rate for IPPS MS–DRG 227 as proposed. Instead, under the OPPS, we will recognize CPT codes 33225 and 33249 as a single, composite service when they are performed on the same day as proposed. However, for CY 2012, rather than assigning the procedures described by CPT codes 33225 and 33249 when they are performed on the same day to composite APC 8009, we are assigning them to existing APC 0108. When not performed on the same day as the service described by CPT code 33225, the service described by CPT code 33249 will continue to be assigned to APC 0108. When not performed on the same day as the service described by CPT code 33249, the service described by CPT code 33225 will be assigned to APC 0655 (we note that this is a modification from our proposal to assign CPT code 33225 when it does not appear with CPT code 33249 to APC 0108).

Based on the above modifications to establish the OPPS payment amount for CRT–D services, the payment rate for CRT–D services in ASCs for CY 2012 will be based on the OPPS payment rate applicable to APC 0108 when procedures described by CPT codes 33225 and 33249 are performed on the same date of service in an ASC. Because CPT codes 33225 and 33249 are on the list of device-intensive procedures finalized for CY 2012, APC payment for CRT–D services will be established using the device-intensive payment methodology. ASCs will use the corresponding HCPCS Level II G-code (G0448) for proper reporting when the procedures described by CPT codes 33225 and 33249 are performed on the same date of service. When not performed on the same day as the service described by CPT code 33225, ASC payment for the service described by CPT code 33249 will be based on APC 0108 using the device-intensive methodology. When not performed on the same day as the service described by CPT code 33249, ASC payment for the service described by CPT code 33225 will be based on APC 0655 using the device-intensive methodology.

2. Payment for Covered Ancillary Services

a. Background

Our final payment policies under the revised ASC payment system for covered ancillary services vary according to the particular type of service and its payment policy under the OPPS. Our overall policy provides separate ASC payment for certain ancillary items and services integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPS and provides packaged ASC payment for other ancillary items and services that are packaged under the OPPS. Thus, we established a final policy to align ASC payment bundles with those under the OPPS (72 FR 42495). In all cases, in order for those ancillary services also to be paid, ancillary items and services must be provided integral to the performance of ASC covered surgical procedures for which the ASC bills Medicare.

Our ASC payment policies provide separate payment for drugs and biologicals that are separately paid under the OPPS at the OPPS rates, while we generally pay for separately payable radiology services at the lower of the MPFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (72 FR 42497). However, as finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to ''Z2'' so that payment is made based on the ASC standard ratesetting methodology rather than the MPFS nonfacility PE RVU amount, regardless of which is lower. This modification to the ASC payment methodology for ancillary services was finalized in response to a comment on the CY 2011 OPPS/ASC proposed rule that suggested it is inappropriate to use the MPFS-based payment methodology for nuclear medicine procedures because the associated diagnostic radiopharmaceutical, although packaged under the ASC payment system, is separately paid under the MFPS. We set the payment indicator to ''Z2'' for nuclear medicine procedures in the ASC setting so that payment for these procedures would be based on the OPPS relative payment weight rather than the MPFS nonfacility PE RVU-based amount to ensure that the ASC will be compensated for the cost associated with the diagnostic radiopharmaceuticals.

ASC payment policy for brachytherapy sources generally mirrors the payment policy under the OPPS. We finalized our policy in the CY 2008 OPPS/ASC final rule with comment period (72 FR 42499) to pay for brachytherapy sources applied in ASCs at the same prospective rates that were adopted under the OPPS or, if OPPS rates were unavailable, at contractor-priced rates. After publication of that rule, section 106 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Pub. L. 110–173) mandated that, for the period January 1, 2008 through June 30, 2008, brachytherapy sources be paid under the OPPS at charges adjusted to cost. Therefore, consistent with our final overall ASC payment policy, we paid ASCs at contractor-priced rates for brachytherapy sources provided in ASCs during that period of time. Beginning July 1, 2008, brachytherapy sources applied in ASCs were to be paid at the same prospectively set rates that were finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 67165 through 67188). Immediately prior to the publication of the CY 2009 OPPS/ASC proposed rule, section 142 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275) amended section 1833(t)(16)(C) of the Act (as amended by section 106 of the Medicare, Medicaid, and SCHIP Extension Act of 2007, Pub. L. 110–173) to extend the requirement that brachytherapy sources be paid under the OPPS at charges adjusted to cost through December 31, 2009. Therefore, consistent with final ASC payment policy, ASCs continued to be paid at contractor-priced rates for brachytherapy sources provided integral to ASC covered surgical procedures during that period of time. Since December 31, 2009, ASCs have been paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS.

Other separately paid covered ancillary services in ASCs, specifically

corneal tissue acquisition and device categories with OPPS pass-through status, do not have prospectively established ASC payment rates according to the final policies of the revised ASC payment system (72 FR 42502 and 42509; § 416.164(b)). Under the revised ASC payment system, corneal tissue acquisition is paid based on the invoiced costs for acquiring the corneal tissue for transplantation. Devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system. Currently, the three devices that are eligible for pass-through payment in the OPPS are described by HCPCS code C1749 (Endoscope, retrograde imaging/illumination colonoscope device (Implantable), HCPCS code C1830 (Powered bone marrow biopsy needle), and HCPCS code C1840 (Lens, intraocular (telescopic)). Payment amounts for HCPCS codes C1749, C1830, and C1840 under the ASC payment system are contractor priced.

b. Payment for Covered Ancillary Services for CY 2012

For CY 2012, we proposed to update the ASC payment rates and make changes to ASC payment indicators as necessary to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2012 OPPS and ASC payment rates (76 FR 42303). The proposed CY 2012 OPPS payment methodologies for separately payable drugs and biologicals and brachytherapy sources were discussed in section II.A. and section V.B. of that proposed rule, respectively, and we proposed to set the CY 2012 ASC payment rates for those services equal to the proposed CY 2012 OPPS rates.

Consistent with established ASC payment policy (72 FR 42497), the proposed CY 2012 payment for separately payable covered radiology services was based on a comparison of the CY 2012 proposed MPFS nonfacility PE RVU-based amounts (we referred readers to the CY 2012 MPFS proposed rule) and the proposed CY 2012 ASC payment rates calculated according to the ASC standard ratesetting methodology and then set at the lower of the two amounts. Alternatively, payment for a radiology service may be packaged into the payment for the ASC covered surgical procedure if the radiology service is packaged under the OPPS. The payment indicators in Addendum BB to the proposed rule indicate whether the proposed payment rates for radiology services are based on the MPFS nonfacility PE RVU-based amount or the ASC standard ratesetting methodology, or whether payment for a radiology service is packaged into the payment for the covered surgical procedure (payment indicator ''N1''). Radiology services that we proposed to pay based on the ASC standard ratesetting methodology are assigned payment indicator ''Z2'' (Radiology service paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS relative payment weight) and those for which the proposed payment is based on the MPFS nonfacility PE RVU-based amount are assigned payment indicator ''Z3'' (Radiology service paid separately when provided integral to a surgical procedure on ASC list; payment based on MPFS nonfacility PE RVUs).

As finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to ''Z2'' so that payment is made based on the OPPS relative payment weights rather than the MPFS nonfacility PE RVU-based amount, regardless of which is lower. In the CY 2012 OPPS/ASC proposed rule (76 FR 42303), we proposed to continue this modification to the payment methodology and, therefore, set the payment indicator to ''Z2'' for these nuclear medicine procedures in CY 2012. In addition, because the same issue exists for radiology procedures that use contrast agents (the contrast agent is packaged under the ASC payment system but is separately paid under the MFPS), we proposed to set the payment indicator to ''Z2'' for radiology services that use contrast agents so that payment for these procedures will be based on the OPPS relative payment weight and will, therefore, include the cost for the contrast agent. We made proposed changes to the regulation text at § 416.171(d) to reflect this proposal.

Most covered ancillary services and their proposed payment indicators were listed in Addendum BB to the CY 2012 OPPS/ASC proposed rule (which was available via the Internet on the CMS Web site).

Comment: One commenter urged CMS to modify the payment methodology for separately payable covered radiology services such that the amounts paid are equivalent to the OPPS payment rates, as is the case for brachytherapy sources and separately payable drugs and biologicals, instead of the lower of the amount calculated according to the standard methodology of the ASC payment system or the MPFS nonfacility PE RVU-based amount. The commenter expressed concern that the payment rates for certain separately payable covered radiology services that are based on the established methodology are far below the amounts necessary to cover the costs involved in providing the service.

Response: We do not agree with the commenter that we should alter our established policy to pay for separately payable covered radiology services at the lower of the MPFS nonfacility PE RVU-based amounts and the ASC payment rates calculated according to the ASC standard ratesetting methodology. We believe that this approach is the most appropriate to prevent the creation of payment incentives for services to move from physicians' offices to ASCs and that the ASC payment rates established under this methodology are adequate to the cover costs for providing covered radiology services in ASCs.

Comment: Commenters requested that CMS pay for low dose rate (LDR) prostate brachytherapy services under the ASC payment system based on the composite APC methodology used under the OPPS rather than making two separate payments for the service reported by CPT codes 55675 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) and 77778 (Interstitial radiation source application; complex). The composite APCs were developed for procedures like LDR prostate brachytherapy in which two procedures are frequently performed in a single hospital visit. The commenters asserted that basing ASC payments for the services on the composite APC methodology in which one payment is made for the combination of the two services would result in a more accurate payment than is currently being made to ASCs because ASC payment is based on the median costs from single-service claims that CMS has acknowledged are mostly incorrectly coded claims.

Response: Although we have tried to align the ASC and OPPS packaging policies to the fullest extent, we have not done so in the case of the LDR prostate brachytherapy composite (APC 8001). We will take the commenter's request into consideration in future rulemaking, recognizing the lead time that is necessary for the creation of the associated G-code that would be used to identify when the procedures in the LDR prostate brachytherapy composite

are performed on the same date of service in an ASC.

Comment: One commenter indicated that ASCs are experiencing problems with obtaining payment from several of the ASC contractors for the pass-through device identified by HCPCS code C1749 (Endoscope, retrograde imaging/illumination colonoscope device (Implantable)) and requests that CMS provide further guidance in the final rule with comment period as to the ASC pricing level for the pass-through device.

Response: Devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system and are paid at contractor-priced rates. CMS will remind contractors that payment for HCPCS code C1749 is not packaged into the payment for the associated procedure. However, the local contractor makes final decisions regarding coverage determinations and the payment amount for the pass-through device.

After consideration of the public comments we received, we are providing CY 2012 payment for covered ancillary services in accordance with the policies finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), with one modification. As described above, we are setting the payment indicator to ''Z2'' for radiology services that use contrast agents so that payment for these procedures will be based on the OPPS relative payment weight and, therefore, will include the cost for the contrast agent. We also are finalizing proposed changes to § 416.171(d). However, we are making a technical change to the proposed regulation text to make it clear that the proposed reference to paragraphs (d)(1) and (2) is a reference to paragraphs (d)(1) and (d)(2). Covered ancillary services and their final CY 2012 payment indicators are listed in Addendum BB (which is available via the Internet on the CMS Web site) to this final rule with comment period.

E. New Technology Intraocular Lenses (NTIOLs)

1. NTIOL Cycle and Evaluation Criteria

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68176), we finalized our current process for reviewing applications to establish new classes of new technology intraocular lenses (NTIOLs) and for recognizing new candidate intraocular lenses (IOLs) inserted during or subsequent to cataract extraction as belonging to an NTIOL class that is qualified for a payment adjustment. Specifically, we established the following process:

- We announce annually in the proposed rule updating the ASC and OPPS payment rates for the following calendar year, a list of all requests to establish new NTIOL classes accepted for review during the calendar year in which the proposal is published. In accordance with section 141(b)(3) of Public Law 103–432 and our regulations at § 416.185(b), the deadline for receipt of public comments is 30 days following publication of the list of requests in the proposed rule.
- In the final rule updating the ASC and OPPS payment rates for the following calendar year, we—
  - Provide a list of determinations made as a result of our review of all new NTIOL class requests and public comments; and
  - Announce the deadline for submitting requests for review of an application for a new NTIOL class for the following calendar year.

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68227), we finalized our proposal to base our determinations on consideration of the following three major criteria set out at 42 CFR 416.195:

- Criterion 1 (42 CFR 416.195(a)(1),(2)): The IOL must have been approved by the FDA and claims of specific clinical benefits and/or lens characteristics with established clinical relevance in comparison with currently available IOLs must have been approved by the FDA for use in labeling and advertising;
- Criterion 2 (42 CFR 416.195(a)(3)): The IOL is not described by an active or expired NTIOL class; that is, it does not share the predominant, class-defining characteristic associated with the improved clinical outcome with designated members of an active or expired NTIOL class; and
- Criterion 3 (42 CFR 416.195(a)(4)): Evidence demonstrates that use of the IOL results in measurable, clinically meaningful, improved outcomes in comparison with use of currently available IOLs. The statute requires us to consider the following superior outcomes:
  - Reduced risk of intraoperative or postoperative complication or trauma;
  - Accelerated postoperative recovery;
  - Reduced induced astigmatism;
  - Improved postoperative visual acuity;
  - More stable postoperative vision; or
  - Other comparable clinical advantages.

Since implementation of the process for adjustment of payment amounts for NTIOLs that was established in the June 16, 1999 **Federal Register**, we have approved three classes of NTIOLs, as shown in the table entitled *CMS Approved NTIOLs,* with the associated qualifying IOL models, posted on the CMS Web site at: *http://www.cms.gov/ASCPayment/08_NTIOLs.asp#TopOfPage*.

2. NTIOL Application Process for Payment Adjustment

For a request to be considered complete, we require submission of the information that is found in the guidance document entitled ''Application Process and Information Requirements for Requests for a New Class of New Technology Intraocular Lens (NTIOL)'' posted on the CMS Web site at: *http://www.cms.gov/ASCPayment/08_NTIOLs.asp#TopOfPage*. For each completed request for a new class that is received by the established deadline, a determination is announced annually in the final rule updating the ASC and OPPS payment rates for the next calendar year.

We also summarize briefly in the final rule the evidence that we reviewed, the public comments we received timely, and the basis for our determinations in consideration of applications for establishment of a new NTIOL class. When a new NTIOL class is created, we identify the predominant characteristic of NTIOLs in that class that sets them apart from other IOLs (including those previously approved as members of other expired or active NTIOL classes) and that is associated with an improved clinical outcome. The date of implementation of a payment adjustment in the case of approval of an IOL as a member of a new NTIOL class would be set prospectively as of 30 days after publication of the ASC payment update final rule, consistent with the statutory requirement.

3. Requests To Establish New NTIOL Classes for CY 2012

As discussed in the CY 2012 OPPS/ASC proposed rule (76 FR 42303 through 42309), we received four requests for review to establish a new NTIOL class for CY 2012 by the March 5, 2011 due date. Below we summarize the evidence that we reviewed, the public comments we received timely, and the basis for our determinations in consideration of the applications for establishment of a new NTIOL class. For each application, we invited public comments on certain specific questions as well as all of the NTIOL evaluation criteria. We thank the public for their comments concerning our review of the four CY 2012 NTIOL requests.

a. Requestor/Manufacturer: Alcon Laboratories, Inc. (Alcon)

Lens Model Numbers: AcrySof Natural IQ and AcrySof Natural IOLs, Models SN60WF (aspheric optic, single piece), SN60AT (spherical optic, single piece), MN60MA (spherical optic, multi-piece), MN60AC (spherical optic, multi-piece).

Summary of the Request: Alcon submitted a request for CMS to determine that its AcrySof Natural IOLs meet the criteria for recognition as NTIOLs and to concurrently establish a new class of NTIOLs for ''blue-light-filtering IOLs that improve driving safety under glare conditions,'' with these IOLs as members of the class. These IOLs will be referred to as either blue-light-filtering IOLs or blue blocking IOLs. We reviewed a similar request by Alcon during the CY 2011 NTIOL application cycle (75 FR 72052). As part of its CY 2012 request, Alcon submitted descriptive information about the candidate IOLs as outlined in the guidance document that is available on the CMS Web site for the establishment of a new class of NTIOLs, as well as information regarding approval of the candidate IOLs by the FDA. This information included the approved labeling for the candidate IOLs, a summary of the IOLs' safety and effectiveness, a copy of the FDA's approval notifications, and instructions for their use.

In its CY 2012 request, Alcon asserted that its request is based on studies demonstrating that the AcrySof Natural IOLs with a blue-light-filtering chromophore filter light in a manner that approximates the human crystalline lens in the 400–475 nm blue light wavelength range to reduce glare that impairs the ability of the eye to differentiate objects from the background. Alcon further stated that glare reduction can help beneficiaries avoid hazards that can be caused by glare. Alcon also stated that at present there are no active or expired NTIOL classes that describe IOLs similar to the AcrySof Natural IOLs.

We established in the CY 2007 OPPS/ASC final rule with comment period that when reviewing a request for recognition of an IOL as an NTIOL and a concurrent request to establish a new class of NTIOLs, we would base our determination on consideration of the three major criteria at 42 CFR 416.195(a) and listed above. We solicited public comment on these candidate IOLs with respect to the established three major NTIOL criteria and certain specific issues related to this application in the CY 2012 OPPS/ASC proposed rule (76 FR 42303 through 42309). We have reviewed Alcon's request to recognize its AcrySof Natural IOLs as NTIOLs and concurrently establish a new class of NTIOLs and all of the related comments.

First, for an IOL to be recognized as an NTIOL we require that the IOL must have been approved by the FDA and claims of specific clinical benefits and/or lens characteristics with established clinical relevance in comparison with currently available IOLs must have been approved by the FDA for use in labeling and advertising. The approved labels for the Alcon IOLs all state the following: ''Alcon's proprietary blue light filtering chromophore filters light in a manner that approximates the human crystalline lens in the 400–475 nm blue light wavelength range.'' The FDA-approved labeling for these IOLs do not otherwise reference specific clinical benefits of blue-light-filtering. We were interested in public comments on the clinical relevance of blue-light-filtering in an IOL. Specifically, in the proposed rule (76 FR 42303 through 42309), we stated that we were interested in public comments regarding the assertion that the specific blue-light-filtering properties associated with the candidate IOLs improve driving safety via the reduction of glare disability.

Second, according to 42 CFR 416.195(a)(3), we also require that the candidate IOL not be described by an active or expired NTIOL class; that is, it does not share the predominant, class-defining characteristic associated with improved clinical outcomes with designated members of an active or expired NTIOL class. In the CY 2007 OPPS final rule, in response to a comment we explained our interpretation of 42 CFR 416.195(a)(3) as follows:

''[R]evised § 416.195(a)(3) does not preclude from consideration as a member of a new class of NTIOL a lens that includes as one of its characteristics a class-defining characteristic associated with members of an active or expired class. Only if that shared characteristic were the predominant characteristic of the lens would it be precluded from approval as a new class of NTIOL. However, if the lens featured other characteristics, one or more of which predominated, that were clearly tied with improved clinical outcomes, the lens would not be disqualified from consideration as an NTIOL just because it also shared a characteristic with members of an active or expired class.'' (71 FR 68178.)

As noted above, since implementation of the process for adjustment of payment amounts for NTIOLs that was established in the June 16, 1999 **Federal Register**, we have approved three classes of NTIOLs: Multifocal and Reduction in Preexisting Astigmatism classes, both of which were created in 2000 and expired in 2005; and the Reduced Spherical Aberration class, which was created in 2006 and expired on February 26, 2011. As mentioned above, a table entitled *CMS Approved NTIOLs,* with the associated qualifying IOL models, is posted on the CMS Web site at: *http://www.cms.gov/ASCPayment/08_NTIOLs.asp#TopOfPage*. The class-defining characteristic specific to IOLs that are members of these three expired classes is evident in the name assigned to the class. For example, IOLs recognized as members of the reduced spherical aberration class are characterized by their aspheric design that results in reduced spherical aberration. Based on the information in the table entitled CMS *Approved NTIOLs,* a candidate IOL's predominant characteristic may not be described by any of the three expired NTIOL classes.

In the case of one of four of Alcon's candidate IOLs, the AcrySof Natural IQ Aspheric IOL model SN60WF, it is a member of the expired reduced spherical aberration NTIOL class (75 FR 72052). For the purposes of satisfying § 416.195(a)(3), CMS must be able to determine which lens characteristic is predominant for Alcon's model SN60WF, asphericity (resulting in reduced spherical aberration) or blue-light-filtering. If the predominant characteristic is asphericity, then the model SN60WF IOL would be disqualified under § 416.195(a)(3). This determination is particularly relevant given that the clinical benefit attributed to both of these lens characteristics is improved driving under glare conditions. In the proposed rule (76 FR 42303 through 42309), we solicited public comments on whether blue-light-filtering can be considered the predominant IOL characteristic for the model SN60WF IOL. We also welcomed public comments that addressed whether blue-light-filtering and the associated clinical benefits of the other three of Alcon's candidate IOLs (that is, SN60AT, MN60MA, MN60AC) are described by any of the expired NTIOL classes.

Third, our NTIOL evaluation criteria also require that an applicant submit evidence demonstrating that use of the IOL results in measurable, clinically meaningful, improved outcomes in comparison to currently available IOLs. Importantly, the statute specifies the following outcomes: (1) Reduced risk of intraoperative or postoperative complication or trauma; (2) accelerated

postoperative recovery; (3) reduced induced astigmatism; (4) improved postoperative visual acuity; (5) more stable postoperative vision; or (6) other comparable clinical advantages. We note that in the CY 2007 OPPS/ASC final rule with comment period, we sought comments as to what constitutes currently available IOLs for purposes of such comparisons, and we received several comments in response to our solicitation (71 FR 68178). We agreed with commenters that we should remain flexible with respect to our view of ''currently available lenses'' for purposes of reviewing NTIOL requests, in order to allow for consideration of technological advances in lenses over time. This means that we do not expect that ''currently available lenses'' would remain static over time and always necessarily default to the classic spherical monofocal IOL for every candidate NTIOL class. Therefore, we believe that ''currently available lenses'' for purposes of reviewing NTIOL requests should depend upon the class-defining characteristic and the associated purported improved clinical outcome of the candidate NTIOL. For example, for some candidate NTIOLs the most appropriate comparison IOL would be a spherical monofocal IOL, while other candidate NTIOLs may be more appropriately compared to aspheric IOLs.

For purposes of reviewing Alcon's request to establish a new NTIOL class for CY 2012, in the proposed rule (76 FR 42304 through 42309), we proposed that aspheric monofocal IOLs represent the currently available IOLs against which the candidate NTIOLs should be compared in order to establish a new class. According to publicly available data from Market Scope, LLC, IOLs with aspheric optics accounted for over 86 percent of the IOLs implanted in the United States during 2010. In addition, data submitted by Alcon shows that the overwhelming majority of IOLs sold by Alcon have aspheric optics. Furthermore, the aspheric design that results in reduced spherical aberration was the class defining characteristic for IOLs recognized as members of the expired reduced spherical aberration NTIOL class. The primary clinical outcome associated with reduced spherical aberration (for purposes of establishing it as an NTIOL class) was safer night driving (71 FR 4588). Alcon asserted that what makes its candidate IOLs superior to other currently available IOLs is improved driving safety under glare conditions. Glare conditions during driving primarily occur at night due to headlights from oncoming cars. The primary improved clinical outcome from reduced spherical aberration IOLs (an expired NTIOL class) was safer night driving. We believed that Alcon was also claiming that its blue-light-filtering IOLs resulted in safer night driving. Therefore, we proposed that the most relevant type of currently available IOLs against which the Alcon blue-light-filtering IOLs should be compared is aspheric IOLs. In particular, we proposed that the relevant comparison would be the performance of an aspheric blue-light-filtering IOL versus an aspheric nonblue-light-filtering IOL. In the proposed rule, we sought public comment on our view of ''currently available lenses'' for the purposes of evaluating Alcon's candidate IOLs against currently available IOLs.

We reviewed the evidence submitted with Alcon's CY 2012 request. Although Alcon submitted various types of literature in support of its application, it relies primarily on two studies in support of its hypothesis that blue light filtering IOLs improve driving safety under glare conditions as compared to currently available IOLs. The first of these two submitted articles is: Hammond B, *et al.,* ''Contralateral comparison of blue-filtering intraocular lenses: glare disability, heterochromic contrast, and photostress recovery,'' *Clinical Ophthalmology*. 2010;4:1465–1473 (Hammond 2010). This article compared visual performance (as measured by glare disability, heterochromic contrast threshold, and photostress recovery time) in eyes with blue-light-filtering IOLs versus contralateral eyes with IOLs that do not filter blue light. The second article, which Alcon describes as its ''pivotal study,'' is: Gray R, *et al.,* ''Reduced effect of glare disability on driving performance in patients with blue-light-filtering intraocular lenses,'' *J Cataract Refract Surg.,* 2011;37:38–44. This study compared the effects of glare on driving performance using a driving simulator in patients who had implantation of a blue-light-filtering acrylic IOL and those who had implantation of an acrylic IOL with no blue-light-filter. Overall, the evidence submitted provides us with important information that is critical to our review of this request. However, in making our decision as to whether to establish a new class of NTIOL based on the primary characteristic of the candidate lenses, we also were interested in what other information the public could contribute related to the asserted benefits of the blue-light-filtering IOL. Specifically, in the proposed rule (76 FR 42304 through 42309), we sought public comment and relevant data on the following:

- Are there other peer-reviewed studies or other information that would support or disprove the claims of clinical benefit made by Alcon?
- How would you interpret the results of the Hammond 2010 study, given that the blue-light-filtering group included patients with spherical blue-light-filtering IOLs and patients with aspheric blue-light-filtering IOLs?
- Does the Maxwellian optical system that was employed in the Hammond 2010 study mitigate the impact of the aspheric optics of some of the study subjects in the blue light-filtering group?
- Is the sample size used in both studies sufficient to conclude that a blue-light-filtering IOL would reduce glare disability and improve driving safety in the Medicare population?
- What kind of study design would be appropriate to prove the claim of significant clinical benefit due to glare reduction on which the new class would be based?
- Are the submitted data enough to prove that the blue-light-filtering optic is responsible for reduction in glare disability as asserted by applicant?
- Did these studies use an appropriate comparator IOL?

Furthermore, in accordance with our established NTIOL review process, in the proposed rule, we also sought public comments on all of the review criteria for establishing a new NTIOL class that would be based on the ability of the AcrySof Natural IOLs to filter blue light and subsequently help beneficiaries avoid hazards that can be caused by glare while driving. We stated that we would give all comments full consideration regarding Alcon's candidate IOLs.

Comment: Regarding criterion 1, the requestor asserted that the AcrySof Natural IOLs contain a blue-light-filtering chromophore that reduces glare disability that impairs the ability of individuals to differentiate objects from the background. The blue-light-filtering chromophore is a characteristic of the AcrySof Natural IOLs that is listed in the FDA-approved labeling. Whether the blue-light-filtering chromophore has established clinical relevance in comparison with currently available IOLs is discussed below under the discussion of criterion 3, as the clinical relevance of the blue-light-filtering chromophore in comparison with currently available IOLs depends upon whether, as required by criterion 3, evidence demonstrates that use of the IOL (and in particular the blue-light-filtering chromophore) results in measurable, clinically meaningful,

improved outcomes in comparison with use of currently available IOLs. One commenter stated that because Alcon's submission lacks the requisite FDA-approved labeling references regarding clinical benefit or established clinical relevance for the AcrySof Natural IOLs, it does not satisfy criterion 1.

Response: Our current interpretation of criterion 1, which is based on 42 CFR 416.195(a)(1),(2), is that the candidate IOL must have been approved by the FDA and have claims of specific clinical benefits *and/or* lens characteristics with established clinical relevance in comparison with currently available IOLs in the FDA-approved labeling. Therefore, there can be either claims of specific clinical benefits in the FDA-approved labeling or lens characteristics in the FDA-approved labeling with evidence of established clinical relevance in comparison with currently available IOLs outside of the FDA-approved labeling, such as in peer-reviewed journals. If the evidence for clinical relevance of the IOL characteristic was required to be contained in the FDA-approved labeling, that would be the same as requiring a claim of specific clinical benefit of the IOL in the FDA-approved labeling, which would be redundant. As stated above, the clinical relevance of the blue-light-filtering chromophore will depend on whether Alcon's blue-light-filtering IOLs satisfy criterion 3, which is discussed below. In future rulemaking, we may consider exploring refinements to the regulations such that a claim of specific clinical benefit of the IOL in comparison with currently available IOLs would be required in the FDA-approved labeling.

Comment: Regarding criterion 2, the applicant and several other commenters stated that the measured clinical benefit of Alcon's blue-light-filtering IOLs is improved driving safety under daytime driving conditions with glare simulating low-angle sun, not nighttime driving conditions with and without glare. They stated that low angle sun occurs at sunrise and sunset and cited the article by Gray (which Alcon describes as its pivotal study) which states the following: ''In a real-world task such as driving, 2 major contributors of glare are the headlights of an oncoming car during nighttime driving and low-angle sun conditions (e.g., sunset).'' In submitted comments, Alcon clarified that its blue-light-filtering IOLs only aid drivers with glare due to low angle sun, and not that blue-light-filtering IOLs aid with glare from the headlights of an oncoming car during nighttime driving.

Prior to its clarifying comments, we originally believed that Alcon was claiming that its blue-light-filtering IOLs aided drivers with both nighttime glare and daytime glare. We now understand that the purported clinical benefit of the blue-light-filtering IOLs is improved driving during the daytime when the sun is at a low angle and not at nighttime when headlights cause glare. This distinction is important in evaluating criterion 2, which requires that the blue-light-filtering IOLs not be described by an active or expired NTIOL class; that is, the blue-light-filtering IOLs do not share the predominant, class-defining characteristic associated with the improved clinical outcome with designated members of an active or expired NTIOL class. One of the four candidate blue-light-filtering IOLs, the AcrySof Natural IQ Aspheric IOL model SN60WF, is a member of the expired reduced spherical aberration NTIOL class (75 FR 72052).

The requestor and other commenters argued that because asphericity does not contribute to visual performance during daytime driving conditions due to pupillary constriction during daytime driving conditions, blue-light-filtering is the predominant characteristic of the AcrySof Natural IQ Aspheric IOL model SN60WF for the associated outcome of improved driving safety under daytime driving conditions with glare from low-angle sun. Another commenter stated that because no evidence exists to establish the clinical benefit of blue-light-filtering, it is impossible to separate the predominant characteristic of reduced spherical aberration in the AcrySof Natural IQ Aspheric IOL model SN60WF from any other lens characteristic with regard to clinical benefit. Therefore, this commenter stated that, because the AcrySof Natural IQ Aspheric IOL model SN60WF is a member of a recently expired category, it should be disqualified from new NTIOL category consideration.

Response: For the purposes of satisfying § 416.195(a)(3), we must determine which lens characteristic is predominant for Alcon's model SN60WF, asphericity (resulting in reduced spherical aberration) or blue-light-filtering. If the predominant characteristic is asphericity, the model SN60WF IOL would be ineligible under § 416.195(a)(3). Although we briefly discussed our interpretation of § 416.195(a)(3) and the concept of a predominant characteristic as it relates to § 416.195(a)(3) in the CY 2007 final rule (71 FR 68178), we have not further elaborated on the factors that influence a determination of predominance regarding different IOL characteristics. We believe that when the clinical outcomes associated with different lens characteristics are related, comparative clinical data are required to demonstrate that one characteristic is predominant over another. However, when the clinical outcomes associated with the different lens characteristics are sufficiently unrelated, comparative clinical data are not required to demonstrate the predominance of a characteristic as it relates to the clinical outcome associated with the lens characteristic that is the subject of NTIOL review.

We agree with the requestor and other commenters that, with respect to the purported outcome of improved driving safety under daytime driving conditions with glare simulating low-angle sun, the predominant characteristic of the model SN60WF is blue-light blocking. Pupillary constriction from the sun diminishes or negates the benefits of asphericity, which was shown to reduce spherical aberration and positively affect night driving performance. If a night driving benefit were claimed instead of only a daytime driving benefit for Alcon's blue-light-filtering IOLs, the determination of the predominant characteristic for the model SN60WF would be more complicated. However, because the purported clinical benefit of the blue-light-filtering IOLs is limited to improved driving safety under daytime driving conditions with glare simulating low-angle sun, under these conditions the blue-light-filtering characteristic is predominant. Also, the description of the requestor's proposed new class of NTIOLs should be revised as follows: ''Blue-light-filtering intraocular lenses that improve driving safety under daytime glare from low angle sun conditions.''

Comment: Comments on the question regarding whether the blue-light-filtering characteristic has established clinical relevance and whether the Acrysof blue-light-filtering IOLs satisfy criterion 3, addressed that the first issue is what are the appropriate currently available IOLs to which Alcon's blue blocking IOLs should be compared. The requestor and several other commenters believed that an appropriate comparator IOL for the blue-light-filtering IOL is a spherical monofocal IOL for the following reasons:

- Because market share was not mentioned as a factor in considering which lenses are appropriate comparators for other NTIOL requests, it should not be a factor in the blue-light-filtering request;
- Because the requestor has not claimed that the blue-light-filtering IOLs affect or improve night driving, it would be illogical to suggest that the blue

blocker IOL should be compared to an aspheric IOL;

• Because in prior rulemaking cycles CMS mentioned PMMA IOLs as part of a group of ''currently available IOLs,'' and PMMA IOLs have had a low market share for many years, there is a precedent for considering low market share IOLs to be currently available IOLs;

• Because an aspheric colorless Acrysof IOL does not exist, and other manufacturers' aspheric colorless IOLs are different from Acrysof IOLs in many ways, the model SN60WF IOL cannot be appropriately compared to an aspheric colorless IOL; and

• It is unfair for CMS to propose an aspheric comparator IOL by applying a new definition of ''currently available IOLs'' after this year's NTIOL application deadline.

Response: The requestor, through its comments on the proposed rule, has made clear that the only claimed clinical benefit of the blue-light-filtering IOLs is improved daytime driving under simulated low angle sun conditions and not improved night driving under glare from car headlights. Therefore, we agree that it is not necessary that the blue-light-filtering IOLs be compared to an aspheric IOL because under daytime low angle sun glare conditions pupillary constriction would generally limit the effect of the aspheric optics. However, we believe that it would be beneficial to clarify the meaning of our flexible approach to ''currently available IOLs.'' Our flexible approach means that the appropriate comparator can vary depending upon the candidate IOL and the associated claimed clinical outcome and can also change over time. With some candidate IOLs, lens optics may be the focus of the claimed benefit, while with others, the IOL material may be the focus of the claimed benefit. For example, a new IOL material that claimed the elimination of posterior capsular opacity (PCO) would have to be compared to IOL materials in which PCO occurred. However, the particular optics of the IOLs in this hypothetical case would likely not necessarily matter. If the claim was that the candidate IOL corrected some type of higher order optical aberration that resulted in improved night driving, such an IOL would have to be compared to an aspheric IOL to determine whether it improved night driving beyond that of an aspheric IOL.

Furthermore, as IOL use patterns change over time, what is considered ''currently available'' will also change over time. Although spherical monofocal IOLs have represented the standard, conventional IOL, they now represent a relatively small minority of IOLs implanted in the United States. This trend is at least partially attributed to the NTIOL program for aspheric IOLs and the CMS Rulings for presbyopia correcting IOLs and astigmatism correcting IOLs. Therefore, our flexible approach to currently available comparator IOLs means that manufacturers should account for contemporary practices among U.S. cataract surgeons when designing studies and resist the temptation to select a comparator IOL that would most likely yield a statistically significant result in a study but that may not best fit the proposed hypothesis or NTIOL regulatory requirements.

Regarding the evidence submitted by the requestor in support of its proposition that the blue-light-filtering characteristic has established clinical relevance and that evidence demonstrates that use of the blue-light-filtering IOL results in measurable, clinically meaningful, improved outcomes in comparison with use of currently available IOLs, the requestor submitted a variety of supporting information. However, the requestor relied primarily on the studies by Hammond *et al.* and Gray *et al.* that are cited above. Therefore, although we will discuss other submitted supporting information as appropriate, we will focus primarily on the Hammond and Gray studies as they are the primary support for the requestor's clinical benefit hypothesis. We begin with the Hammond study.

Comment: Some commenters remarked that the Hammond study provides important evidence that supports the requestor's hypothesis that blue blocking IOLs improve driving performance while driving in low angle sun conditions. Other commenters provided detailed critiques of the Hammond study. Because the requestor submitted a similar application last year and some of the same comments were made in response to last year's application, the requestor has had an opportunity to rebut many of these comments. The main points made by some of the commenters on the Hammond study and the associated rebuttals by the requestor are summarized below:

• Figure 3 in the Hammond study mislabels the gray and blue traces. A commenter claims that Xenon's spike is actually in the blue part of the spectrum. The commenter claims that this mislabeling hides a study bias of having a blue glare source (which would be filtered by the blue blocker) but a different wavelength for the target illumination source.

Rebuttal by requestor: Although the figure labels were inadvertently reversed, the glare and target sources were correctly described in the body of the Hammond paper, and a correction has been made through a letter to the journal's editor.

• No IOL or optical filter can decrease disability glare when target and glare illumination have the same spectrum because every filter decreases target and glare illumination in exactly the same proportion. Thus, the retinal image contrast cannot be increased by a color filter; therefore, disability glare cannot be decreased by the filter. The commenter cited several articles in support of this proposition, including a 2007 article (*Optom Vis Sci* 84: 859–64, 2007) by Hammond *et al.*, one of the investigators for the study submitted by the requestors as primary support for their NTIOL application. In this 2007 study macular pigment (MP) was the light filter, and Hammond *et al.* stated the following: ''Increased MP density will also not reduce glare disability when the wavelength conditions between the target and surround are the same. If MP absorbs light from both the target and the surround in equal proportion, that ratio will stay the same irrespective of the MP level. In such instances, high MP levels might reduce photostress and glare discomfort but it will not make a target more visible (that is, improve glare disability). This same interpretation could be applied to other yellow filters (for example, tinted intraocular lenses) and may explain why yellow filters improve visibility in some situations but not in others.''

Rebuttal by requestor: In the real world it is rare that the wavelength of the target and the glare source are the same, because most glare sources are broad spectrum and most targets have a color such that the target absorbs certain wavelengths and reflects others.

• Hammond's heterochromatic contrast threshold testing is designed to advantage the blue-light-filtering IOL because it used a small yellow target surrounded by a large violet-blue glare source, which would be preferentially filtered out by blue blocking IOLs.

Rebuttal by requestor: There is no extant literature suggesting that the glare and target sources should have the same spectral characteristics, and shorter wavelengths such as blue light are scattered more than longer wavelengths, which makes shorter wavelengths more common glare sources and therefore more appropriate for testing.

• The mix of aspheric and spherical blue blocking IOLs in that study group is a confounding variable.

Rebuttal by requestor: The use of the Maxwellian optical system controls for these differences in IOL design. (Several other commenters also stressed this point about the importance of Maxwellian optics in the Hammond *et al.* study design.)

• Hammond's photostress tests have no value for assessing the visual performance of older adults in real world situations because people do not ordinarily stare directly into brilliant, uncomfortable light sources for many seconds, and any colored or neutral density filter that reduces light exposure will decrease recovery time from flash blindness.

Response: We agree with the requestor that the use of the Maxwellian optical system eliminates any potential confounding due to the mix of aspheric and spherical lens designs in the blue-light-filtering IOL study group. However, we agree with the commenters that a violet-blue glare source surrounding a yellow target may advantage the blue-light-filtering IOL in some of the testing conducted in the Hammond study. In the real world, it would seem that, under some circumstances, target and glare sources would have similar wavelength profiles, and therefore, according to the literature, a filter would not affect disability glare. Under other circumstances, the target and glares sources may have a different wavelength profile, and then a filter such as the blue blocker IOL could be of some benefit. We also agree with the commenters that there are significant unanswered questions regarding whether the photostress test results are clinically meaningful in proving that blue-light-filtering IOLs reduce the effects of glare. Overall, there appears to be some significant unanswered questions as to how well the Hammond study supports the requestor's hypothesis in the real world situation of driving during low angle sun conditions.

While the Hammond study was offered as underlying support for the hypothesis that blue-light-filtering IOLs reduce the effects of glare on certain aspects of visual performance or visual function, we now turn to the study that the requestor has characterized as the ''pivotal'' study for its application, which was performed by Gray *et al.,* and is described above. The Gray study is the primary evidence for the purported improved outcome attributed to the blue-light-filtering IOLs of improved driving safety under daytime driving conditions with glare simulating low-angle sun.

Comment: The requestor and several other commenters stated that the Gray study is sufficient evidentiary support for the blue blocker NTIOL application. The requestor and several other commenters stated that the Gray study documents a 0.33 second improvement in the safety margin for patients with blue-light-filtering IOLs as compared to those with colorless IOLs. They maintained that the 0.33 second improvement is clinically significant because driving safety experts agree on the safety benefits of the Center High Mounted Stop Light, which showed an improvement in stopping time of 0.11 seconds, and has been demonstrated to have prevented automobile accidents. Some commenters suggested that there are flaws in the Gray study. (Again, because the requestor submitted a similar application last year and some of the same comments were made in response to last year's application, the requestor has rebutted many of these comments.) The key points made by some of the commenters in critiquing the Gray study and the associated rebuttals by the requestor and other commenters are summarized below:

• The computer monitor simulation used by Gray *et al.* created an unlikely situation in which the pseudophakic Medicare beneficiary is driving into low-lying sun toward a 4-way intersection on a 2 lane rural highway at 55 miles an hour and must make a left hand turn with one eye shut in front of an oncoming car that is also approaching the intersection at 55 miles per hour.

Rebuttal by requestor: The Gray study represents a real-world test of subject performance to determine critical patient safety information.

• The Gray driving simulator was a computer monitor test and not a realistic driving simulator with a car body on a moving base with a wide-field viewing screen.

Rebuttal by requestor: The driving simulator used in the Gray study is a validated driving simulator.

• The driving simulator used in the Gray study did not conform to guidelines for driving simulators outlined in ANSI Z80.12–2007, Annex G. In particular, the commenters stated that the simulation should have been performed binocularly instead of monocularly; the study did not mention matching on age, gender, or driving experience; the study did not have exclusion criteria for medication that may have affected vision or motor abilities; the study did not mention exclusion criteria for capsular haze or large capsulotomy.

Rebuttal by requestor: Patients with pathology including PCO were excluded from the Gray study.

• Sampling approach and bias may be problematic because of the lack of detail on exactly how the subjects were recruited into the study. Potential confounding due to use of a convenience sample, meaning that the sample was chosen at the convenience of the researcher and that there was little or no demonstrated attempt to ensure that the sample accurately represents the target population.

Rebuttal by requestor: Selection bias was addressed by enrolling subjects who were matched for age, time after cataract surgery, and visual acuity.

• Commenters further stated that differences in judging distance to oncoming vehicles could be attributable to motion processing differences between the two groups, which is impaired in older drivers.

• The driving simulator used in the Gray study is not a valid representation of on-road driving performance in older drivers because the validation study cited in the Gray article was done with novice drivers.

Rebuttal by requestor: The trial by Gray et al. used a validated driving simulator system that represents the real-world visual experience by drivers.

Response: We believe that the commenters raise important questions about the Gray trial design and the driving simulator. The requestor has responded to many of these questions and criticisms, but some remain at issue. Questions also remain about whether the Gray study accurately represents realistic driving by Medicare beneficiaries in low angle sun conditions and whether such a small study accurately represents the population of Medicare beneficiaries. Furthermore, the Gray study is a single 17 patient-per-study arm driving simulator study that is the primary support for the requestor's assertion that blue-light-filtering IOLs result in superior outcomes for Medicare beneficiaries as compared to other IOLs. We must evaluate this study in the context of the totality of the evidence of the impact of glare on driving and the significance of this problem for Medicare beneficiaries. We believe that a significant question remains as to whether the Gray study results are sufficient to support the conclusion of a significant real world improved outcome for blue-light-filtering IOLs in Medicare beneficiaries. We discuss these issues below.

Comment: Commenters asserted that ''studies over the past two decades show that glare problems are not associated with crash involvement in older drivers.'' In support of this assertion the commenters cited several studies,

including studies by Owsley and Cross. The requestor rebutted the commenters' assertion by stating that none of the studies cited by the commenters involved driving simulation or other real-world situations, and that because of historical limitations in studying glare, the cited studies' methods of driving safety are inaccurate and that the studies are otherwise methodologically flawed.

Response: The commenters raise an important issue. The following summary on this issue is from a very recent 2010 review article by Owsley and McGwin (that was submitted by the requestor in its application) and that summarizes the conclusions of the literature (some of which was cited by the commenters): ''Disability glare (increased glare sensitivity), particularly among older drivers, is discussed as a serious threat to the safety of older drivers (e.g., Wolbarsht, 1977) but studies have not scientifically supported this notion (Ball, *et al.* 1993; Owsley, Ball, *et al.,* 1998; Owsley, *et al.,* 2001). This failure to find an association between glare and road safety may be attributed to methodological difficulties in defining ''glare'' and in measuring a multifaceted phenomenon (for example, discomfort glare, disability glare), as well as to a poor understanding of what people mean when they say they have ''glare'' problems. Rubin *et al.* (2007) reported a seemingly paradoxical relationship between disability glare and motor vehicle collisions. They found that disability glare reduced crash risk in older drivers with good vision, which could not be attributed to changes in driving habits (e.g., reduced exposure).'' Section 416.195(a)(2) of our regulations requires that the lens characteristic of the candidate IOL have established clinical relevance in comparison to currently available IOLs. If, as stated above by Owsley and McGwin, the association between glare and decreased driving safety among the elderly has not been supported by the published scientific evidence as of 2010, a significant question remains as to whether the single new 17-patient-per-group study by Gray sufficiently establishes the clinical relevance of blue-light-filtering IOLs for improving driving safety under glare conditions from low angle sun. We believe that in light of the totality of all of the published evidence regarding glare and driving in older adults, as summarized above by Owsley and McGwin, the lone study by Gray is currently insufficient to establish the clinical relevance of the blue-light-filtering IOLs.

Comment: One commenter stated that most drivers would use the windshield visor and/or sunglasses, or take other common-sense precautions to mitigate the effects of glare from low angle sun.

Response: We believe that this comment introduces a topic that is worthy of further discussion. The intent of the Gray study was to test driving ability during simulated glare from low-angle sun during the daytime. Glare from low angle sun is encountered when driving east shortly after sunrise and when driving west shortly before sunset. We believe that there is a significant question as to whether the results of the experiment performed by Gray (assuming for the purpose of this response that the results are valid within Gray's experimental context) represent a real-world improved clinical outcome or clinical benefit in the context of real-world daytime driving during times of low angle sun by Medicare beneficiaries. Most people have experienced the bothersome effects of low angle sun (or having the ''sun in your eyes'') during a variety of daytime activities including driving. As the commenter pointed out, there are currently several daytime glare countermeasures that are both widely recommended by ophthalmologists, optometrists, and others and that have been widely adopted by the public for mitigating the bothersome effects of low angle sun during daytime driving. These include (but are not necessarily limited to) the automobile's sun visor, tinted windshield glass, polarized sunglasses, and antireflective (AR) coatings on glasses. Such daytime glare countermeasures are included in the following recommendations for mitigation of the effects of glare from low angle sun during driving by the Vision Council of America:

- Drive cautiously and leave a proper distance to ensure ample reaction time;
- Make it a habit to lower visors, to help block the reflected light;
- Avoid using high-gloss cleaners on dashboards;
- Keep the car windshield clean and the windshield washer fluid reservoir full;
- When possible, take an alternate route lined with trees or tall buildings instead of one with extreme glare;
- Turn on headlights to reduce the possible poor visibility of oncoming drivers;
- *Most importantly, wear sunglasses at all times. Even more important is to wear sunglasses with polarized lenses to reduce glare, and lenses with UV protection to shield the eyes from damage* (emphasis added).

The benefits of these daytime glare countermeasures are well known by both eye care professionals and the general public. Given all of these common countermeasures for managing glare from the sun during driving, we do not know, despite the Gray study, exactly what additional benefit blue-light-filtering IOLs (when combined with the common glare countermeasures described above) would provide to Medicare beneficiaries while driving at times of low angle sun. For example, the Gray study does not assess the function of blue-light-filtering IOLs underneath polarized sunglasses that already typically absorb a broad spectrum of light including blue light and also reduce glare through the polarized property of the lenses in the sunglasses. We believe that it would be important to account for these common daytime glare countermeasures that are in widespread use when assessing the real-world benefit of blue-light-filtering IOLs for problems associated with low angle sun while driving.

Comment: One commenter stated that Gray's decision to limit his experiments to daytime conditions is a critical problem, because nighttime conditions are the greatest challenge to Medicare beneficiaries, causing many older drivers to self-restrict their driving to avoid driving at night.

Response: The commenter raises the issue of daytime versus nighttime driving, which we believe is an important issue as it relates to the purported clinical benefit of blue blocking IOLs to Medicare beneficiaries. Specifically, the issue is whether improved driving performance during low angle sun conditions is a clinical outcome that would satisfy 42 CFR 416.195(a)(4), which states that there must be evidence that demonstrates that use of the IOL results in measurable, clinically meaningful, improved outcomes in comparison with use of currently available IOLs. The statutory provision that is the basis of this regulation specifies the following outcomes: (1) Reduced risk of intraoperative or postoperative complication or trauma; (2) accelerated postoperative recovery; (3) reduced induced astigmatism; (4) improved postoperative visual acuity; (5) more stable postoperative vision; or (6) other comparable clinical advantages. The question is whether improved driving performance during low angle sun conditions is a ''comparable clinical advantage'' and, therefore, an outcome that would satisfy the statutory and regulatory requirements.

The most analogous clinical outcome associated with an expired NTIOL class is the improved night driving associated with the expired reduced spherical aberration NTIOL class. However, there

are significant differences between daytime driving with glare from low angle sun and nighttime driving with glare from headlights. The nighttime driving benefit of reduced spherical aberration IOLs was a clinical benefit to Medicare beneficiaries because (other than abstaining from driving at night) there is very little that drivers can do at nighttime to mitigate the effect of glare from headlights. Therefore, even a modest night driving benefit from a reduced spherical aberration IOL can have an overall significant impact on Medicare beneficiaries' night driving because of the lack of other countermeasures that can assist with night driving. However, with daytime driving during low angle sun, an IOL that possibly mitigates the effects of glare under these conditions appears less significant given all of the other glare countermeasures available to the daytime driver.

Furthermore, the most effective means of mitigating the effects of glare is avoidance of the glare source. During nighttime, this is a significant inconvenience because to do so means not driving at night. However, for glare from the sun, as mentioned above, there are many countermeasures for glare caused by low-angle sun, which is only a problem for certain drivers (those driving east in the morning and west in the evening) during a relatively short period of time each day. For these drivers, avoidance can be a practical alternative to driving into the bright sun. As mentioned above, the Vision Council of America recommends that drivers take a shady route if available. However, even if an alternate non-sunny route is not available, Medicare beneficiaries who are particularly bothered (despite using all of the daytime glare countermeasures such as polarized sunglasses, the car's sun visor, among others) by glare from low-angle sun could simply wait a short period of time before driving while the angle of the sun changes so that the sun is in a less glare-inducing position relative to the earth. Unlike nightfall that lasts for hours each day and, therefore, is inconvenient to avoid, waiting a short period of time for the sun to move a bit higher in the sky would be a relatively minor inconvenience for those Medicare beneficiaries who are particularly sensitive to glare from low angle sun.

While this may not be true for the larger working-age population who may be locked into a relatively rigid commuting schedule and, therefore, may find it difficult due to job obligations to shift their commuting schedules even slightly, the overwhelming majority of Medicare beneficiaries tend to be retirees who generally do not face such rigid transportation schedule restrictions. In their 2007 study, Gray and Regan acknowledge this point as follows: ''Our present study is restricted to disability glare produced by low sun *as experienced by very many drivers on their way to work or returning from work*'' (emphasis added). Furthermore, waiting to drive until the low-angle sun has moved slightly in the morning could have a collateral benefit if doing so allowed the driver to avoid rush hour traffic. Driving in lower density traffic would likely lower the probability of a traffic accident thereby promoting driving safety, which seems to be one goal of this NTIOL application and other recent developments in IOL technology.

Therefore, given the significant differences between nighttime driving and daytime driving, we do not believe that improved driving performance limited only to daytime under conditions of glare from low angle sun in this context is a ''comparable clinical advantage'' when compared to those outcomes listed above and in the statute and the outcomes associated with the three expired NTIOL classes, including improved night driving under conditions of glare from headlights. For this reason (and others discussed elsewhere in this preamble), the request does not satisfy 42 CFR 416.195(a)(4) because the purported outcome is not a comparable clinical advantage for Medicare beneficiaries.

Comment: Some commenters mentioned certain detrimental effects of blue-light-filtering IOLs, such as blue-light-filtering IOLs negatively affecting: (1) Certain aspects of photoreceptor function; (2) aspects of night vision; (3) sleep and mood; and (4) visual function due to glistenings. Other commenters stated that blue-light-filtering IOLs have none of these detrimental effects.

Response: We are aware that there has been, and continues to be, a vigorous debate in the literature regarding some of these issues. We do not have enough information to evaluate these issues, which we consider important but somewhat collateral to the issues under review for this NTIOL application. The decision on the blue-light-filtering NTIOL request is not based on and does not take into account these particular comments except to acknowledge them and the arguments and data supporting both sides of these issues. Also, we believe that FDA is best situated to address any problems from glistenings.

In summary, we have reviewed the application and evidence submitted by the requestor and the public comments received. We conclude that, based on the totality of the available information and our analysis, the evidence is insufficient to conclude that the blue-light-filtering characteristic of the Acrysof blue-light-filtering IOLs has established clinical relevance in comparison to currently available IOLs. We also conclude that the evidence does not demonstrate that the use of the Acrysof blue-light-filtering IOLs results in measurable, clinically meaningful, improved outcomes in comparison with use of currently available IOLs. Therefore, Alcon's request for NTIOL status for its Acrysof blue-light-filtering IOLs is denied.

b. Requestor/Manufacturer: Bausch & Lomb, Inc. (B&L)

Lens Model Numbers: Xact Foldable Hydrophobic Acrylic Ultraviolet Light-Absorbing Posterior Chamber Intraocular Lenses, Models X–60 and X–70 (Xact IOLs).

Summary of the Request: B&L submitted a request for CMS to determine that its Xact IOLs meet the criteria for recognition as NTIOLs and to concurrently establish a new class of NTIOLs for ''glistening-free'' IOLs. Glistenings are fluid-filled microvacuoles that can form within an IOL optic when the IOL is in an aqueous environment. According to B&L, ''glistenings have been associated with decreased contrast sensitivity, increased glare, decreased visual acuity, and impaired fundus visualization.'' B&L further states that ''in some cases, this has led to IOL explantation and exchange, which carries significant risks that increase the longer the IOL is implanted.'' As part of its request, B&L submitted descriptive information about the candidate IOLs as outlined in the guidance document that is available on the CMS Web site for the establishment of a new class of NTIOLs, as well as information regarding approval of the candidate IOL by the FDA. This information included draft FDA-approved labeling for the Xact IOLs.

In its CY 2012 request, B&L asserts that because the Xact IOLs are glistening-free, they eliminate the decreased contrast sensitivity, increased glare, decreased visual acuity, and impaired fundus visualization associated with glistenings, and may likewise decrease the need for explantations associated with those conditions. B&L also concludes that use of a glistening-free IOL results in measurable, clinically meaningful, improved outcomes in comparison with currently available IOLs. B&L also states that the glistening-free characteristic is not described by a previously-approved NTIOL class.

As with the other CY 2012 NTIOL applications discussed in the CY 2012 OPPS/ASC proposed rule, we base our determination of the B&L application on consideration of the three major evaluation criteria that are discussed above. We reviewed B&L's request to recognize its Xact IOLs as NTIOLs and concurrently establish a new class of NTIOLs, and in the proposed rule we solicited public comment on these candidate IOLs with respect to the established NTIOL criteria as discussed above.

First, for an IOL to be recognized as an NTIOL, we require that the IOL must have been approved by the FDA and claims of specific clinical benefits and/or lens characteristics with established clinical relevance in comparison with currently available IOLs must have been approved by the FDA for use in labeling and advertising. The submitted FDA-approved labeling for the Xact IOLs states the following:

''In the IDE [investigational device exemption] clinical trial, 'glistenings' were observed in some cases. Glistenings, known to sometimes occur in some other hydrophobic acrylic IOLs, are microscopic vacuoles within the optic of the IOL that are visible through the slit lamp as multiple small refractile specks. *Analysis of the clinical data confirmed no effect of glistenings on visual outcomes*'' [emphasis added].

''Testing established that glistenings were eliminated by a change in the IOL hydration solution from 10.0% saline to 0.9% saline. This was confirmed in an additional clinical trial conducted outside of the United States. In this study, 172 eyes of 142 patients were examined at least once between 1 and 6 months, and 123 eyes of 101 patients were examined at least once between 6 months and 2 years. No glistenings were observed at any time.''

The FDA-approved labeling for the Xact IOLs does not otherwise reference specific clinical benefits of the glistening-free property. In fact, the above-quoted language on the IDE study from the FDA-approved labeling states that an ''[a]nalysis of the clinical data confirmed no effect of glistenings on visual outcomes.'' In the proposed rule (76 FR 42303 through 42309), we stated that we were interested in public comments on the clinical relevance of glistenings in IOLs, and the incidence of glistenings severe enough to cause measurable visual symptoms in recently pseudophakic Medicare beneficiaries. In addition, we were interested in public comments regarding the assertion by B&L that the glistening-free property associated with the Xact IOLs would eliminate the decreased contrast sensitivity, increased glare, decreased visual acuity, and impaired fundus visualization associated with glistenings, and may likewise decrease the need for explantations associated with those conditions.

Second, we also require that the candidate IOL not be described by an active or expired NTIOL class; that is, it does not share the predominant, class-defining characteristic associated with improved clinical outcomes with designated members of an active or expired NTIOL class. We refer readers to the discussion above for more information on the three expired NTIOL classes. The proposed class-defining characteristic and associated clinical benefits of the Xact IOLs, specifically the glistening-free property, cannot be similar to the class-defining characteristics and associated benefits of the three expired NTIOL classes. In the proposed rule (76 FR 42303 through 42309), we welcomed public comments that address whether the proposed class-defining characteristic and associated clinical benefits of the candidate B&L IOLs are described by the expired NTIOL classes.

Third, our NTIOL evaluation criteria also require that an applicant submit evidence demonstrating that use of the IOL results in measurable, clinically meaningful, improved outcomes in comparison to currently available IOLs. As discussed above, we remain flexible with respect to our view of ''currently available lenses'' for purposes of reviewing NTIOL requests, in order to allow for consideration of technological advances in lenses over time. We also believe that ''currently available lenses'' for purposes of reviewing NTIOL requests should depend upon the class-defining characteristic and the associated purported improved clinical outcome of the candidate NTIOL class. For purposes of reviewing B&L's request to establish a new NTIOL class for CY 2012, we believe that the full spectrum of currently available IOL materials should be represented in the comparator IOLs, but that the particular design of the optic (for example, aspheric versus spherical) is less critical to evaluating the benefits of glistening-free IOLs as glistenings are related more to the IOL optic material than to the optical surface characteristics of the IOL. In the proposed rule (76 FR 42303 through 42309), we sought public comment on our view of ''currently available lenses'' for the purposes of evaluating B&L's candidate IOLs against currently available IOLs.

We reviewed the evidence submitted with B&L's CY 2012 request. B&L submitted a variety of articles including studies and case reports focused on IOLs with glistenings. It is apparent from these articles that glistenings are a real phenomenon and that glistenings are primarily associated with acrylic hydrophobic IOLs, but they can also occur to some degree in IOLs of other material types. However, there are several significant questions with respect to glistenings, and we solicited public comment on these questions as follows:

- Is there a particular IOL material type that is more likely to result in symptomatic glistenings relative to other material types?
- What is the clinical significance (from the patient's perspective) of glistenings? More specifically, what evidence is available to demonstrate that glistenings cause any of the following:
  - Decreased contrast sensitivity;
  - Increased glare disability;
  - Decreased visual acuity;
  - Impaired fundus visualization;
  - Symptoms resulting in IOL explantations.
- What is the incidence of glistenings in IOLs currently available in the United States?
- If a certain level of severity of glistenings is required before they cause symptoms, what is the incidence of glistenings of this severity level in IOLs currently available in the United States?

Comment: The requestor asserted that the FDA-approved labeling for the Xact IOLs states that these IOLs are glistening-free and that such a statement qualifies as a ''lens characteristic'' that satisfies 42 CFR 416.195(a)(2), and that glistening-free IOLs are not described by an expired NTIOL class. One commenter remarked that the term glistening-free is imprecise, and wonders whether it means the complete absence of any glistenings whatsoever, regardless of severity, and whether subclinical glistenings could be present to some degree in a glistening-free IOL. Another commenter argued that because the Xact IOL label does not identify any approved claim of clinical benefit or any lens characteristic with established clinical relevance, it does not satisfy the requirements of 42 CFR 416.195(a)(2).

Response: We agree with the requestor. As stated above, 42 CFR 416.195(a)(2) can be satisfied by a lens characteristic listed in the FDA-approved labeling with the evidence of established clinical relevance in comparison with currently available IOLs provided outside of the FDA-approved labeling, such as in peer-reviewed journals. The Xact IOL FDA-approved labeling states that for patient follow-up up to 2 years, ''[n]o

glistenings were observed at any time.'' We accept that statement to mean that the Xact IOLs are glistening-free, at least for the time period of the study referenced in the FDA-approved labeling. In response to the commenter who remarked that the term glistening-free is imprecise, and asked whether it means the complete absence of any glistenings whatsoever, regardless of severity, and whether subclinical glistenings could be present to some degree in a glistening-free IOL, we believe that, although this is an important point, it will not be discussed further because it is rendered moot by the discussion below. We also agree with the requester and other commenters that the proposed glistening-free Xact IOLs are not described by an expired NTIOL class.

Comment: The requestor reiterated its belief that glistenings cause compromised visual performance in patients, and that ''[t]he growing concern regarding glistenings is evidenced by the high level of attention that has been paid to them in the medical literature. A 2010 review article cited over 70 studies related to glistenings, most published after 2000, a staggering figure that itself demonstrates that glistenings are widely viewed by clinicians as problematic.'' Therefore, according to the requestor, a glistening-free IOL offers the clinical benefit of avoiding visual problems associated with glistenings. The requestor offers the following information as specific evidence that glistenings are clinically significant:

- A study by Gunenc *et al.* that showed a statistically significant difference in contrast sensitivity at high spatial frequency between eyes with and without glistenings;
- A study by Christiansen *et al.* that showed decreased visual acuity with a glare source versus without a glare source in patients with glistenings and decreased visual acuity in patients with severe glistenings versus patients with mild glistenings;
- A case study by Werner *et al.* in which an IOL with glistenings was explanted due to impaired fundus visualization;
- There were 24 reports between 1997 and 2011 of IOL explantation due to glistenings from the FDA medical device adverse event database.

Other commenters asserted that the currently available peer-reviewed literature does not yield any clinical studies supporting a clinical benefit associated with the ''glistening-free'' property of the Xact IOLs.

Response: We agree with the commenters who conclude that the clinical significance of glistenings is not established in the ophthalmic literature and, therefore, there is no proven clinical benefit of glistening-free IOLs. The requestor is correct that a high level of attention has been paid to glistenings in the ophthalmic literature. However, the majority of the literature on glistenings is either inconclusive with respect to the clinical significance of glistenings or shows no effect on visual function from the glistenings.

The limited evidence offered by the requestor is not dispositive. The requestor is correct that the 2001 Gunenc *et al.* study showed a statistically significant difference in contrast sensitivity at high spatial frequency between eyes with and without glistenings. However, that study showed no difference in visual acuity and contrast sensitivity at low or medium spatial frequencies between eyes with and without glistenings. Furthermore, the overall conclusion of the Gunenc *et al.* study is as follows: ''Although glistenings and folding marks were observed after the implantation of Acrysof IOLs, *they did not significantly affect visual function*'' (emphasis added).

Similarly, the conclusion of the 2001 Christiansen *et al.* study was as follows: ''Glistenings occurred frequently in AcrySof IOLs, with most cases mild. A larger study of this lens is needed to determine whether severe presentations affect visual function and to understand how glistenings change over time.'' As noted by some commenters, further studies have been performed on the AcrySof IOLs by Colin, Monestam and others who did not find that glistenings affected visual function. The 2008 Werner *et al.* paper mentioned by the requestor is a single case report of an explanted IOL due to glistenings. Regarding this patient, Werner stated that ''[a]lthough it was difficult to ascertain the exact effect on the patient's visual function, the pattern of glistening formation was very unusual.'' The investigator's characterization of the glistening pattern in this case makes this case seem more anomalous than typical. More importantly, considering that the Werner *et al.* case report is relatively recent, the authors state that ''[t]here is still controversy about whether glistenings affect the visual function of the patient and whether they progress over time[,]'' and they cite seven articles in support of this statement.

The lack of a consensus in the literature regarding the clinical significance of glistenings is significant for the purposes of this NTIOL application because 42 CFR 416.195(a)(2) requires that the lens characteristic have established clinical relevance, not merely theoretical clinical relevance. If glistenings are not proven through proper scientific studies to affect visual function, the clinical relevance of the glistening-free lens characteristic is not established. Regarding this point, the requestor stated in its comment letter that ''[t]he effects of glistenings on a patient's vision are not easily captured using existing tests.'' Assuming that this statement is true, it presents an issue for this application, because 42 CFR 416.195(a)(4) requires evidence that demonstrates that use of the IOL results in *measurable,* clinically meaningful, improved outcomes in comparison with use of currently available IOLs (emphasis added). If clinical visual function testing cannot measure the effect of glistenings, then it is impossible to determine the extent to which glistenings affects patients' vision. The fourth piece of evidence offered by the requestor regarding the clinical significance of glistenings is that there were 24 reports between 1997 and 2011 of IOL explantation due to glistenings from the FDA medical device adverse event database. Assuming that these explantations can be accurately attributed to glistenings, 24 cases, among the tens of millions of cataract surgeries performed in the United States since 1997, is too small to establish clinical relevance. In essence, the requestor corrected a perceived problem (glistenings) with the Xact IOLs by changing the IOL storage solution that eliminated the glistenings, although the glistenings had no effect on visual function in patients with the Xact IOLs.

In summary, because the applicant has not demonstrated the established clinical relevance of the glistening-free characteristic of the Xact IOLs in comparison to currently available IOLs, these IOLs do not satisfy 42 CFR 416.195(a)(2). And, because the evidence is insufficient to demonstrate that use of the Xact IOLs result in measurable, clinically meaningful, improved outcomes in comparison with use of currently available IOLs, they fail to satisfy 42 CFR 416.195(a)(4). Therefore, the Xact IOL NTIOL application is denied.

c. Requestor/Manufacturer: Hoya Surgical Optics, Inc. (Hoya)

Lens Model Numbers: iSert IOL System, Model PY–60R

Summary of the Request: Hoya submitted a request for CMS to determine that its iSert IOL System satisfies the criteria for recognition as an NTIOL and to concurrently establish a new class of NTIOLs for ''aseptically

integrated IOL and injector systems.'' The iSert IOL System is an IOL preloaded in a plastic, sterile, disposable injection system. According to Hoya, the iSert System provides a lens injector with an integrated IOL inside it within a single, sterile package for delivery to the operating field. According to Hoya, the iSert System has the following benefits, in that compared to other IOLs it:

- Eliminates the risk of complications associated with improper processing of reusable forceps or injectors used for all other foldable IOLs;
- Accelerates postoperative recovery through decreased risk of ocular damage due to complications associated with improper processing of reusable forceps or injectors used for other foldable IOLs;
- Provides a clinical advantage compared to existing IOLs by allowing the IOL to be placed in the eye without contacting external ocular tissues or reusable injection instruments; and
- Improves overall safety of cataract/IOL surgery by reducing the number of reusable instruments that must be properly cleaned and sterilized between cases.

As part of its request, Hoya submitted descriptive information about the iSert System as outlined in the guidance document described above that is available on the CMS Web site for the establishment of a new class of NTIOLs, as well as information regarding approval of the candidate IOL by the FDA. This information included the FDA-approved labeling, the FDA letter of approval, and the summary of safety and effectiveness for the iSert System.

As with the other CY 2012 NTIOL requests, we based our determination of the Hoya request on consideration of the three major criteria that are discussed above. We reviewed Hoya's request to recognize its iSert System as an NTIOL and concurrently establish a new class of NTIOLs. In the CY 2012 OPPS/ASC proposed rule, we solicited public comment on this candidate IOL with respect to the established NTIOL criteria.

First, for an IOL to be recognized as an NTIOL we require that the IOL must have been approved by the FDA and claims of specific clinical benefits and/or lens characteristics with established clinical relevance in comparison with currently available IOLs must have been approved by the FDA for use in labeling and advertising. The FDA-approved labeling for the iSert System states the following under the heading ''DEVICE DESCRIPTION'':

''The Hoya iSert™ Model PY–60R Intraocular Lens (IOL) is an ultraviolet absorbing posterior chamber intraocular lens designed to be implanted posterior to the iris where the lens will replace the optical function of the natural crystalline lens. However, accommodation will not be replaced. PY–60R is loaded in a disposable injector consists [sic] of Case, Tip, Body, Slider, Rod, Plunger, and Screw.''

The FDA-approved labeling for the iSert System states the following under the heading INDICATIONS:

''The Hoya iSert™ Model PY–60R Intraocular Lens is indicated for primary implantation in the capsular bag of the eye for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed.''

The FDA-approved labeling for the iSert System does not otherwise reference claims of specific clinical benefits and/or lens characteristics with established clinical relevance in comparison with currently available IOLs. Section 416.195(a)(2) requires that ''[c]laims of specific clinical benefits and/or lens characteristics with established clinical relevance in comparison with currently available IOLs are approved by the FDA for use in labeling and advertising.'' The FDA-approved labeling for the iSert System lacks any such claims. The only statement in the above-quoted language from the FDA-approved labeling that is any different from the typical device description and indications for a standard spherical monofocal IOL is the statement that the ''PY–60R is loaded in a disposable injector consists [sic] of Case, Tip, Body, Slider, Rod, Plunger, and Screw.'' However, this statement merely describes the IOL as loaded in a disposable injector. It does not appear to describe a benefit or characteristic of the IOL itself. Therefore, it would appear that the Hoya iSert System PY–60R IOL would not satisfy the requirements of 42 CFR 416.195(a)(2). However, in the proposed rule, we solicited public comments on this matter and stated that we would give all comments full consideration regarding Hoya's candidate IOL.

Comment: With regard to whether the Hoya iSert System PY–60R IOL describes a benefit or characteristic of the IOL itself such that it would satisfy the requirements of 42 CFR 416.195(a)(2), two commenters stated that the HOYA iSert System has neither an approved claim of clinical benefit nor a characteristic with established clinical relevance attributable to the actual IOL that is a part of the HOYA iSert System, and therefore, the HOYA iSert System is not eligible for NTIOL status.

Response: We agree with these commenters.

Because the IOL itself within the Hoya iSert System lacks an associated claim or IOL characteristic as required by 42 CFR 416.195(a)(2), the Hoya iSert System is not eligible for NTIOL status, and Hoya's request for NTIOL status for the Hoya iSert System is denied.

d. Requestor/Manufacturer: Lenstec, Inc. (Lenstec)

Lens Model Numbers: Softec HD PS

Summary of the Request: Lenstec submitted a request for CMS to determine that its Softec HD PS meets the criteria for recognition as an NTIOL and to concurrently establish a new class of NTIOLs that result in a ''reduction of postoperative residual refractive error.'' According to Lenstec, the Softec HD PS IOL achieves a ''reduction of postoperative residual refractive error'' by its availability in 0.25 diopter (D) increments with a tolerance of ±0.11 D, while all other current monofocal IOLs are available in only 0.50 D increments with tolerances allowed up to ±0.40 D. According to Lenstec, patients implanted with the Softec HD PS are much more likely to be closer to the intended refractive outcome than those implanted with IOLs available only in 0.50 D increments. This greater refractive accuracy of the Softec HD PS is due to the chosen IOL power likely being closer to the calculated (desired) IOL power and because the tighter tolerance of the 0.25 D increment IOL results in the actual power of the implanted IOL to be closer to the power that the surgeon expects to implant into the patient. Lenstec also asserts that because the 0.25 D increment IOL provides greater IOL power accuracy, patients have less postoperative residual refractive error and hence reduced postoperative blur. As part of its request, Lenstec submitted descriptive information about the candidate IOLs as outlined in the guidance document that is available on the CMS Web site for the establishment of a new class of NTIOLs, as well as information regarding approval of the candidate IOL by the FDA. This information included the FDA-approved labeling, FDA approval letter, and summary of safety and effectiveness for the Softec HD PS IOL.

As with the other three CY 2012 NTIOL applications discussed above, we based our determination of the Lenstec application on consideration of the three major evaluation criteria that are discussed above. We reviewed Lenstec's request to recognize its Softec HD PS IOL as an NTIOL and concurrently establish a new class of NTIOLs. In the CY 2012 OPPS/ASC proposed rule, we solicited public

comment on this candidate IOL with respect to the established NTIOL criteria as discussed above.

First, for an IOL to be recognized as an NTIOL we require that the IOL must have been approved by the FDA and claims of specific clinical benefits and/or lens characteristics with established clinical relevance in comparison with currently available IOLs must have been approved by the FDA for use in labeling and advertising. The submitted FDA-approved labeling for the Softec HD PS IOL states under the heading DEVICE DESCRIPTION that ''[t]he [LENSTEC Softec HD PS] IOL is offered in quarter diopter increments from 15.0 to 25.0.'' The FDA-approved labeling for the Softec HD PS IOL does not otherwise reference claims of specific clinical benefits and/or lens characteristics with established clinical relevance in comparison with currently available IOLs. We were interested in public comments on whether an IOL being offered in quarter diopter increments can be considered a ''lens characteristic with established clinical relevance in comparison with currently available IOLs,'' as required by 42 CFR 416.195(a)(2), or whether IOL availability in quarter diopter increments is more appropriately considered not a lens characteristic per se, but instead just a manufacturer specification. In the proposed rule (76 FR 42303 through 42309), we also sought public comments on the clinical relevance of an IOL being available in quarter diopter increments.

Second, as required by 42 CFR 416.195(a)(3), the candidate IOL must not be described by an active or expired NTIOL class; that is, it does not share the predominant, class-defining characteristic associated with improved clinical outcomes with designated members of an active or expired NTIOL class. Refer to the discussion above for more information on the three expired NTIOL classes. Lenstec states the following in its application:

''The Softec HD IOL, the parent to the Softec HD PS, was first approved for marketing in the United States on April 17, 2010 and on March 15, 2006 in the 'Outside the US' (OUS) environment. This IOL is included in the just-closed 'Reduced Spherical Aberration' NTIOL category. The Softec HD PS was approved for marketing by the FDA on February 2, 2011. It is currently pending approval for OUS marketing. Both IOLs are single piece, hydrophilic acrylic, aspheric, monofocal IOLs. The difference between the two is that the Softec HD has previously been available in whole, 0.50 and 0.25 diopter increments, based on dioptric power. The Softec HD PS is offered *only* in the dioptric range of 15.0 D to 25.0 D, in 0.25 diopter increments (each of which is manufactured to a tolerance of ±0.11D).''

Based on this statement by Lenstec, the Softec HD PS is the same lens as the Softec HD, but the Softec HD PS is available only in 0.25 D increments for a specific power range instead of being available (as is the Softec HD) in 1.0, 0.5, and 0.25 D increments. The Softec HD was included in the expired Reduced Spherical Aberration NTIOL class, and both of these IOLs share the asphericity characteristic that defines the expired Reduced Spherical Aberration NTIOL class. It appears that the predominant characteristic of the Softec HD PS could be asphericity, as it affects the optical characteristics of the lens. Although the availability of the Softec HD PS in 0.25 D increments allows more IOL power choices for the surgeon, it does not appear to affect the functionality of the IOL. In the proposed rule, we requested comments regarding what characteristic of the Softec HD PS is predominant, asphericity or availability of the IOL in 0.25 D increments.

Third, our NTIOL evaluation criteria also require that an applicant submit evidence demonstrating that use of the IOL results in measurable, clinically meaningful, improved outcomes in comparison to currently available IOLs. As discussed above, we remain flexible with respect to our view of ''currently available lenses'' for purposes of reviewing NTIOL requests, in order to allow for consideration of technological advances in lenses over time. We also believe that ''currently available lenses'' for purposes of reviewing NTIOL requests should depend upon the class-defining characteristic and the associated purported improved clinical outcome of the candidate NTIOL class. For purposes of reviewing Lenstec's request to establish a new NTIOL class for CY 2012, we believe that the full spectrum of currently available monofocal IOLs should be represented in the comparator IOLs. Lenstec asserts that what makes its candidate IOL superior to other currently available IOLs is improved IOL power accuracy as compared to IOLs available in 0.50 D increments, and because the Softec HD PS provides greater IOL power accuracy patients implanted with it have less postoperative residual refractive error and hence reduced post-operative blur.

We reviewed the evidence submitted with Lenstec's CY 2012 request. Lenstec submitted information and reviewed the literature on IOL optics related to the Softec HD PS. Lenstec relies primarily on one study that is the subject of an article that is currently in press and another unpublished study to support its hypothesis that the Softec HD PS IOL results in less postoperative refractive error than other IOLs. The first study submitted by Lenstec was the study that it conducted under an IDE for FDA approval of the Softec HD PS IOL. This study is being published in the journal, *Contact Lens and Anterior Eye* (*Brown DC, Gills JP 3rd, et al.* Prospective multicenter trial assessing effectiveness, refractive predictability and safety of a new aberration free, bi-aspheric intraocular lens. *Cont Lens Anterior Eye.* 2011 May 24 (electronic publication in advance of print release), and is available on the Internet at *http://www.sciencedirect.com/science/article/pii/S1367048411000634.* Refractive accuracy was not a planned outcome variable in this study. There was no control group in this study that would have allowed the investigators to control for all of the variables that impact post-cataract surgery refractive outcome and/or isolate the effect of the availability of the Softec HD PS IOL in quarter diopter increments. Lenstec compared the postoperative refractive errors of these study subjects to the results from an unrelated study performed outside of the United States (using IOLs that were available only in 0.50 D increments) and concluded based on this comparison that implantation of the Softec HD PS IOL, which is available in quarter diopter increments, results in superior refractive outcomes as compared to other IOLs.

The second study is a retrospective study of cataract cases with aspheric monofocal IOL implantation between 2009 and 2011. Of the 118 eligible eyes, 67 were implanted with IOLs available in 0.25 D increments and labeled with a manufacturing tolerance of ±0.11D (the labeled group) and 51 were implanted with IOLs available in 0.50 D increments without a labeled manufacturing tolerance (the unlabeled group). Postoperative outcomes were assessed, and prediction error was calculated and compared between groups. Mean error of prediction was −0.03 (±0.35) D for the labeled group and −0.05 (±0.46) D for the unlabeled group (p=0.64) post optimization. Mean absolute error of prediction was statistically significantly smaller in the labeled group (0.26±0.23 D) than the unlabeled group (0.37±0.28 D, p=0.04). It was observed that within ±0.25 D prediction error was achieved in 63 percent of the patients in the labeled group compared to 43 percent in the unlabeled group (p=0.03), and for

within ±0.50 D, 84 percent and 69 percent (p=0.06), respectively. In the proposed rule (76 FR 42303 through 42309), we requested comments from the public regarding the Lenstec NTIOL request and the evidence submitted by Lenstec, and in particular we requested public comment on the following:

- What is the clinical significance (from the patient's perspective) of a small amount of residual spherical refractive error after cataract surgery?
- What is the likelihood that a Medicare beneficiary receiving a monofocal IOL will require some form of postoperative refractive correction (that is, post-cataract surgery glasses), which is a Medicare benefit?
- If the overwhelming majority of Medicare beneficiaries receiving a monofocal IOL will require some form of postoperative refractive correction (that is, post-cataract surgery glasses), does that lessen the clinical significance of reduced postoperative residual refractive error?
- Are the studies described above properly designed to test Lenstec's hypothesis?
- Do the studies described above adequately prove Lenstec's hypothesis?

Comment: Several commenters stated that availability in 0.25 D increments with a tolerance of ± 0.11 D is a lens characteristic that satisfies criterion 1. One commenter argued that lens power increments are not a characteristic within the meaning of the NTIOL regulations, and, even if they are, they have no established clinical relevance.

Response: We agree with the majority of the commenters that, for the purposes of this NTIOL application, availability in 0.25 D increments with a tolerance of ±0.11 D for the HD PS IOL is a lens characteristic within the meaning of the regulation. Whether the requestor has established the clinical relevance of this characteristic is discussed further below.

Comment: Several commenters believed that, for the purposes of this NTIOL application, the predominant characteristic of the HD PS IOL is availability in 0.25 D increments with a tolerance of ± 0.11 D and not asphericity resulting in reduced spherical aberration. One commenter stated that because Lenstec has not presented evidence to distinguish the contribution of the 0.25 D increments from the contribution of the aspheric optic (an expired NTIOL class) to the optical performance of the lens, the 0.25 D increments cannot be considered the predominant characteristic and the Lenstec application should be disqualified from consideration for a new NTIOL category.

Response: We agree with the majority of commenters. As discussed above, we believe that when the clinical outcomes associated with different lens characteristics are related, then comparative clinical data are required to demonstrate that one characteristic is predominant over another. However, if the clinical outcomes associated with the different lens characteristics are sufficiently unrelated, then comparative clinical data are not required to demonstrate the predominance of a characteristic as it relates to the clinical outcome associated with the lens characteristic that is the subject of NTIOL review. In the case of this candidate IOL, the purported clinical benefit is greater refractive precision whereas the clinical benefit of reduced spherical aberration is improved night driving. We believe that these outcomes are sufficiently unrelated such that comparative clinical data are not required to demonstrate the predominance of the 0.25 D increments as it relates to greater refractive precision.

Comment: Many commenters supported NTIOL designation for the HD PS IOL. The commenters are primarily ophthalmologists who related their anecdotal experience with the HD PS lens stating that it was their belief that their patients benefited from this IOL. Many commenters also believed that the studies described above are sufficient to demonstrate a clinical benefit for the HD PS IOL. Some of these commenters reported the results of case series from their practices that, according to them, support greater refractive precision of the HD PS IOL versus another lens. One commenter summarized data to support the position that the HD PS remains in a more stable position in the eye postoperatively. Several commenters stated that whether or not a patient must wear distance correction postoperatively has no bearing on whether greater refractive precision should be considered an improved outcome for patients.

Response: We appreciate these comments and that several ophthalmologists believe that the HD PS benefits their patients. However, NTIOL status requires evidence of an improved clinical outcome versus currently available IOLs, and the underlying studies must be well-controlled such that the improved outcome can be appropriately attributed to the candidate IOL characteristic. We discuss clinical outcomes and the evidentiary requirements in greater detail below.

Comment: One commenter stated that the results of the HD PS are not significantly different than those of other currently available IOLs. The commenter cited studies by Aristodemou *et al.* and Norrby *et al.* using IOLs available in 0.5 D increments showing results that are similar to Brown *et al.,* one of the studies submitted by the requestor summarized above. The commenter also stated that the results of Brown *et al.* are average and that similar or better results can be obtained with lenses supplied in 0.5 D increments by manufacturers adhering to the ISO 11979–2 tolerances. In addition, the commenter remarked that Brown et al. has several study design flaws and other deficiencies, including refractive predictability not being a planned outcome of the study, no comparator lens in the study resulting in bias, and inappropriate comparison studies. Also, this commenter stated that the number of subjects required to show a statistically significant difference in refractive error for lenses provided in 0.25 D steps versus 0.5 D steps would be many thousands for each IOL type. The commenter also criticized the retrospective design of the second study submitted by the requestor (summarized above), and stated that the results are not significantly different from those of published studies of refractive outcomes for IOLs available in 0.5 D increments.

Response: We agree with this commenter and believe that these points merit further discussion. As cataract surgery has improved in all aspects over the past several decades, refractive outcomes have become even more important as many of the other issues that historically have affected the ultimate postoperative outcome, that is, how well the patient sees after surgery, have been solved. There is a certain intuitive appeal to the hypothesis proffered by the requestor that smaller dioptric increments and, therefore, a greater number of available individual lens powers requires less rounding or approximation of the implant power and therefore a postoperative refractive state that is closer to the target.

As intuitively appealing as this concept is, we believe that it should be evaluated in the context of the many factors that affect the ultimate refractive state of the patient after cataract surgery. These include, but are not limited to, the anatomy and functioning of the patient's eye, the surgical technique, aspects of the IOL unrelated to the power increment, preoperative refractive error, systemic factors, A-scan method, IOL power calculation, and surgeon specific factors, among others. All of these factors would have to be properly controlled in a large, prospective randomized clinical trial in

order to try to prove the underlying hypothesis. An appropriate control/comparator IOL is absolutely essential. The studies submitted by the requestor and the anecdotal reports submitted by the commenters who use the HD PS IOL fall far short of this evidentiary requirement. In addition, greater refractive precision alone is not enough, as one would have to prove a superior outcome of significance to the average Medicare beneficiary, such as true spectacle independence for distance vision. Most patients would not notice (even if it were the case) that their postoperative refractive state was a bit closer (that is, within measurement error) to their target refraction if they still had to wear spectacles to achieve functional distance vision.

Comment: One commenter stated that as a practical matter the variability in postoperative refractive state due to other factors exceeds 0.25 D, and that patients will not benefit from this ''pseudo-accuracy.'' The commenter suggested that the actual limitation in postoperative refractive state currently lies with the preoperative measurement techniques, and that when the accuracy of these techniques improve, IOLs with 0.25 D increments may be of benefit to patients.

Response: We generally agree with this commenter, but we are not sure whether the HD PS IOL would provide greater actual refractive accuracy or, as the commenter stated, ''pseudoaccuracy.'' We also agree that the preoperative measurements are critical for accuracy but suffer from limitations and are highly variable from surgeon to surgeon. That is why a large, prospective, randomized, controlled clinical trial is necessary, with careful attention in the trial design to all of the factors that influence refractive outcome.

In summary, we have reviewed the application and evidence submitted by the requestor and the comments received. We conclude that because the evidence submitted is insufficient to conclude that the 0.25 D increment ±0.11 D tolerance characteristic of the Lenstec HD PS IOL has established clinical relevance in comparison to currently available IOLs, and because the evidence presented does not demonstrate that the use of the HD PS IOL results in measurable, clinically meaningful, improved outcomes in comparison with use of currently available IOLs for Medicare beneficiaries, Lentec's request for NTIOL status for its HD PS IOL is denied.

Comment: One commenter suggested certain changes to the NTIOL regulations, including having FDA as the only evaluator of clinical benefit for candidate IOLs and establishing a timeframe for when a candidate IOL can be considered new and therefore eligible for NTIOL payments.

Response: We believe these suggestions may have some merit and will consider exploring them in future rulemaking.

We would like to briefly address what may be a misunderstanding or misconception among some of the commenters regarding the purpose and role of the NTIOL payment adjustment. Several comment letters from ophthalmologists included a statement similar to the following: ''I would like to have lens X or a lens with characteristic X available to my patients.'' We want to make it clear that the FDA has approved all of the IOLs that are the subject of the CY 2012 NTIOL applications, and the NTIOL candidate lenses are available on the U.S. market to ophthalmologists. Those ophthalmologists along with ASCs can freely choose to implant any of this year's candidate IOLs, with payment for the IOL bundled into the facility payment for the cataract with IOL implantation surgery. From the comments, it appears that at least three of the four candidate IOLs have a current following among ophthalmologists. In fact, one of this year's candidate IOLs is the current U.S. market leader. NTIOL status does not affect U.S. market availability or Medicare coverage of an IOL. Instead, the NTIOL payment adjustment is reserved for new technology IOLs with sound evidence of measurable, clinically meaningful, improved outcomes in comparison with currently available IOLs, and these outcomes must have a meaningful impact on Medicare beneficiaries.

Finally, we appreciate IOL manufacturers' interest in the NTIOL program, and encourage the submission of future applications as new IOL technology is developed. However, we strongly encourage applicants to pay close attention to the NTIOL regulatory requirements, which are rigorous and are discussed extensively above in this final rule with comment period and in prior OPPS/ASC rules. We emphasize that an IOL characteristic or claim of superiority and associated data that may be useful for marketing purposes are not necessarily sufficient for NTIOL status, which requires sound scientific proof of measurable, clinically meaningful, improved outcomes in comparison with currently available IOLs for Medicare beneficiaries.

4. Payment Adjustment

The current payment adjustment for a 5-year period from the implementation date of a new NTIOL class is $50 per lens. Since implementation of the process for adjustment of payment amounts for NTIOLs in 1999, we have not revised the payment adjustment amount, and we did not propose to revise the payment adjustment amount for CY 2012.

We did not receive any public comments on the amount of the payment adjustment, and we are not revising the payment adjustment amount for CY 2012.

5. Announcement of CY 2012 Deadline for Submitting Requests for CMS Review of Appropriateness of ASC Payment for Insertion of an NTIOL Following Cataract Surgery

In accordance with 42 CFR 416.185(a) of our regulations, CMS announces that in order to be considered for payment effective January 1, 2013, requests for review of applications for a new class of new technology IOLs must be received at CMS by 5 p.m. EST, on March 2, 2012. Send requests to ASC/NTIOL, Division of Outpatient Care, Mailstop C4–05–17, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850. To be considered, requests for NTIOL reviews must include the information requested on the CMS Web site at: *http://www.cms.gov/ASCPayment/downloads/NTIOLprocess.pdf*.

F. ASC Payment and Comment Indicators

1. Background

In addition to the payment indicators that we introduced in the August 2, 2007 final rule, we also created final comment indicators for the ASC payment system in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66855). We created Addendum DD1 to define ASC payment indicators that we use in Addenda AA and BB to provide payment information regarding covered surgical procedures and covered ancillary services, respectively, under the revised ASC payment system. The ASC payment indicators in Addendum DD1 are intended to capture policy relevant characteristics of HCPCS codes that may receive packaged or separate payment in ASCs, such as whether they were on the ASC list of covered services prior to CY 2008; payment designation, such as device-intensive or office-based, and the corresponding ASC payment methodology; and their classification as separately payable ancillary services

including radiology services, brachytherapy sources, OPPS pass-through devices, corneal tissue acquisition services, drugs or biologicals, or NTIOLs.

We also created Addendum DD2 that lists the ASC comment indicators. The ASC comment indicators used in Addenda AA and BB to the proposed rules and final rules with comment period serve to identify, for the revised ASC payment system, the status of a specific HCPCS code and its payment indicator with respect to the timeframe when comments will be accepted. The comment indicator ''NI'' is used in the OPPS/ASC final rule with comment period to indicate new HCPCS codes for the next calendar year for which the interim payment indicator assigned is subject to comment. The comment indicator ''NI'' is also assigned to existing codes with substantial revisions to their descriptors such that we consider them to be describing new services, as discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60622). In this CY 2012 OPPS/ASC final rule with comment period, we respond to public comments and finalize the ASC treatment of all codes that are labeled with comment indicator ''NI'' in Addenda AA and BB to the CY 2011 OPPS/ASC final rule with comment period. These addenda can be found in a file labeled ''January 2011 ASC Approved HCPCS Code and Payment Rates to Reflect the Medicare and Medicaid Extenders Act of 2010'' in the ASC Addenda Update section of the CMS Web site.

The ''CH'' comment indicator was used in Addenda AA and BB to the CY 2012 OPPS/ASC proposed rule (which were available via the Internet on the CMS Web site) to indicate that the payment indicator assignment has changed for an active HCPCS code; an active HCPCS code is newly recognized as payable in ASCs; or an active HCPCS code is discontinued at the end of the current calendar year. The ''CH'' comment indicators that are published in the final rule with comment period are provided to alert readers that a change has been made from one calendar year to the next, but do not indicate that the change is subject to comment. The full definitions of the proposed payment indicators and comment indicators were provided in Addenda DD1 and DD2 to the CY 2012 OPPS/ASC proposed rule (which were available via the Internet on the CMS Web site).

2. ASC Payment and Comment Indicators

The revised ASC payment system included a 4-year transition to payment rates under the standard methodology for the procedures on the ASC list in CY 2007. CY 2011 was the first year of full payment under the standard methodology for the revised ASC payment system. Payment indicators ''A2'' (Surgical procedure on ASC list in CY 2007, payment based on OPPS relative payment weight) and ''H8'' (Device-intensive procedure on ASC list in CY 2007; paid at adjusted rate) were developed to identify procedures that were included on the list of ASC covered surgical procedures in CY 2007 and were, therefore, subject to transitional payment prior to CY 2011.

Because the 4-year transitional payment period has ended and it is no longer necessary to identify device-intensive procedures that are subject to transitional payments, in the CY 2012 OPPS/ASC proposed rule (76 FR 42310), we proposed to delete the ASC payment indicator ''H8.'' We proposed that all device-intensive procedures, for which the modified rate calculation methodology will apply, be assigned payment indicator ''J8'' in CY 2012 and later. In addition, we proposed to modify the definition for payment indicator ''J8'' by removing ''added to ASC list in CY 2008 or later'' as this distinction is no longer necessary.

Although payment indicator ''A2'' is no longer required to identify surgical procedures subject to transitional payment, we proposed to retain payment indicator ''A2'' because it is used to identify procedures that are exempted from application of the office-based designation.

As detailed in section XIV.K. of the proposed rule (76 FR 42336 through 42349), we proposed to establish an ASC Quality Reporting Program with the collection of seven claims-based quality measures beginning in CY 2012. We proposed to require ASCs to report on ASC claims a quality data code (QDC) to be used for reporting quality data. We proposed that an ASC would need to add a QDC to any claim involving a proposed claims-based quality measure. CMS is in the process of developing QDCs for each adopted claims-based quality measure. The QDC will be a CPT Category II code or a HCPCS Level II G-code if an appropriate CPT code is not available. More information on the ASC Quality Reporting Program is provided in section XIV.K. of this CY 2012 OPPS/ASC final rule with comment period. Additionally, CMS proposed to create a new ASC payment indicator ''M5'' (Quality measurement code used for reporting purposes only; no payment made) for assignment to the QDCs to clarify that no payment is associated with the QDC for that claim. We proposed that this payment indicator would be effective January 1, 2012.

We did not propose any changes to the definitions of the ASC comment indicators for CY 2012. We refer readers to Addenda DD1 and DD2 to the CY 2012 OPPS/ASC proposed rule (which were referenced in section XVII. of the proposed rule and available via the Internet on the CMS Web site) for the complete list of ASC payment and comment indicators proposed for the CY 2012 update.

We did not receive any public comments on the ASC payment and comment indicators. Therefore, we are finalizing our proposed CY 2012 payment and comment indicators, without modification, in Addenda DD1 and DD2 to this final rule with comment period (which are available via the Internet on the CMS Web site).

G. ASC Policy and Payment Recommendations

MedPAC was established under section 1805 of the Act to advise Congress on issues affecting the Medicare program. Subparagraphs (C) and (D) of section 1805(b)(1) of the Act require MedPAC to submit reports to Congress not later than March 15 and June 15 of each year that present its Medicare payment policy reviews and recommendations and its examination of issues affecting the Medicare program, respectively. The March 2011 MedPAC ''Report to the Congress: Medicare Payment Policy'' included the following recommendation relating specifically to the ASC payment system for CY 2012:

Recommendation 5: The Congress should implement a 0.5 percent increase in payment rates for ambulatory surgical center services in calendar year 2012 concurrent with requiring ambulatory surgical centers to submit cost and quality data.

CMS Response: In the August 2, 2007 final rule (72 FR 42518 through 42519), we adopted a policy to update the ASC conversion factor for consistency with section 1833(i)(2)(C) of the Act, which requires that, if the Secretary has not updated the ASC payment amounts in a calendar year, the payment amounts shall be increased by the percentage increase in the Consumer Price Index for All Urban Consumers (CPI–U) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved. The statute set the

update at zero for CY 2008 and CY 2009. We indicated that we planned to implement the annual updates through an adjustment to the conversion factor under the ASC payment system beginning in CY 2010 when the statutory requirement for a zero update no longer applied. Further, we noted that that we would update the conversion factor for the CY 2010 ASC payment system by the percentage increase in the CPI–U (codified at § 416.171(a)(2)).

As we indicated in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60622), we did not require ASCs to submit cost data to the Secretary for CY 2010. We explained that the 2006 GAO report, ''Medicare: Payment for Ambulatory Surgical Centers Should Be Based on the Hospital Outpatient Payment System'' (GAO–07–86), concluded that the APC groups in the OPPS reflect the relative costs of surgical procedures performed in ASCs in the same way they reflect the relative costs of the same procedures when they are performed in HOPDs. Consistent with the GAO findings, CMS is using the OPPS as the basis for the ASC payment system, which provides for an annual revision of the ASC payment rates under the budget neutral ASC payment system. In addition, we noted that, under the methodology of the revised ASC payment system, we do not utilize ASC cost information to set and revise the payment rates for ASCs, but instead rely on the relativity of hospital outpatient costs developed for the OPPS, consistent with the recommendation of the GAO. Furthermore, we explained that we have never required ASCs to routinely submit cost data and expressed our concern that requiring this could be administratively burdensome for ASCs.

In 2009, MedPAC made a similar recommendation to that made in Recommendation 5 above. In light of that MedPAC recommendation, in the CY 2010 OPPS/ASC proposed rule (74 FR 35391), we solicited public comment on the feasibility of ASCs submitting cost information to CMS, including whether costs should be collected from a sample or the universe of ASCs, the administrative burden associated with such an activity, the form that such a submission could take considering existing Medicare requirements for other types of facilities and the scope of ASC services, the expected accuracy of such cost information, and any other issues or concerns of interest to the public on this topic.

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60623), we summarized and responded to these comments. As noted in that final rule with comment period, commenters expressed varied opinions regarding the feasibility of requiring ASCs to submit cost data to the Secretary. Some commenters believed that requiring ASCs to submit such data would not be an insurmountable obstacle and pointed out that other small facilities submit cost reports to CMS. They argued that ASC cost reports are necessary to assess the adequacy of Medicare payments and evaluate the ASC update. Other commenters, however, opposed the requirement that ASCs submit cost data to CMS because they believed such a requirement would be unnecessary and administratively burdensome. Commenters generally supported a requirement that ASCs report quality data. We refer readers to the CY 2010 OPPS/ASC final rule with comment period for a full discussion of the comments we received on the feasibility of requiring ASCs to report cost and quality data (74 FR 60623). Consistent with our CY 2010 policy, we proposed not to require ASCs to submit cost data to the Secretary for CY 2011 (75 FR 46356 through 463557). We stated that we continue to believe that our established methodology results in appropriate payment rates for ASCs. For CY 2012, consistent with this policy and for the same reasons, we did not propose to require ASCs to submit cost data (76 FR 42311). However, we did propose to require ASCs to submit quality data beginning in CY 2012.

Section 109(b) of the MIEA–TRHCA (Pub. L. 109–432) gives the Secretary the authority to implement ASC quality measure reporting and to reduce the payment update for ASCs that fail to report those required measures. In the CY 2012 OPPS/ASC proposed rule, we proposed to require ASCs to report seven quality measures in CY 2012. Details associated with ASC quality reporting proposed for CY 2012 were discussed in section XIV.K. of the CY 2012 OPPS/ASC proposed rule (76 FR 42336 through 42349).

Finally, in the CY 2012 OPPS/ASC proposed rule (76 FR 42311), we did not propose to implement MedPAC's recommended CY 2012 ASC update of 0.5 percent. The annual update to the ASC payment system is the CPI–U. Section 3401(k) of the Affordable Care Act requires that the annual ASC payment update be reduced by a productivity adjustment. As discussed in section XIII.H.2.b. of the proposed rule (76 FR 42312 through 42313), the Secretary estimated that the CPI–U is 2.3 percent and the MFP adjustment is 1.4 percent. Therefore, we proposed a 0.9 percent update for CY 2012.

Comment: Commenters urged CMS to require ASCs to routinely report cost data to allow for future validation of the relative appropriateness of ASC payment weights and rates. MedPAC commented that ASCs should be required to submit cost and quality data, arguing that ASC cost data are needed to examine whether an existing input price index is an appropriate proxy for the costs of ASCs or whether an ASC-specific market basket should be developed. MedPAC pointed out that businesses such as ASCs typically keep records of their costs for filing taxes and other purposes, and other small providers, such as home health agencies and hospices, submit cost data to CMS. MedPAC stated that CMS should create a streamlined process for ASCs to submit cost data in order to minimize the burden on ASCs and CMS.

Other commenters, however, supported CMS' proposal not to require ASCs to routinely submit cost data, a process that the commenters characterized as administratively burdensome. The commenters stated that the quality of such data, if required, would be questionable because of the varying types of services and cost structures among ASCs and would not be suitable for ratesetting.

Response: We did not propose to require ASCs to submit cost data to the Secretary for CY 2012 because, as noted previously in this section and in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72058), we continue to believe that our established methodology results in appropriate payment rates for ASCs. Therefore, we are finalizing our proposal not to require cost reporting in this final rule with comment period. We will keep the commenters' perspectives about collecting cost information from ASCs in mind as we further consider the adequacy of the Medicare ASC payment rates. We also appreciate the commenters' perspectives regarding ASC quality reporting and refer readers to section XIV.K. of this final rule with comment period for more detailed discussion of ASC quality data reporting.

H. Calculation of the ASC Conversion Factor and the ASC Payment Rates

1. Background

In the August 2, 2007 final rule (72 FR 42493), we established our policy to base ASC relative payment weights and payment rates under the revised ASC payment system on APC groups and relative payment weights. Consistent with that policy and the requirement at section 1833(i)(2)(D)(ii) of the Act that

the revised payment system be implemented so that it would be budget neutral, the initial ASC conversion factor (CY 2008) was calculated so that estimated total Medicare payments under the revised ASC payment system in the first year would be budget neutral to estimated total Medicare payments under the prior (CY 2007) ASC payment system (the ASC conversion factor is multiplied by the relative payment weights calculated for many ASC services in order to establish payment rates). That is, application of the ASC conversion factor was designed to result in aggregate Medicare expenditures under the revised ASC payment system in CY 2008 equal to aggregate Medicare expenditures that would have occurred in CY 2008 in the absence of the revised system, taking into consideration the cap on ASC payments in CY 2007 as required under section 1833(i)(2)(E) of the Act (72 FR 42522).

We note that we consider the term ''expenditures'' in the context of the budget neutrality requirement under section 1833(i)(2)(D)(ii) of the Act to mean expenditures from the Medicare Part B Trust Fund. We do not consider expenditures to include beneficiary coinsurance and copayments. This distinction was important for the CY 2008 ASC budget neutrality model that considered payments across hospital outpatient, ASC, and MPFS payment systems. However, because coinsurance is almost always 20 percent for ASC services, this interpretation of expenditures has minimal impact for subsequent budget neutrality adjustments calculated within the revised ASC payment system.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66857 through 66858), we set out a step-by-step illustration of the final budget neutrality adjustment calculation based on the methodology finalized in the August 2, 2007 final rule (72 FR 42521 through 42531) and as applied to updated data available for the CY 2008 OPPS/ASC final rule with comment period. The application of that methodology to the data available for the CY 2008 OPPS/ASC final rule with comment period resulted in a budget neutrality adjustment of 0.65.

For CY 2008, we adopted the OPPS relative payment weights as the ASC relative payment weights for most services and, consistent with the final policy, we calculated the CY 2008 ASC payment rates by multiplying the ASC relative payment weights by the final CY 2008 ASC conversion factor of $41.401. For covered office-based surgical procedures and covered ancillary radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents, as discussed in section XIII.D.2.b. of this final rule with comment period) the established policy is to set the relative payment weights so that the national unadjusted ASC payment rate does not exceed the MPFS unadjusted nonfacility PE RVU-based amount. Further, as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66841 through 66843), we also adopted alternative ratesetting methodologies for specific types of services (for example, device-intensive procedures).

As discussed in the August 2, 2007 final rule (72 FR 42518) and as codified at § 416.172(c) of the regulations, the revised ASC payment system accounts for geographic wage variation when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage indices to the labor-related share, which is 50 percent of the ASC payment amount. Beginning in CY 2008, CMS accounted for geographic wage variation in labor cost when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage index values that CMS calculates for payment, using updated Core Based Statistical Areas (CBSAs) issued by OMB in June 2003. The reclassification provision provided at section 1886(d)(10) of the Act is specific to hospitals. We believe that using the most recently available raw pre-floor and pre-reclassified hospital wage indices results in the most appropriate adjustment to the labor portion of ASC costs. In addition, use of the unadjusted hospital wage data avoids further reductions in certain rural statewide wage index values that result from reclassification. We continue to believe that the unadjusted hospital wage indices, which are updated yearly and are used by many other Medicare payment systems, appropriately account for geographic variation in labor costs for ASCs.

We note that in certain instances there might be urban or rural areas for which there is no IPPS hospital whose wage index data would be used to set the wage index for that area. For these areas, our policy has been to use the average of the wage indices for CBSAs (or metropolitan divisions as applicable) that are contiguous to the area that has no wage index (where ''contiguous'' is defined as sharing a border). We have applied a proxy wage index based on this methodology to ASCs located in CBSA 25980 Hinesville-Fort Stewart, GA, and CBSA 22 Rural Massachusetts. In CY 2011, we identified another area, specifically, CBSA 11340 Anderson, SC for which there is no IPPS hospital whose wage index data would be used to set the wage index for that area. Generally, we would use the methodology described above; however, in this situation, all of the areas contiguous to CBSA 11340 Anderson, SC are rural. Therefore, in the CY 2011 OPPS/ASC final rule with comment (75 FR 72058 through 72059), we finalized our proposal to set the ASC wage index by calculating the average of all wage indices for urban areas in the State when all contiguous areas to a CBSA are rural and there is no IPPS hospital whose wage index data could be used to set the wage index for that area. In other situations, where there are no IPPS hospitals located in a relevant labor market area, we will continue our current policy of calculating an urban or rural area's wage index by calculating the average of the wage indices for CBSAs (or metropolitan divisions where applicable) that are contiguous to the area with no wage index.

Comment: Several commenters made the same comment that was made in the CY 2011 rulemaking—that is that CMS adopt for the ASC payment system the same wage index values used for hospital payment under the OPPS (75 FR 72059 contains an explanation of such comment). At a minimum, commenters recommended that CMS apply the out-migration adjustment to ASCs in qualifying counties.

Response: We have responded to this comment in the past, and believe our prior rationale for using unadjusted wage indices is still a sound one. We refer readers to our response to this comment in last year's final rule with comment period (75 FR 72059). We discuss our budget neutrality adjustment for changes to the wage indices below in section XIII.H.2.b. of this final rule with comment period.

After consideration of the public comments we received, we are continuing our established policy to account for geographic wage variation in labor cost when calculating individual ASC payment by applying the pre-floor and pre-reclassified hospital wage index values that CMS calculated for payment, using updated CBSAs. For CY 2012, we also are continuing our policy established in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72058 through 72059) to set the ASC wage index by calculating the average of all wage indices for urban areas in the state when there is no IPPS hospital whose wage index data could be used to set the wage index for that area, and all contiguous areas to the CBSA are rural.

2. Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2012 and Future Years

We update the ASC relative payment weights each year using the national OPPS relative payment weights (and MPFS nonfacility PE RVU-based amounts, as applicable) for that same calendar year and uniformly scale the ASC relative payment weights for each update year to make them budget neutral (72 FR 42531 through 42532). Consistent with our established policy, in the CY 2012 OPPS/ASC proposed rule (76 FR 42312), we proposed to scale the CY 2012 relative payment weights for ASCs according to the following method. Holding ASC utilization and the mix of services constant from CY 2010, we proposed to compare the total payment weight using the CY 2011 ASC relative payment weights (calculated under the ASC standard ratesetting methodology) with the total payment weight using the CY 2012 ASC relative payment weights (calculated under the ASC standard ratesetting methodology) to take into account the changes in the OPPS relative payment weights between CY 2011 and CY 2012. We proposed to use the ratio of CY 2011 to CY 2012 total payment weight (the weight scaler) to scale the ASC relative payment weights for CY 2012. The proposed CY 2012 ASC scaler was 0.9373 (76 FR 42312) and scaling would apply to the ASC relative payment weights of the covered surgical procedures and covered ancillary radiology services for which the ASC payment rates are based on OPPS relative payment weights.

Scaling would not apply in the case of ASC payment for separately payable covered ancillary services that have a predetermined national payment amount (that is, their national ASC payment amounts are not based on OPPS relative payment weights), such as drugs and biologicals that are separately paid or services that are contractor-priced or paid at reasonable cost in ASCs. Any service with a predetermined national payment amount would be included in the ASC budget neutrality comparison, but scaling of the ASC relative payment weights would not apply to those services. The ASC payment weights for those services without predetermined national payment amounts (that is, those services with national payment amounts that would be based on OPPS relative payment weights) would be scaled to eliminate any difference in the total payment weight between the current year and the update year.

For any given year's ratesetting, we typically use the most recent full calendar year of claims data to model budget neutrality adjustments. At the time of the CY 2012 proposed rule, we had available 98 percent of CY 2010 ASC claims data. For this final rule with comment period, we have approximately 99 percent of all ASC claims data for CY 2010.

To create an analytic file to support calculation of the weight scalar and budget neutrality adjustment for the wage index (discussed below), we summarized available CY 2010 ASC claims by provider and by HCPCS code. We used the National Provider Identifier for the purpose of identifying unique ASCs within the CY 2010 claims data. We used the supplier zip code reported on the claim to associate State, county, and CBSA with each ASC. This file, available to the public as a supporting data file for the proposed rule, is posted on the CMS Web site at: *http://www.cms.gov/ASCPayment/ASCRN/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=3&sortOrder=descending&itemID=CMS1249114&intNumPerPage=10*.

Comment: Many commenters again expressed their opposition to scaling the ASC relative payment weights. Many of the commenters on the CY 2012 OPPS/ASC proposed rule offered the same views as the public commenters on each rule since the CY 2009 OPPS/ASC proposed rule CY 2009 was the year when CMS first applied the scaling policy that was finalized in the August 2, 2007 final rule. The commenters expressed many concerns, including that scaling is contrary to the intent of using the cost-based OPPS relative payment weights as the basis for determining the relative payments for the same services in ASCs and that scaling would continue to erode the payment relationship between the OPPS and ASC payment system. They asserted that, although scaling is intended to maintain budget neutrality within the ASC payment system, it is instead creating increasingly large payment differentials between the ASC and OPPS payments for the same services without evidence of growing differences in capital and operating costs between the two settings, and depriving ASCs of real increases in the relative costs of procedures. The commenters believed that the OPPS relative payment weights represent real growth in the costs of services provided in HOPDs and the annual change in relative weights should move in the same direction in both the ASC and HOPD setting. The commenters argued that the difference in payments between the ASC and HOPD services at the aggregate and procedure level should be driven only by changes in the conversion factor.

The commenters also pointed out that, while CMS has suggested that scaling of the relative weights is a design element that will protect ASCs from changes in the OPPS relative weights that could significantly decrease payments for certain procedures, the trend in the OPPS relative weights suggests that the scaling factor for ASCs will rarely result in an increase in ASC relative weights.

The commenters argued that CMS is not required to scale the ASC relative weights and that it should use its authority to suspend the application of scaling the ASC relative weights for CY 2012. They noted that the regulations establishing the revised ASC payment system give CMS the flexibility to scale ''as needed.'' In addition, some commenters stated that Congress imposed a budget neutrality requirement on the ASC payment system only during the CY 2008 implementation year, and that CMS is under no legal obligation to continue to apply a scaling factor.

Response: Many of these comments are similar to public comments on the proposal for the revised ASC payment system that we responded to in the August 2, 2007 final rule (72 FR 42531 through 42533). For example, with regard to scaling, we addressed these same concerns raised by commenters that annual rescaling would cause divergence of the relative weights between the OPPS and the revised ASC payment system for individual procedures in the August 2, 2007 final rule (72 FR 42532). We refer the commenters to that discussion for our detailed response in promulgating the scaling policy that was initially applied in CY 2009 (72 FR 42531 through 42533).

As we have stated in the past (74 FR 60627), the ASC weight scaling methodology is entirely consistent with the OPPS methodology for scaling the relative payment weights and, for the most part, the increasing payment differentials between the ASC and OPPS payments for the same services are not attributable to scaling ASC relative payment weights. Considerations of differences between the capital and operating costs of ASCs and HOPDs are not part of the ASC standard ratesetting methodology, which relies only on maintaining the same relativity of payments for services under the two payment systems, as well as budget neutrality within each payment system. Furthermore, unlike HOPDs, we do not have information about the costs of ASC services in order to assess differences in

capital and operating costs over time between the two settings. In order to maintain budget neutrality of the ASC payment system, we need to adjust for the effects of changes in relative weights. The ASC payment system adopts the OPPS relative weights as the mechanism for apportioning total payments, after application of the update factor, among all of the services covered by the ASC payment system. The OPPS relative weights serve the same purpose in the OPPS. The OPPS relative weights do not represent an estimate of absolute cost of any given procedure; rather, they reflect our estimate of the cost of the procedure within the context of our cost estimation methodology for the OPPS. With the exception of services with a predetermined national payment amount, the use of a uniform scaling factor for changes in total weight between years in the ASC payment system does not alter the relativity of the OPPS payment weights as used in the ASC payment system. Differences in the relativity between the ASC relative payment weights and the OPPS relative payment weights are not driven by the application of the uniform scaling factor. The ASC weight scaling methodology is entirely consistent with the OPPS weight scaling methodology and the weights serve the same purpose in both systems, to apportion total budget neutral payment allowed under the update.

We do not agree with commenters' assertion that we should eliminate the scaling methodology because the scaling factor will rarely result in an increase in ASC relative weights, therefore continuing to hurt rather than protect ASCs in the future. As we stated in the August 2, 2007 final rule (72 FR 42532), aggregate payments to ASCs could, in the absence of rescaling, be affected by changes in the cost structure of HOPDs that ought to be relevant only under the OPPS. A sudden increase in the costs of hospital outpatient emergency department or clinical visits due, for instance, to an increase in the volume of cases, would have the effect of increasing the weights for these services relative to the weights for surgical procedures in the hospital outpatient setting. In the absence of scaling the ASC payment weights, this change in the relative weights under the OPPS would result in a decrease in the relative weights for surgical procedures under the ASC payment system, and, therefore, a decrease in aggregate ASC payments for these same procedures. We continue to believe that changes in relative weights each year under the OPPS should not, in and of themselves, cause aggregate payments under the revised ASC payment system to increase or decrease. It is important to note that the specific adjustment factor applied in the scaling process could be positive or negative in any particular year; the fact that the scaler has not resulted in an increase to the ASC payment weights in any given year or series of years does not mean the same trend will continue, nor does it mean that the principle of preventing the ASC payment weights from being affected by fluctuations in the OPPS payment weights is inherently flawed.

As we stated in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68754), with respect to the use of ''as needed'' in the text of § 416.171(e)(2) that commenters have interpreted to mean that CMS has the authority to suspend scaling the relative payment weights if it determines there is not a need to do so, the phrase does not mean that we will determine whether or not to adjust for budget neutrality. Rather, it means that we adjust the relative payment weights as needed to ensure budget neutrality. Therefore, we do not agree with the commenters' assertion that we are under no legal obligation to continue to apply a scaling factor. If we were not to scale the ASC relative payment weights, we estimate that the CY 2012 revisions would not be budget neutral.

Establishing budget neutrality under the OPPS does not result in budget neutrality under the revised ASC payment system; it only maintains budget neutrality under the OPPS. Scaling the ASC relative payment weights is an integral and separate process for maintaining budget neutrality under the ASC prospective payment system. Scaling is the budget neutrality adjustment that ensures that changes in the relative weights do not, in and of themselves, change aggregate payment to ASCs. It ensures a specific amount of payment for ASCs in any given year. Without scaling, total ASC payment could increase or decrease relative to changes in hospital outpatient payment.

Although the commenters believe that scaling prevents increases in ASC spending that may be appropriate because ASC costs have increased over time, increases in cost in a prospective payment system are handled by the update factor. In a budget neutral system, we remove the independent effects of increases or decreases in payments as a result of changes in the relative payment weights or the wage indices and constrain increases to the allowed update factor. Therefore, changes in aggregate ASC expenditures related to payment rates are determined by the update to the ASC conversion factor, not by changes in the relative payment weights.

For this final rule with comment period, we used our proposed methodology described above to calculate the scaler adjustment using updated ASC claims data. The final CY 2012 scaler adjustment is 0.9466. This scaler adjustment is necessary to budget neutralize the difference in aggregate ASC payments calculated using the CY 2011 ASC relative payment weights and the CY 2012 relative payment weights. We calculated the difference in aggregate payments due to the change in relative payment weights (including drugs and biologicals) holding constant the ASC conversion factor, the most recent CY 2010 ASC utilization from our claims data, and the CY 2011 wage index values. For this final CY 2012 calculation, we used the CY 2011 ASC conversion factor updated by the CY 2012 CPI–U, which is estimated as 2.7 percent, less the multifactor productivity adjustment of 1.1 percent, as discussed below in section XV.H.2.b. of this final rule with comment period.

After consideration of the public comments we received, we are finalizing our CY 2012 ASC relative payment weight scaling methodology, without modification. The final CY 2012 ASC payment weight scaler is 0.9466.

b. Updating the ASC Conversion Factor

Under the OPPS, we typically apply a budget neutrality adjustment for provider level changes, most notably a change in the wage index values for the upcoming year, to the conversion factor. Consistent with our final ASC payment policy, for the CY 2012 ASC payment system, in the CY 2012 OPPS/ASC proposed rule (76 FR 42312 through 42313), we proposed to calculate and apply the pre-floor and pre-reclassified hospital wage indices that are used for ASC payment adjustment to the ASC conversion factor, just as the OPPS wage index adjustment is calculated and applied to the OPPS conversion factor. For CY 2012, we calculated this proposed adjustment for the ASC payment system by using the most recent CY 2010 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2012 pre-floor and pre-reclassified hospital wage indices. Specifically, holding CY 2010 ASC utilization and service-mix and the proposed CY 2012 national payment rates after application of the weight scaler constant, we calculated the total adjusted payment using the CY 2011

pre-floor and pre-reclassified hospital wage indices and the total adjusted payment using the proposed CY 2012 pre-floor and pre-reclassified hospital wage indices. We used the 50-percent labor-related share for both total adjusted payment calculations. We then compared the total adjusted payment calculated with the CY 2011 pre-floor and pre-reclassified hospital wage indices to the total adjusted payment calculated with the proposed CY 2012 pre-floor and pre-reclassified hospital wage indices and applied the resulting ratio of 1.0003 (the proposed CY 2012 ASC wage index budget neutrality adjustment) to the CY 2011 ASC conversion factor to calculate the proposed CY 2012 ASC conversion factor.

Section 1833(i)(2)(C)(i) of the Act requires that, if the Secretary has not updated the ASC payment amounts in a calendar year, the payment amounts ''shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.'' Because the Secretary does update the ASC payment amounts annually, we adopted a policy, which we codified at § 416.171(a)(2)(ii), to update the ASC conversion factor using the CPI–U for CY 2010 and subsequent calendar years. Therefore, the annual update to the ASC payment system is the CPI–U (referred to as the CPI–U update factor).

Section 3401(k) of the Affordable Care Act amended section 1833(i)(2)(D) of the Act by adding a new clause (v) which requires that ''any annual update under [the ASC payment] system for the year, after application of clause (iv), shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II)'' of the Act (which we refer to as the MFP adjustment) effective with the calendar year beginning January 1, 2011. Clause (iv) authorizes the Secretary to provide for a reduction in any annual update for failure to report on quality measures. Clause (v) states that application of the MFP adjustment to the ASC payment system may result in the update to the ASC payment system being less than zero for a year and may result in payment rates under the ASC payment system for a year being less than such payment rates for the preceding year. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72062 through 72064), we revised § 416.160 and § 416.171 to reflect this provision of the Affordable Care Act (we note that these regulations do not reflect any reduction in the annual update for failure to report on quality measures because CMS had not implemented an ASC quality reporting program).

As discussed in section XIV.K. of the CY 2012 OPPS/ASC proposed rule (76 FR 42336 through 42349), we proposed that ASCs begin submitting data on quality measures in CY 2012 for the CY 2014 payment determination. Because any reduction to the annual update under the ASC Quality Reporting Program will not occur until CY 2014, we did not propose any changes to the payment methodology. We stated that we intend to address payment changes based on failure to submit quality data under the ASC Quality Reporting Program in a future rulemaking.

Without regard to the ASC Quality Reporting Program and in accordance with section 1833(i)(2)(C)(i) of the Act, before applying the MFP adjustment, the Secretary first determines the ''percentage increase'' in the CPI–U, which we interpret cannot be a negative number. Thus, in the instance where the percentage change in the CPI–U for a year is negative, in the CY 2012 OPPS/ASC proposed rule (76 FR 42313), we proposed to hold the CPI–U update factor for the ASC payment system to zero. Section 1833(i)(2)(D)(v) of the Act, as added by section 3401(k) of the Affordable Care Act, requires that the Secretary reduce the CPI–U update factor (which would be held to zero if the CPI–U percentage change is negative) by the MFP adjustment, and states that application of the MFP adjustment may reduce this percentage change below zero. If the application of the MFP adjustment to the CPI–U percentage increase would result in an MFP-adjusted CPI–U update factor that is less than zero, the annual update to the ASC payment rates would be negative and payments would decrease relative to the prior year. Illustrative examples of how the MFP adjustment would be applied to the ASC payment system update are found in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72062 through 72064).

In the CY 2012 OPPS/ASC proposed rule (76 FR 42313), for the 12-month period ending with the midpoint of CY 2012, the Secretary estimated that the CPI–U is 2.3 percent. The Secretary estimated that the MFP adjustment is 1.4 percentage points based on the methodology for calculating the MFP adjustment finalized in the CY 2011 MPFS final rule with comment period (75 FR 73391 through 73399) as revised by the proposal discussed in the CY 2012 MPFS proposed rule. We proposed to reduce the CPI–U of 2.3 percent by the MFP adjustment specific to this CPI–U of 1.4 percentage points, resulting in an MFP-adjusted CPI–U update factor of 0.9 percent. Therefore, we proposed to apply a 0.9 percent MFP-adjusted update to the CY 2011 ASC conversion factor.

For CY 2012, we also proposed to adjust the CY 2011 ASC conversion factor ($41.939) by the wage adjustment for budget neutrality of 1.0003 in addition to the MFP-adjusted update factor of 0.9 percent discussed above, which resulted in a proposed CY 2012 ASC conversion factor of $42.329 (76 FR 42313).

Comment: As in prior years, many commenters requested that CMS adopt the hospital market basket to update the ASC payment system. The commenters explained that not only is the CPI–U lower than the hospital market basket but it is not appropriate for updating health care providers because, unlike the hospital market basket which analyzes hospital spending, the CPI–U is designed to capture household spending. The commenters stated that, in the most recent years, the CPI–U has been dominated by inflation in the housing sector rather than healthcare provider spending, and that the goods and services provided by ASCs are very similar to those provided by hospitals.

The commenters also argued that the CPI–U is a poor proxy of ASC cost inflation, noting that the CPI–U has faced criticism from independent researchers and economists, who indicate that the CPI–U consistently underestimates the rate of inflation according to the commenters. In addition, because commenters view the CPI–U as a highly volatile index, the commenters suggested that CMS adjust for prior year forecast errors.

Commenters stated that adopting the hospital market basket would minimize the divergence in CY 2012 payment between the ASC payment system and the OPPS and prevent the update from causing further divergence when the productivity adjustment is applied to both settings in the future. The commenters asserted that CMS has the authority to use an alternative update mechanism, and believed CMS should adopt the hospital market basket as the update for the ASC payment system.

Commenters also indicated that the hospital market basket is a more appropriate index to use for the ASC update now that CMS is required to apply the MFP adjustment to the ASC annual update. Commenters stated that, as an output price index, the CPI–U index already accounts for productivity thus ASCs, in essence, are receiving a productivity adjustment that is twice that applied to the HOPD update. Because CMS has discretion regarding

the index used to update ASCs, but is required in statute to adjust the ASC update by the MFP, commenters urged CMS to use the hospital market basket, which is an input price index that does not already account for productivity, to update ASC payment rates and thereby allow the appropriate application of the required productivity adjustment. With regard to the MFP adjustment itself, commenters requested that, because the MFP is a volatile measure that is subject to substantial year-to-year fluctuations, the MFP measurement period be uniform across providers.

As mentioned in section XV.G. of this final rule with comment period, MedPAC commented that ASCs should be required to submit cost and quality data, concurrent with a 0.5 percent increase in ASC payment rates for CY 2012, arguing that ASC cost data are needed to examine whether an existing input price index is an appropriate proxy for the costs of ASCs or whether an ASC-specific market basket should be developed.

Response: While commenters argue that the items included in the CPI–U index may not adequately measure inflation for the goods and services provided by ASCs and that use of the hospital market basket would minimize the divergence in the payment rates between the OPPS and ASC payment system, we believe that the hospital market basket does not align with the cost structures of ASCs. A much wider range of services, such as room and board and emergency services, are provided by hospitals but are not costs associated with providing services in ASCs. Therefore, at this time, we do not believe that it is appropriate to use the hospital market basket for the ASC annual update. We may consider, in future rulemaking, suggestions by MedPAC to find a way to obtain cost data from ASCs, in a manner that will minimize the burden on ASCs and CMS, so that we can examine whether an alternative input price index would be an appropriate proxy for ASC costs or whether an ASC-specific market basket should be developed.

We recognize that the CPI–U is an output price index that accounts for productivity. However, the agency is required by law to apply the MFP adjustment to provider payments according to section 3401(k) of the Affordable Care Act and, for the reasons stated above, we do not believe that the hospital market basket reflects the cost structures of ASCs. Regarding alignment of the MFP adjustment across payment systems, for reasons stated in the CY 2011 MPFS final rule (75 FR 73396), we believe that it is more appropriate to align the MFP adjustment with the CPI–U timeframes rather than aligning the MFP adjustment across payment systems. In regards to the commenters' statement on the volatility of the MFP and its year-to-year fluctuations, the statute requires the MFP adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity which lessens and often negates any large year-to-year fluctuations.

Although commenters raise concerns regarding the difference in the CPI–U forecast and the actual inflation using historical data, we do not believe it is appropriate to provide an adjustment to the ASC annual update to correct previous forecast errors. The ASC system is prospective and the update provided is based on the most current data available to establish a forecast for inflation.

After consideration of the public comments we received, we are applying our established methodology for determining the final CY 2012 ASC conversion factor. Using more complete CY 2010 data for this final rule with comment period than was available for the proposed rule, we calculated a wage index budget neutrality adjustment of 1.0004. Based on updated data, the CPI–U for the 12-month period ending with the midpoint of CY 2012 is now estimated to be 2.7 percent, while the MFP adjustment (using the revised IGI series to proxy the labor index used in the MFP forecast calculation as discussed and finalized in the CY 2012 MPFS final rule with comment period) is 1.1 percent, resulting in an MFP-adjusted CPI–U update factor of 1.6 percent. The final ASC conversion factor of $42.627 is the product of the CY 2011 conversion factor of $41.939 multiplied by the wage index budget neutrality adjustment of 1.0004 and the MFP-adjusted CPI–U payment update of 1.6 percent.

3. Display of CY 2012 ASC Payment Rates

Addenda AA and BB to this CY 2012 OPPS/ASC final rule with comment period (which are available via the Internet on the CMS Web site) display the final updated ASC payment rates for CY 2012 for covered surgical procedures and covered ancillary services, respectively. These addenda contain several types of information related to the CY 2012 payment rates. Specifically, in Addendum AA, a ''Y'' in the column titled ''Subject to Multiple Procedure Discounting'' indicates that the surgical procedure will be subject to the multiple procedure payment reduction policy. As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66829 through 66830), most covered surgical procedures are subject to a 50-percent reduction in the ASC payment for the lower-paying procedure when more than one procedure is performed in a single operative session. Display of the comment indicator ''CH'' in the column titled ''Comment Indicator'' indicates a change in payment policy for the item or service, including identifying discontinued HCPCS codes, designating items or services newly payable under the ASC payment system, and identifying items or services with changes in the ASC payment indicator for CY 2012. Display of the comment indicator ''NI'' in the column titled ''Comment Indicator'' indicates that the code is new (or substantially revised) and that the payment indicator assignment is an interim assignment that is open to comment on the final rule with comment period.

The values displayed in the column titled ''CY 2012 Payment Weight'' are the relative payment weights for each of the listed services for CY 2012. The payment weights for all covered surgical procedures and covered ancillary services whose ASC payment rates are based on OPPS relative payment weights were scaled for budget neutrality. Thus, scaling was not applied to the device portion of the device-intensive procedures, services that are paid at the MPFS nonfacility PE RVU-based amount, separately payable covered ancillary services that have a predetermined national payment amount, such as drugs and biologicals that are separately paid under the OPPS, or services that are contractor-priced or paid at reasonable cost in ASCs.

To derive the CY 2012 payment rate displayed in the ''CY 2012 Payment'' column, each ASC payment weight in the ''CY 2012 Payment Weight'' column was multiplied by the CY 2012 conversion factor of $42.627. The conversion factor includes a budget neutrality adjustment for changes in the wage index values and the CPI–U update factor as reduced by the productivity adjustment (as discussed in section XV.H.2.b. of this final rule with comment period).

In Addendum BB, there are no relative payment weights displayed in the ''CY 2012 Payment Weight'' column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The ''CY 2012 Payment'' column displays the CY 2012 national unadjusted ASC payment rates for all items and services. The CY 2012

ASC payment rates listed in Addendum BB for separately payable drugs and biologicals are based on ASP data used for payment in physicians' offices in October 2011.

We did not receive any public comments regarding the continuation of our policy to provide CY 2012 ASC payment information as detailed in Addenda AA and BB. Therefore, Addenda AA and BB to this final rule with comment period (which are available via the Internet on the CMS Web site) display the updated ASC payment rates for CY 2012 for covered surgical procedures and covered ancillary services, respectively, and provide additional information related to the CY 2012 rates.

XIV. Hospital Outpatient Quality Reporting Program Updates and ASC Quality Reporting Program

A. Background

1. Overview

CMS has implemented quality measure reporting programs for multiple settings of care. These programs promote higher quality, more efficient health care for Medicare beneficiaries. The quality data reporting program for hospital outpatient care, known as the Hospital Outpatient Quality Reporting (Hospital OQR) Program, formerly known as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP), has been generally modeled after the quality data reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting (Hospital IQR) Program (formerly known as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program). Both of these quality reporting programs for hospital services, as well as the program for physicians and other eligible professionals, known as the Physician Quality Reporting System (PQRS) (formerly known as the Physician Quality Reporting Initiative (PQRI)), have financial incentives for the reporting of quality data to CMS. CMS also has implemented quality reporting programs for home health agencies and skilled nursing facilities that are based on conditions of participation, and an end-stage renal disease (ESRD) Quality Incentive Program (76 FR 628 through 646) that links payment to performance.

In implementing the Hospital OQR Program and other quality reporting programs, we have focused on measures that have high impact and support CMS and HHS priorities for improved quality and efficiency of care for Medicare beneficiaries. Our goal is ultimately to align the clinical quality measure requirements of the Hospital OQR Program and various other programs, including the Hospital IQR Program, and the proposed ASC Quality Reporting Program, with the reporting requirements implemented under the Health Information Technology for Economic and Clinical Health (HITECH) Act, so that the burden of reporting can be reduced. In developing this and other quality reporting programs, as well as the Hospital Inpatient Value-Based Purchasing (Hospital Inpatient VBP) Program, we applied the following principles for the development and use of measures:

- Pay-for-reporting, public reporting, and value-based purchasing programs should rely on a mix of standards, processes, outcomes, and patient experience of care measures, including measures of care transitions and changes in patient functional status. Across all programs, we seek to move as quickly as possible to the use of primarily outcome and patient experience of care measures. To the extent practicable and appropriate, outcome and patient experience of care measures should be adjusted for risk factors or other appropriate patient population or provider characteristics.
- To the extent possible and recognizing differences in payment system maturity and statutory authorities, measures should be aligned across public reporting and payment systems under Medicare and Medicaid. The measure sets should evolve so that they include a focused set of measures appropriate to the specific provider category that reflects the level of care and the most important areas of service and measures for that provider category.
- The collection of information burden on providers should be minimized to the extent possible. To this end, we continuously seek to align our measures with the adoption of meaningful use standards for health information technology (HIT), so that data can be submitted and calculated via certified EHR technology with minimal burden.
- To the extent practicable and feasible, and recognizing differences in statutory authorities, measures used by CMS should be endorsed by a national, multi-stakeholder organization. Measures should be aligned with best practices among other payers and the needs of the end users of the measures.

In the CY 2012 OPPS/ASC proposed rule (76 FR 42314), we invited public comment on these principles.

Comment: Several commenters commended CMS for creating the synergy between the Hospital OQR Program and the Hospital IQR Program and noted that this is a great opportunity to foster meaningful links between the two Medicare programs. The commenters encouraged adherence to the National Quality Strategy which transforms national priorities into the focal point for measurement, reporting, and financial incentives. Commenters added that all HOPD Program measures should be thoroughly tested for accuracy, validity and applicability to hospital-level care prior to implementation. A commenter recommended that CMS adopt only measures endorsed by the National Quality Forum (NQF) and the Measures Application Partnership (MAP), and approved by the Hospital Quality Alliance (HQA). The commenter also supported public reporting and CMS' approach to propose measures well in advance of the payment year affected.

Response: We appreciate the commenters' support and valuable input. Generally, we follow the framework of the National Quality Strategy to prioritize our measure selection, and implement quality reporting initiatives. We are required by statute to select measures for the Hospital OQR Program that reflect consensus among affected parties and, to the extent feasible and practicable, that these measures include measures set forth by one or more national consensus building entities. The NQF, MAP, and HQA are organizations composed of a diverse representation of consumer, purchaser, provider, academic, clinical, and other health care stakeholders with which we consult or convene for their input. In instances where we develop our own measures, we generally employ a rigorous consensus-based measure development process that incorporates broad stakeholder input. Details regarding the process we have used in connection with some measures are available on our Web site at: *http://www.cms.gov/MMS/19_MeasuresManagementSystemBlueprint.asp#TopOfPage.* Also, we will continue our multi-year approach for proposing and finalizing of measures as it has been well-received by most providers.

Comment: Several commenters praised CMS' shifting approach to focus more on outcome measures but they also believed there is value in the process measures that are linked to outcomes. One commenter specifically urged CMS not to dismiss process measures when there is evidence that supports a direct link between the process being measured and the patient outcome. One commenter suggested that CMS follow The Joint Commission (TJC) (a not-for-profit organization that

accredits and certifies health care organizations and programs in the U.S.) accountability measure criteria as a guide to select quality measures for the Hospital OQR Program. The commenter stated that TJC defines accountability measures as those for which there are large volumes of research linking the measure to improved clinical outcomes; the measure accurately captures the evidence-based care delivered; and implementation of the measure has minimal unintended adverse consequences.

Response: We agree with the commenters that evidence-based process measures that are associated with better outcomes are important to include in the Hospital OQR Program and we have taken steps to include these types of measures each year. We are aware of TJC's accountability criteria for assessment of measures, and consider these criteria, among others, in selecting measures for the Hospital OQR Program because we agree that accountability is crucial in quality improvement processes. We thank the commenters for their support.

Comment: A commenter expressed concerns that the time span between the finalization of the Hospital OQR Program measures and their implementation generally does not provide sufficient time for hospitals to implement process changes to capture quality data. The commenter stated that insufficient preparation would hinder hospital performance improvement and accurate reporting of quality data.

Response: We thank the commenter for this input. We agree that when measures require the capture or collection of new chart-abstracted measure information not previously captured, hospitals need a sufficient amount of time to prepare operationally to meet the new data submission requirements. We generally provide four to six months lead time to hospitals to collect and submit new data that are needed for new measures. However, not all new measures finalized for the Hospital OQR Program may require the capture or collection of new data elements for chart-abstracted measures.

Comment: A commenter strongly urged CMS to include an update on the NQF status of each quality measure in every proposed and final rule, to foster an open and transparent environment, given the significant statutory and contractual roles that NQF plays in the hospital quality measures.

Response: We thank the commenter for the input. We note that in our rulemakings, we provide the NQF endorsement number and endorsement status of each measure when applicable.

Comment: One commenter urged CMS to consider the relevance of Hospital OQR Program measures in rural hospitals and to make modifications of the measures as necessary to minimize the burden on the small hospitals.

Response: We believe that the current Hospital OQR Program measures are relevant to rural hospitals because they address topics that are broadly applicable to hospital outpatient departments, including rural hospital outpatient departments. We agree that it is important to seek to minimize the collection burden associated with measurement, and that some types of providers may be more greatly impacted by collection burden than others. In maintaining the measures, we have sought and will continue to seek to streamline the data elements needed for the measures to the extent possible.

Comment: A commenter requested that CMS clarify the patient population to which the Hospital OQR Program measure applies, for example, traditional Medicare patients, Medicare Advantage, and Medicare replacement policyholders.

Response: The Hospital OQR chart-abstracted and NHSN measures apply to all patients meeting the inclusion criteria for the measure regardless of payer, while the claims-based measures are calculated using only Medicare Fee-for-Service claims. The structural measures apply to the hospital outpatient department.

2. Statutory History of the Hospital Outpatient Quality Reporting (Hospital OQR) Program

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72064) for a detailed discussion of the statutory history of the Hospital OQR Program.

3. Technical Specification Updates and Data Publication

a. Maintenance of Technical Specifications for Quality Measures

Technical specifications for each Hospital OQR measure are listed in the Hospital OQR Specifications Manual, which is posted on the CMS QualityNet Web site at *http://www.QualityNet.org*. We maintain the technical specifications for the measures by updating this Hospital OQR Specifications Manual and including detailed instructions and calculation algorithms. In some cases where the specifications are available elsewhere, we may include links to Web sites hosting technical specifications. These resources are for hospitals to use when collecting and submitting data on required measures.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766 through 68767), we established a subregulatory process for making updates to the technical specifications that we use to calculate Hospital OQR measures. This process is used when changes to the measure specifications are necessary due to changes in scientific evidence, treatment guidelines, or consensus among affected parties. Changes due to these reasons may not coincide with the timing of our regulatory actions, but nevertheless should be made so that the Hospital OQR measures are calculated based on the most up-to-date scientific and consensus standards. We indicated that notification of technical changes to the measure specifications is made via the QualityNet Web site, *http://www.QualityNet.org*, and in the Hospital OQR Specifications Manual. The notification of changes to the measure technical specifications occurs no less than 3 months before any changes become effective for purposes of reporting under the Hospital OQR Program.

The Hospital OQR Specifications Manual is released every 6 months and addenda are released as necessary. This release schedule provides at least 3 months of advance notice for substantial changes such as changes to ICD–9, CPT, NUBC, and HCPCS codes, and at least 6 months of advance notice for changes to data elements that would require significant systems changes.

Comment: A commenter requested that for future new measure proposals, CMS also post the associated measure specification publicly at least 6 months prior to inclusion in a proposed rule.

Response: We provide specifications or links to specifications as part of the proposal. We also seek to incorporate measure specifications as quickly as possible into the Hospital OQR Specifications Manual in order to provide enough lead time (generally six months) prior to the beginning of data collection for the measure under the Hospital OQR Program.

b. Publication of Hospital OQR Program Data

Section 1833(t)(17)(E) of the Act requires that the Secretary establish procedures to make data collected under Hospital OQR available to the public. It also states that such procedures must ensure that a hospital has the opportunity to review the data that are to be made public with respect to the hospital prior to such data being made public. To meet these requirements,

data that a hospital has submitted for the Hospital OQR Program are typically displayed on CMS Web sites such as the *Hospital Compare* Web site, *http://www.hospitalcompare.hhs.gov*, after a preview period. The *Hospital Compare* Web site is an interactive Web tool that assists beneficiaries by providing information on hospital quality of care. This information motivates beneficiaries to work with their doctors and hospitals to discuss the quality of care hospitals provide to patients, providing additional incentives to hospitals to improve the quality of care that they furnish.

Under our current policy, we publish quality data by the corresponding hospital CCN, and indicate instances where data from two or more hospitals are combined to form the publicly reported measures on the *Hospital Compare* Web site. This approach is consistent with the approach taken under the Hospital IQR Program. Consistent with our current policy, we make Hospital OQR data publicly available whether or not the data have been validated for payment purposes.

In general, we strive to display hospital quality measures on the *Hospital Compare* Web site as soon as possible after they have been adopted and have been reported to CMS. However, if there are unresolved display issues or pending design considerations, we may make the data available on other, non-interactive, CMS Web sites such as *http://www.cms.hhs.gov/HospitalQualityInits/*. Publicly reporting the information in this manner, though not on the interactive *Hospital Compare* Web site, allows us to meet the requirement under section 1833(t)(17)(E) of the Act for establishing procedures to make quality data submitted available to the public following a preview period. When we display hospital quality information on non-interactive CMS Web sites, affected parties will be notified via CMS listservs, CMS email blasts, national provider calls, and QualityNet announcements regarding the release of preview reports followed by the posting of data on a Web site other than *Hospital Compare.*

We also require hospitals to complete and submit a registration form (''participation form'') in order to participate in the Hospital OQR Program. With submission of this participation form, participating hospitals agree that they will allow CMS to publicly report the quality measure data submitted under the Hospital OQR Program, including measures that we calculate using Medicare claims.

Comment: A commenter urged CMS to continue using both the stakeholder and focus groups to develop and evaluate terminology for presenting measurement data to the public to avoid misleading and alarming the public unnecessarily.

Response: We appreciate this feedback. Prior to presenting new measurement topics or new types of measures on the *Hospital Compare* Web site, we strive to incorporate stakeholder feedback into the display, and to test the display with consumers in order to ensure that the concepts are easily understood by consumers and that the display and accompanying text will not lead to misinterpretation or inappropriate comparisons.

Comment: Two commenters believed that the imaging measures displayed on the *Hospital Compare* Web site have caused confusion regarding how they should be interpreted.

Response: Currently, we are displaying the imaging efficiency measures as rates or ratios as well as observed averages and rates by percentile among all those facilities that meet the minimum case count (a minimum case count is needed for statistical validity purposes. We plan to evaluate whether alternative ways of displaying efficiency measures, such as categorical displays, may be more informative to consumers than the current method of displaying the measures.

Comment: A commenter suggested linking cost data to publicly displayed quality data. Another commenter was concerned that posting data in multiple places other than *Hospital Compare* may cause confusion. A commenter recommended that CMS postpone the display of data with issues on *Hospital Compare* to a later date when the issues are resolved rather than displaying them at a different site temporary. A few commenters were concerned that the Hospital OQR data on *Hospital Compare* may be outdated, and urged CMS to consider a more current time frame for displaying outpatient quality measures to provide more timely and accurate information for the public. For future display of e-measures, a commenter urged CMS to indicate the method of data collection (that is, electronic versus chart-abstracted) on *Hospital Compare* so that consumers are aware of the different collection methods used.

Response: We use the *Hospital Compare* Web site as the primary vehicle for displaying hospital quality data reported for the Hospital OQR Program. As we stated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72070), the data we display on Web sites other than *Hospital Compare* is displayed on a temporary basis because of pending display design and other unresolved issues so as to not confuse beneficiaries who intend to use data in making healthcare decisions. Once an appropriate display mechanism has been determined, the information is added to the *Hospital Compare* Web site. The data for the Hospital OQR Program are made available on the Hospital Compare Web site as soon as possible, and the most recent time periods for the data that are available to us are posted on the Web site. The chart-abstracted measure data are refreshed on a quarterly basis, and the claims-based and structural measures are refreshed once annually. We currently provide information on the data sources for the various measures on *Hospital Compare* under the ''information for professionals'' link, which is accessible to the public. We will consider alternatives to make this information more transparent to the public.

B. Revision to Measures Previously Adopted for the Hospital OQR Program for the CY 2013, and CY 2014 Payment Determinations

1. Background

We refer readers to the following OPPS/ASC final rules with comment periods for a history of measures adopted for the Hospital OQR Program, including lists of: 11 measures adopted for the CY 2011 payment determination (74 FR 60637); 15 measures adopted for the CY 2012 payment determination (75 FR 72083 through 72084); 23 measures adopted for the CY 2013 payment determination (75 FR 72090); and 23 measures adopted for the CY 2014 payment determination (75 FR 72094). The table below also shows the 23 measures previously adopted for these payment determinations:

BILLING CODE 4120–01–P

Hospital OQR Program Measures Previously Adopted for the CY 2011, CY 2012, CY 2013, and CY 2014* Payment Determinations**
OP-1: Median Time to Fibrinolysis
OP-2: Fibrinolytic Therapy Received Within 30 Minutes
OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
OP-4: Aspirin at Arrival
OP-5: Median Time to ECG
OP-6: Timing of Antibiotic Prophylaxis
OP-7: Prophylactic Antibiotic Selection for Surgical Patients
OP-8: MRI Lumbar Spine for Low Back Pain
OP-9: Mammography Follow-up Rates
OP-10: Abdomen CT – Use of Contrast Material
OP-11: Thorax CT – Use of Contrast Material
OP-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data*
OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non Cardiac Low Risk Surgery*
OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)*
OP-15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache*
OP-16: Troponin Results for Emergency Department acute myocardial infarction (AMI) patients or chest pain patients (with Probable Cardiac Chest Pain) Received Within 60 minutes of Arrival**
OP-17: Tracking Clinical Results between Visits**
OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients**
OP-19: Transition Record with Specified Elements Received by Discharged Patients**
OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional**
OP-21: ED- Median Time to Pain Management for Long Bone Fracture **
OP-22: ED- Left Without Being Seen**
OP-23: ED- Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 minutes of Arrival **

* New measure adopted beginning with the CY 2012 payment determination.

** New measure adopted beginning with the CY 2013 payment determination.

*** All 23 measures were adopted for the CY 2014 payment determination.

BILLING CODE 4120–01–C

We received specific comments, discussed below, on some of these previously finalized measures.

- OP–3 Median time to transfer to another facility for acute coronary intervention

Comment: One commenter recommended the retirement of this measure but provided no rationale for the recommendation.

Response: Periodically, we perform measure review for relevancy, potential topped-out status, program alignment, and harmonization. We have not observed any evidence indicating that the measure should be retired at this time. This measure is important because it measures the promptness of care intervention for life threatening coronary events, which is associated with better outcomes for patients experiencing such events.

- OP–4: Aspirin at Arrival and OP–5: Median Time to ECG

Comment: A commenter disagreed with the inclusion code for ''Chest Pain Not Elsewhere Classified (NEC)'' for the identification of probable cardiac chest pain cases in these two measures.

Response: We disagree with the commenter that this code should be excluded. By including this code, we take into account the wide variability of patient symptoms and how health care providers use codes to capture symptoms of chest pain. According to the ICD–9 manual, this code applies to symptoms of discomfort in chest, chest pressure and tightness in chest. These symptoms are also associated with cardiac chest pain. Because OP–4 and OP–5 are process measures which assess the use of aspirin and ECG in patients suspected of having cardiac chest pain, we believe that all codes in the claims data that indicate capture chest pain should be used to identify these types of patients.

- OP–9: Mammography Follow-up Rates
- OP–10: Abdomen CT—Use of Contrast Material
- OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT) *

Comment: A few commenters urged CMS to remove the above imaging efficiency measures because they have not received NQF endorsement and are not HQA-approved. A few commenters were concerned that measures OP–9 and OP–10 may cause potential harm.

Response: Many of the concerns raised by the commenters about the imaging efficiency measures we adopted for the CY 2011 payment determination were also raised at the time these measures were first proposed for the CY 2010 payment determination. We responded to these concerns when we adopted the measures (73 FR 68762 through 68766). We stated that the measures meet the statutory requirement of reflecting consensus among affected parties because of their consensus-based development, and that the measures address important patient safety concerns related to exposure to unnecessary radiation and contrast materials. We also stated that the Secretary is not required to limit measures considered for Hospital OQR Program adoption only to those adopted by the HQA or endorsed by the NQF. We have not found any evidence that implementation of these three measures results in patient harm.

- OP–13: Cardiac imaging for preoperative risk assessment for non-cardiac low risk surgery
- OP–14: Simultaneous use of brain computed tomography (CT) and sinus computed tomography (CT)
- OP–15: Use of brain computed tomography (CT) in the ED for atraumatic headache

Comment: A commenter recommended that for initial implementation of new imaging measures, CMS should keep the ''within range'' rates broad so that hospital performance would not be unfairly presented.

Response: Generally, the hospital outpatient imaging efficiency measures that we have implemented do not provide for any targets or ranges. However, the OP–9: Mammography Follow-Up rates measure uses ranges because the literature supports specified ranges. For the other imaging efficiency measures, we provide rates or ratios as well as observed averages and rates by percentile among all those facilities that meet the minimum case count (a minimum case count is needed for statistical validity purposes).

- OP–13: Cardiac imaging for preoperative risk assessment for non-cardiac low risk surgery

Comment: A commenter stated that imaging measures included in the Hospital OQR Program are claims-based and may not indicate the exclusions and justify the clinical information in context to support the clinical decisions for the imaging studies. The commenter gave the example of measure OP–13. The commenter believed that exclusions should be added that would recognize appropriate use of stress imaging in patients with certain clinical events coincidentally around the time of the ''non-cardiac'' surgery.

Response: We believe that the use of claims data is a non-burdensome data collection approach because hospitals routinely submit claims to Medicare for billing purposes. We are also committed to regularly review whether additional codes should be added to determine exclusions and related clinical information.

We are aware of the commenter's concerns for measure OP–13. During development of the imaging measures, our technical experts determined that additional clinical information beyond what is present on claims is not necessary to identify exclusions. However, we will further consider whether additional clinical information would improve the capture of exclusions for this and other imaging measures during the regular maintenance process for these measures.

- OP–14: Simultaneous use of brain computed tomography (CT) and sinus computed tomography (CT)

Comment: A commenter believed that prior to measure implementation, CMS should include explicit exclusion criteria for patients with signs of serious infection.

Response: We appreciate the commenter's concerns. During the development of this imaging efficiency measure, we completed extensive literature reviews and analyzed appropriate medical guidelines to determine the appropriateness of imaging studies for various medical conditions and exclusions. Currently, we exclude claims with primary or secondary diagnosis codes related to trauma, tumor, orbital cellulitis, or intracranial abscess from the measure as long as these diagnoses were included in one of the diagnoses fields on the Brain CT claim. We regularly review measures to determine whether additional codes should be added in order to determine exclusions. To date, we have not identified any scientific literature or guidelines that would indicate that simultaneous brain and sinus CT imaging would be necessary for patients with signs of serious infection. However, we will review this suggestion with our technical experts during regular maintenance of the measure.

Comment: A commenter noted that OP–14 has too many similarities with measure OP–15. The commenter believed that there is little benefit in this measure because the sample size for patients having both scans may be small at many facilities and that more and more facilities have multi-slice scanners that are capable of reconstructing the data to better evaluate the sinuses without requiring rescanning with additional radiation.

Response: While we recognize that OP–14 and OP–15 may be similar, OP–14's specific focus is reducing unnecessary scans of adjacent body parts, when one scan is clinically appropriate. We recognize that small case counts can be problematic for facilities that do not perform a sufficient volume of CT imaging studies. For this reason, we will establish a minimum

case count requirement for these measures for public reporting purposes. Regarding the comment on the impact of imaging technology on imaging efficiency measure results, currently, we do not collect any information regarding what level of CT technology is employed by a facility. Therefore, it is not currently possible to adjust the CT measures in this manner.

- OP–15: Use of brain computed tomography (CT) in the ED for atraumatic headache

Comment: A commenter noted that certain conditions such as HIV/AIDS, cancer, visual disturbance, protracted nausea and vomiting should be added to the exclusions, as well as structural pathologies and all codes for neurological signs of cerebral origin.

Response: We thank the commenter for the suggestions and will take them into consideration in our measure maintenance process.

Comment: A few commenters opposed measure OP–15 because it is not NQF-endorsed. Commenters stated that the measure is a utilization measure rather than an efficiency measure. The commenters added that there was no scientific basis to suggest this measure addresses patient safety. Commenters urged CMS to reconsider the adoption of measure OP–15, considering potential tort liability in the ED if imaging does not occur, and the potential positive impact on quality of life for patients.

Response: The objective of imaging efficiency measures, including OP–15, is to promote efficient and high quality patient care in the hospital outpatient setting that neither underutilizes nor over utilizes healthcare resources. Unnecessary or duplicative studies are inefficient and detrimental to the patient because CT exposes the patient to higher doses of radiation than conventional x rays and increases the patient's risk for cancer. An analysis of 2007 Medicare claims data indicated that approximately 200,000 Medicare beneficiaries had a visit to the ED with a primary diagnosis of headache with about half of them receiving a brain CT during the ED visit. We encourage use of this important diagnostic tool when clinically indicated.

Earlier this year, we conducted a dry run of the measure and received many suggestions for refinements to the measure in order to better address circumstances in which such imaging is clinically indicated. We intend to have our technical expert panel examine the suggestions we have received regarding the measure during the dry run as well as the comments we have received during this public comment period and during the maintenance process for this measure. We intend to incorporate refinements arising out of this process, such as the formulation and incorporation of addition exclusion criteria to be applied to the measure specifications and calculations, prior to implementing public reporting of the measure.

- OP–16: Troponin results for ED acute myocardial infarction patients or chest pain patients received within 60 minutes of arrival

Comment: One commenter urged CMS not to adopt this measure, based on the assertion that the measure is not a good marker for quality and it may have the unintended consequences of prolonging other ED patients' wait times for lab results.

Response: We are aware that Troponin assessment may not be the only component of a diagnostic workup of patients with chest pain. The focus of this measure is on the timeliness of the receipt of the Troponin results and not on its use or interpretation by HOPDs. However, we believe that use of the Troponin test facilitates decision making in the treatment of time sensitive conditions such as AMI. For this reason, we believe timeliness of the availability of the test results is a marker of quality because it results more timely treatment decisions and treatment delivery, which in turn results in better outcomes for patients.

- OP–17: Tracking clinical results between visits

Comment: A commenter suggested the inclusion of a ''N/A'' option for hospital outpatient departments, in the event that lab tests or diagnostic studies are ordered by physicians or outside vendors not working for the hospital. One commenter believed this measure is more appropriate for the HITECH EHR Incentive Program as a meaningful use decision support or surveillance element.

Response: The use of a ''N/A'' option would be inconsistent with the intent of the measure. The structural measure is designed to assess the ability of HOPDs to track results of clinical tests between the patient visits. This would be true of the facility even in cases where tests are ordered by someone not employed by the facility. The ability to track these results allows facilities to see any changes in values or trends which may indicate a change in a patient's condition over time.

- OP–19: Transition record with specified elements received by discharged patient

Comment: A few commenters supported providing patients with full transition information including diagnosis at discharge or chief complaint, patient instructions, plan for follow-up care, and list of new medications with quantity dispensed. However, other commenters were concerned about the burden in generating and providing patients with a copy of all major procedures and tests performed during ED visits. Some commenters recommended delaying implementation of this measure until EHRs have the functionality to generate real time diagnosis information and copies of all major procedures and tests performed during an ED visit for patients.

Response: We appreciate the support and the recommendations from the commenters. This measure covers outpatient ED encounters only (not other HOPD encounters), and we believe that the HOPD should be able to accurately document diagnostic tests and procedures performed at the facility during the ED visit. If the principal diagnosis has not been determined prior to discharge, the specifications state that the chief complaint can be used to comply with the measure.

We do not believe it is necessary to delay the implementation of this measure because many EDs are already keeping track of patient encounters and related tests and procedures during the ED visit. We do not believe it will incur much burden to report the data. Additionally, certified EHR technology already has the functionality to generate real time diagnosis information and copies of procedures and tests performed during an ED visit.

Comment: Some commenters requested that CMS clarify on the applicability of this measure for patients put on observation. Some commenters noted that observations patients may be under the care of non-ED physicians.

Response: Currently, observation patients discharged from the ED would be captured. However, not all observation patients at the hospital may be seen in or discharged through the ED. We believe this information should be provided for all observation patients, regardless of whether an ED physician was responsible for their care. We intend to revisit how this population can be better defined for the hospital outpatient department as a whole with our technical expert panel during the maintenance of this measure.

Comment: A commenter requested the exclusion of the discontinued medications from the specified elements for this measure. The commenter recommended that only medications prescribed or dispensed by the ED should be included since changes to a

patient's home medication list seldom occur in ED visit. Another commenter inquired if all the required data elements for this measure are included in the Specifications Manual.

Response: There is only one data element (Transition Record received) in this measure and this data element contains several components. Discontinued medications is one of the components in this data element on the ED Measure Information Form: List of new medications and changes to continued medications that patient should take after ED discharge, with quantity prescribed and/or dispensed (OR intended duration) and instructions for each medication. The medications discontinued as a result of the ED visit should be listed to ensure that the patient does not continue taking them after discharge. This would mean a change to the list of home medications. Thus, documentation of discontinued medication is an essential part of the instructions given to a patient upon discharge. Therefore, the transition record should contain a summary of the care, including discontinued medication instruction provided during the ED encounter.

- OP–21: ED-Median time to pain management for long bone fracture

Comment: Two commenters believed that this measure should include NSAIDS, such as ibuprofen on the analgesic medication list as some ED physicians use them to treat pain for long bone fractures.

Response: We acknowledge the importance of listing all possible analgesics in the treatment of long bone fractures in the list of analgesics for OP–21 provided in Table OP 9.1 Analgesic Medications of the Hospital OQR Specifications Manual. We will consider including ibuprofen as a recommended medication in the list of analgesics during the next Specifications Manual update. However, we emphasize that the purpose of OP–21 is to measure the median time to analgesic administration in long bone fractures rather than to measure the type of analgesic administered. The list of analgesic medications in the Specification Manual are only suggestions.

Comment: A commenter contended that this measure does not account for those patients that do not receive pain medication, and questioned how patients not being treated would be appropriately captured.

Response: The commenter is correct, this measure assesses whether patients with long bone fracture who received analgesics did so in a timely manner. During measure development, our technical expert panel decided not to create a measure of administration/lack of administration. We will revisit whether a separate measure is needed, or whether lack of administration should be addressed in the existing measure with our technical expert panel.

- OP–23: ED–Head CT scan results for acute ischemic stroke or hemorrhage stroke who received head CT scan interpretation within 45 minutes of arrival

Comment: One commenter believed that this measure is more appropriate as an inpatient measure rather than an outpatient measure.

Response: We believe that timely interpretation of head CT scan results for acute ischemic stroke or hemorrhage stroke patients is important in both inpatient and outpatient settings. This measure is appropriate to measure the quality of care in the outpatient setting, given that the goals of this measure are to encourage hospitals to assess and improve timeliness of diagnostic reports, clinical decision making, and as a result, reduce unnecessary length of stay in the ED. We expect the measure would reduce radiology report turnaround times and expedite the formulation of ED patient treatment plans.

The measure is limited to patients seen in the ED and subsequently discharged or transferred. This measure is designed to capture those patients that are not admitted to the facility associated with the ED that sees them initially, which would be a significant population not accounted for with an inpatient measure.

Comment: One commenter supported measure OP–23 but requested that CMS exclude patients who present to the ED in cardiopulmonary arrest and patients who suffer a cardiac or pulmonary arrest requiring resuscitation within 45 minutes of arrival to the ED for stabilization, before even considering sending them to CT for a head CT.

Response: We believe that the number of patients who present to the ED in cardiopulmonary arrest and who suffer a cardiac or pulmonary arrest requiring resuscitation within 45 minutes of arrival to the ED for stabilization and eventually survive will be minimal (patients who expire are excluded from the measure). However, we will explore whether excluding cases with diagnosis codes for either Respiratory Arrest (799.1) or Cardiac Arrest (427.5) would be feasible and appropriate during the maintenance of the measure.

Comment: A commenter requested that CMS model measure OP–23 after a TJC stroke care measure that requires a brain imaging study to be read in the hospital within 45 minutes of the time it was ordered, as opposed to within 45 minutes of a patient's arrival (which OP–23 measures).

Response: We appreciate this feedback. Because the therapeutic time window for treatment possibilities is critical, timely completion and results of the CT or MRI scan soon after patient arrival are imperative and will directly impact the quality of care a patient receives. Because results will only be delivered if ordered, this measure implies that tests will be ordered timely as well, so that they can be read within 45 minutes of a patient's arrival.

Comment: A commenter stated that current evidence indicates that as an acute stroke brain imaging modality, MRI is equally good or better than CT in diagnosing stroke. Therefore, the commenter recommended changing the title of the measure to read Brain CT or MRI scan results from acute ischemic stroke or hemorrhagic stroke who received brain CT or MRI scan interpretation within 45 minutes of arrival.

Response: We appreciate the feedback and will consider this suggestion in our measure review.

Comment: Several commenters recommended the retirement of all structural measures adopted in the Hospital OQR Program as the commenters did not believe these measures can be validated and usually they are not tied to quality.

Response: We do not agree with the commenters' statements that structural measures are not tied to quality. Structural measures assess operational conditions that are associated with better quality, and therefore warrant measurement and inclusion in this and other quality reporting programs.

2. Revision to OP–22—Left Without Being Seen

In the CY 2011 OPPS/ASC final rule with comment period, we finalized the adoption of the chart-abstracted measure OP–22—Left Without Being Seen (75 FR 72088 through 72089). This measure was endorsed (NQF # 0499) as part of an NQF project entitled ''National Voluntary Consensus Standards for Emergency Care.'' This measure assesses the percentage of patients who leave the Emergency Department (ED) without being evaluated by qualified medical personnel, which is an indication of ED overcrowding, and lack of timely access to care. In the CY 2012 OPPS/ASC proposed rule (76 FR 42315), we proposed that beginning with the CY

2013 payment determination, hospitals would submit aggregate numerator and denominator counts once a year using a Web-based form available through the QualityNet Web site for this measure. We stated that this proposed process would be different from that which is used to collect other chart-abstracted measures because it would not require hospitals to submit patient-level information for this measure, and would not require quarterly submission of data. We believe this proposed process will reduce the potential data collection and submission burden for this measure.

We proposed that for the CY 2013 payment determination, data submission for this measure would occur between July 1, 2012 and August 15, 2012. We also proposed that for the CY 2013 payment determination, the aggregate counts for the numerator (the total number of patients who left without being evaluated by a physician/advance practice nurse/physician's assistant) and the denominator (total number of patients who signed in to be evaluated for emergency services) would be submitted by hospitals and would span the time period from January 1, 2011 through December 31, 2011. We invited public comment on this proposed approach to data collection for OP–22 for the CY 2013 Hospital OQR Program and subsequent payment determinations, and on the time period to be assessed for this measure for the CY 2013 payment determination. We made the proposed updated specifications for this measure available in the July 2011 Hospital OQR Specifications Manual.

Comment: A few commenters supported the proposed revision for the collection of aggregate counts of the numerator and the denominator for measure OP–22 for burden reduction purposes. A commenter suggested CMS study the results for systematically higher rates for certain types of hospitals such as safety net hospitals so that appropriate adjustments can be made. One commenter was concerned about including this measure in pay for reporting or public reporting but did not provide a reason. Furthermore, the commenter recommended changing this measure into a structural measure and having it reported on an annual basis. One commenter contended that the measure is not a quality of care measure and is hard to validate since there are underlying patient records from which to pull the data and added that the measure should not be implemented.

Response: We thank the commenters for their support of aggregate reporting for this measure and their suggestions for monitoring this measure for differences by type of hospital (for example, safety net hospitals). We point out that the measure would be reported once annually by hospitals. This measure is NQF-endorsed as a measure of ED quality. We have not proposed to validate this measure.

Comment: Several commenters stated that it is burdensome to retrieve the aggregate data retroactively since hospitals may not have been accustomed to collecting the data for aggregate reporting purposes, and indicated that the time period hospitals should begin reporting for this measure should begin after this final rule with comment period is issued rather than CY 2011 as proposed. Other commenters believed that the long lapse of time between 2011 and 2013 would make the data irrelevant. One commenter suggested moving the reporting window to July 1, 2013 to August 15, 2013 instead of July 1, 2012 and August 15, 2012 as proposed. Another commenter suggested delaying implementation of this measure until the data can be submitted electronically.

Response: We believe that most HOPDs are already tracking the number of patients that leave the emergency department without being seen through various logs (for example, triage or presentation logs). We note that electronic systems are not needed to report the measure. However, in response to the public comments we received regarding the burden for retroactive retrieval of aggregate data, we will finalize the time window for the initial reporting of this measure for the CY 2013 payment determination to begin on January 1, 2012 through June 30, 2012. The data submission window for this measure for the CY 2013 payment determination will be July 1, 2012 through August 15, 2012.

Comment: One commenter requested clarification regarding whether the proposed revisions to the measure are endorsed by the NQF. A commenter requested the definitions of ''being seen,'' ''left without being seen,'' as well as clarifications for the inclusion or exclusion of patients who have been triaged but not evaluated by a physician/advance practice nurse/physician's assistant, for data collection purposes.

Response: The revisions do not change the NQF endorsed measure specifications. Only the form, manner, and timing of data submission to CMS are changed. We have not revised this measure or its measure specifications. In the current measure specification, we defined ''being seen'' as being evaluated by a physician or advance practice nurse or physician's assistant.

After consideration of public comment received, we are finalizing our proposal that for the CY 2013 payment determination, with respect to OP–22–Left Without Being Seen, HOPDs will be required to report only aggregate counts for the numerator (the total number of patients who left without being evaluated by a physician/advance practice nurse/physician's assistant) and the denominator (total number of patients who signed in to be evaluated for emergency services). In response to comments, we are finalizing that HOPDs will be required to submit the data between July 1, 2012 and August 15, 2012 with respect to the period January 1, 2012 through June 30, 2012, and will be required to submit the data using a Web-based form for this measure available on the QualityNet Web site.

C. New Quality Measures for the CY 2014 and CY 2015 Payment Determinations

1. Considerations in Expanding and Updating Quality Measures Under the Hospital OQR Program

In general, when selecting measures for the Hospital OQR Program, we take into account several considerations and goals. These include: (a) Expanding the types of measures beyond process of care measures to include an increased number of outcome measures, efficiency measures, and patients' experience-of-care measures; (b) expanding the scope of hospital services to which the measures apply; (c) considering the burden on hospitals in collecting chart-abstracted data; (d) harmonizing the measures used in the Hospital OQR Program with other CMS quality programs to align incentives and promote coordinated efforts to improve quality; (e) seeking to use measures based on alternative sources of data that do not require chart abstraction or that utilize data already being reported by many hospitals, such as data that hospitals report to clinical data registries, or all-payer claims data bases; and (f) weighing the relevance and utility of the measures compared to the burden on hospitals in submitting data under the Hospital OQR Program.

Specifically, we assign priority to quality measures that assess performance on: (a) Conditions that result in the greatest mortality and morbidity in the Medicare population; (b) conditions that are high volume and high cost for the Medicare program; and (c) conditions for which wide cost and treatment variations have been reported, despite established clinical guidelines. We used and continue to use these criteria to guide our decisions regarding

what measures to add to the Hospital OQR Program measure set.

In the CY 2009 OPPS/ASC final rule with comment period, we adopted four claims–based quality measures that do not require a hospital to submit chart-abstracted clinical data (73 FR 68766). This supports our goal of expanding the measures for the Hospital OQR Program while minimizing the burden upon hospitals and, in particular, without significantly increasing the chart abstraction burden. In addition to claims-based measures, we are considering registries and EHRs as alternative ways to collect data from hospitals.

A registry is a collection of clinical data for purposes of assessing clinical performance, quality of care, and opportunities for quality improvement. Many hospitals submit data to and participate in existing registries. In addition, registries often capture outcome information and provide ongoing quality improvement feedback to registry participants. Instead of requiring hospitals to submit the same data to CMS that they are already submitting to registries, we could collect the data directly from the registries with the permission of the hospital, thereby enabling us to expand the Hospital OQR Program measure set without increasing the burden of data collection for those hospitals participating in the registries. The data that we would receive from registries would be used to calculate quality measures required under the Hospital OQR Program, and would be publicly reported like other Hospital OQR Program quality measures, encouraging improvements in the quality of care. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60633), we responded to public comments on such an approach.

In the CY 2009 OPPS/ASC final rule with comment period, we also stated our intention to explore mechanisms for data submission using EHRs (73 FR 68769). When we refer to the term ''Qualified EHR,'' we intend for it to have the same meaning as set forth by the Office of the National Coordinator for Health Information Technology (ONC) (45 CFR 170.102) which has adopted the statutory definition of Qualified EHR found in section 3000(13) of the Public Health Service Act. That section defines a Qualified EHR as ''an electronic record of health-related information on an individual that—(A) includes patient demographic and clinical health information, such as medical history and problem lists; and (B) has the capacity—(i) to provide clinical decision support; (ii) to support physician order entry; (iii) to capture and query information relevant to health care quality; and (iv) to exchange electronic health information with, and integrate such information from other sources.'' Additionally, when we refer to the term, Certified EHR Technology, we intend for it to have the same meaning as set forth by the ONC at 45 CFR 170.102 as follows: ''Certified EHR Technology'' means (1) A complete EHR that meets the requirements included in the definition of a Qualified EHR and has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary; or (2) a combination of EHR Modules in which each constituent EHR Module of the combination has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary, and the resultant combination also meets the requirements included in the definition of a Qualified EHR.

Establishing a data submission mechanism using EHRs will require interoperability between EHRs and our data collection systems, additional infrastructure development on the part of hospitals and CMS, and the adoption of standards for the capturing, formatting, and transmission of data elements that make up the measures. However, once these activities are accomplished, the adoption of measures that rely on data obtained directly from EHRs would enable us to expand the Hospital OQR Program measure set with less cost and burden to hospitals. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60633 through 60634), we responded to public comments on such an approach.

Continuing to reduce our reliance on the chart-abstraction mechanism would allow us and hospital outpatient departments to devote available resources towards maximizing the potential of registries and EHRs for quality measurement reporting. Both mechanisms hold the promise of more sophisticated and timely reporting of clinical quality measures. Clinical data registries allow the collection of more detailed data, including outcomes. Registries can also provide feedback and quality improvement information based on reported data. Finally, clinical data registries can also receive data from EHRs, and therefore, serve as an alternative means to reporting clinical quality data extracted from an EHR.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72071 through 72174), we added new measures over a three year period for the CY 2012, CY 2013, and CY 2014 payment determinations. We believe this process will assist hospitals in planning, meeting future reporting requirements, and implementing quality improvement efforts. We will also have more time to develop, align, and implement the infrastructure necessary to collect data on the measures and make payment determinations. The fact that we finalized measures for a three year period of time (for example, for the CY 2012, CY 2013 and CY 2014 payment determinations in the CY 2011 OPPS/ASC final rule with comment period) does not preclude us from proposing to adopt additional measures or changing the list of measures for these payment determinations through subsequent rulemaking cycles that affect these future payment determinations.

We have previously expanded the Hospital OQR Program measure set dramatically by adopting measures over several payment determinations in order to allow hospital outpatient departments adequate time to plan and implement the reporting of quality data for the CY 2012, CY 2013 and CY 2014 payment determinations. In the CY 2012 OPPS/ASC proposed rule (76 FR 42317), we proposed to add new measures to the existing Hospital OQR measure set for the CY 2014 payment determination and proposed to add new measures for the CY 2015 payment determination.

Comment: Many commenters strongly supported CMS' goal to move from process measures to primarily outcome and patient experience of care measures. Commenters encouraged measure alignment across payers using NQF-endorsed measures. To alleviate burden from chart-abstraction, commenters provided the following suggestions for CMS:

- Identify measures suitable for registry-based reporting in the near future. Commenters described many advantages in using registries such as less resources are needed to report data, and timely analysis of existing practices to improve the quality of care.
- Retire unnecessary measures.
- Add measures linked to health outcomes.
- Limit the number of new chart-abstracted measures in the Hospital OQR Program.

Response: We appreciate the valuable input from commenters. As discussed in previous rules, we are supportive of registry-based measurement which holds promise for reducing burden. During our measure maintenance process, we review the improvement potential for a measure, the measure's continued support by scientific

evidence, any new evidence indicating the measure may cause harm to patients or no longer represents best practice, duplicative measures, and whether a measure could be replaced by an outcome measure. In our discussion of measure selection criteria, we state our intention to focus on outcome measures whenever possible. Additionally, our goal is to reduce burden and minimize the number of chart-abstracted measures.

Comment: A commenter strongly recommended that in future measure proposals, CMS should: (1) Clearly articulate the specific patient inclusion criteria for the measure; and (2) select codes that are appropriate for claims-based measures in HOPD settings.

Response: We note that we provide measure specifications or links to measure specifications, including patient inclusion criteria and the appropriate codes for claims-based measures for the proposed measures, at the time we propose them to assist the public, during the public comment process.

2. New Hospital OQR Program Quality Measures for the CY 2014 Payment Determination

As stated above, the CY 2014 measure set for the Hospital OQR Program currently contains 23 measures that we adopted in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72094). In the CY 2012 OPPS/ASC proposed rule (76 FR 42317 through 42323), we proposed to adopt a number of additional measures for the CY 2014 measure set.

a. Proposed National Healthcare Safety Network (NHSN) Healthcare Associated Infection (HAI) Measure for the CY 2014 Payment Determination: Surgical Site Infection (NQF #0299)

Healthcare Associated Infections (HAIs) is a topic area widely acknowledged by HHS, the Institute of Medicine (IOM), the National Priorities Partnership, and others as a high priority requiring measurement and improvement. HAIs are among the leading causes of death in the United States. CDC estimates that as many as 2 million infections are acquired each year in hospitals and result in approximately 90,000 deaths.[1] It is estimated that more Americans die each year from HAIs than from auto accidents and homicides combined. HAIs not only put the patient at risk, but also increase the days of hospitalization required for patients and add considerable health care costs. HAIs are largely preventable through interventions such as better hygiene and advanced scientifically tested techniques for surgical patients. Therefore, many health care consumers and organizations are calling for public disclosure of HAIs, arguing that public reporting of HAI rates provides the information health care consumers need to choose the safest hospitals, and gives hospitals an incentive to improve infection control efforts. This proposed measure is currently collected by the National Healthcare Safety Network (NHSN) as part of State-mandated reporting and surveillance requirements for hospitals in some States. Additionally, data submission for this measure through EHRs may be possible in the near future.

The NHSN is a secure, Internet-based surveillance system maintained and managed by the CDC, and can be used by all types of healthcare facilities in the United States, including acute care hospitals, long term acute care hospitals, psychiatric hospitals, rehabilitation hospitals, outpatient dialysis centers, ambulatory surgery centers, and long term care facilities. The NHSN is provided free of charge to hospitals. The NHSN enables healthcare facilities to collect and use data about HAIs, clinical practices known to prevent HAIs, the incidence or prevalence of multidrug-resistant organisms within their organizations, and other adverse events. Some States use the NHSN as a means for healthcare facilities to submit data on HAIs mandated through their specific State statute. Currently, 21 States require hospitals to report HAIs using the NHSN, and the CDC supports more than 4,000 hospitals that are using NHSN.

Increasingly, more surgical procedures are being performed in hospital outpatient department settings and ASCs. Therefore, we have determined that this measure is ''appropriate for the measurement of the quality of care furnished by hospitals in outpatient settings'' as required under section 1833(t)(17)(C)(i) of the Act. This proposed HAI measure assesses the percentage of surgical site infections occurring within 30 days after an NHSN-defined operative procedure if no implant is left in place or within one year if an implant is in place, and the infection appears to be related to the operative procedure. Infections are identified on original admission or upon readmission to the facility of original operative procedure within the relevant time frame (30 days for no implants; within 1 year for implants). The specifications for this proposed HAI measure can be found at *http://www.cdc.gov/nhsn/psc.html*.

We also believe that this measure meets the requirement under section 1833(t)(17)(C)(i) of the Act that measures selected for the Hospital OQR Program ''reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.'' This measure was NQF-endorsed in 2007 and was adopted by the Hospital Quality Alliance in 2008. We note that this measure also was adopted for the Hospital IQR Program beginning with the FY 2014 payment determination (75 FR 50211) and its adoption into the Hospital OQR Program would further our goal of aligning measures across programs where feasible.

We proposed that submission of data for this proposed NHSN measure for the CY 2014 payment determination would relate to infection events occurring between January 1, 2013 and June 30, 2013. We proposed that hospital outpatient departments use the existing NHSN infrastructure and protocols that already exist for this proposed measure to report it for Hospital OQR Program purposes. We invited public comment on our proposal to adopt this HAI measure into the Hospital OQR Program for the CY 2014 payment determination.

Comment: Some commenters stated it is inappropriate to include the surgical site infection measure in the Hospital OQR Program based on the measure's NQF endorsement status as an inpatient setting measure. The commenters noted that the measure is appropriate for the inpatient setting because the majority of patients stay in the hospital several days post-surgery. However, the commenters stated that, in the outpatient settings, patients are discharged within hours of surgery and potential outpatient surgery related infections may not have occurred until after discharge. Commenters cited the examples of colon surgery and abdominal hysterectomy, specified for reporting in the Hospital IQR Program, which are seldom performed in hospital outpatient settings.

Response: We agree that currently, the procedures included in the proposed surgical site infection measure do not represent a large number of procedures that are performed in hospital outpatient departments or in ASCs. Based on the public comments we received, we are not finalizing the surgical site infection measure for HOPDs for the CY 2014 payment determination at this time. We intend to re-propose the measure through future

[1] McKibben. L., Horan, T.: Guidance on public reporting of healthcare-associated infections: Recommendations of the Healthcare Infection Control Practices Advisory Committee. AJIC 2005; 33:217–26.

rulemaking once measurement and operational issues for HOPDs are resolved. We will continue to coordinate with the CDC and monitor efforts for adapting the surgical site infection measure to the outpatient setting, and will propose a surgical site infection measure for the Hospital OQR Program when a more suitable set of procedures has been defined for the outpatient setting.

Comment: A commenter contended that currently, less than half of the States required hospitals to report to NHSN. The commenter sought clarification on CMS' plan to collect data from facilities that do not currently report to NHSN. A commenter requested more detailed discussion of the NHSN validation process for HOPDs, such as what kind of sample list of patients that hospitals have to provide, and what format would be used.

Response: As of September 2011, 26 States have opted to use NHSN as the operational system for HAI reporting mandates in their State. As of January 1, 2011, subsection (d) hospitals participating in the Hospital IQR Program began submitting CLABSI data to the NHSN. At this time, we are not finalizing our adoption of the NHSN SSI measures for HOPDs for the CY 2014 payment determination. Should we require reporting through NHSN for this program in the future, facilities not currently participating in NHSN would need to enroll and submit data to NHSN in order to meet the requirements for the Hospital OQR Program. Also, in the event that a surgical site infection measure is implemented in the future through the NHSN, CMS and CDC will collaborate to develop a validation strategy for surgical site infection data.

Comment: Some commenters applauded the addition of the surgical site infection measure in recognition of the significant negative impact of HAIs on hospital patients. Commenters recommended that CMS adopt one to two of the NQF-endorsed CDC/NHSN outpatient surgical procedures initially and they encouraged the inclusion of more HAI measures in the Hospital OQR Program in the future. A commenter indicated that proposal of this measure aligns with The Joint Commission's National Patient Safety Goals.

Response: We thank the commenters for their support and encouragement for HAI measures. To advance the goals of the HHS Action Plan to Reduce HAIs in healthcare facilities, we will strive to include more HAI measures in the Hospital OQR Program as appropriate in the future. As explained above, we are not finalizing our proposal to adopt the NHSN HAI surgical site infection measure at this time. We intend to propose a surgical site infection measure at such time as a set of procedures more suitable for the outpatient setting is identified.

Comment: A commenter was skeptical about the CDC's system capability to handle the influx of NHSN measure data from the Hospital OQR and Hospital IQR Programs, as well as the quality reporting programs for ASCs, LTCHs and Inpatient Rehabilitation Facilities. A commenter noted that CDC is still conducting pilot testing of vendor capability to electronically transfer data.

Response: In preparation for the upcoming influx of data, CDC is adding capacity, both personnel and technical infrastructure, to support the additional use of NHSN. CDC is confident that these upgrades will enable the system to successfully accept data that is reported under our quality programs.

Comment: A commenter stated that some HOPDs could have high surgical site infection rates because they have adopted more comprehensive and sophisticated surveillance systems.

Response: Surveillance efforts may initially result in an increased number of infections being detected that previously may have gone undetected for all HOPDS's participating in the program, because they are now required to submit data for this measure. However, accurate measurement is necessary in order to assess meaningful improvements in outcomes. Accurate measurement of surgical site infections is dependent upon standardized data collection protocols for such things as post-procedure follow up and data validation programs that are consistent with already existing post-procedure protocols in HOPDs or that can be incorporated into those protocols where they need to be introduced. With initiation of this measure, all facilities will be submitting the same type of data using a standardized collection protocol, and therefore more comprehensive and sophisticated surveillance systems would not necessarily equate to a greater number of surgical site infections. In many ways those facilities with comprehensive and sophisticated surveillance systems may be at an advantage, relative to those without sophisticated surveillance systems, in the identification of surgical site infections earlier on.

Comment: A commenter noted that CDC is currently collaborating with surgical associations to develop and harmonize a more robust surgical site infection measure that would be consistent with the approaches and expertise of both organizations. Therefore, the commenter urged postponing the surgical site infection measure until the harmonization process is complete.

Response: The commenter is correct in that the CDC is currently working with the American College of Surgeons (ACS) to develop a harmonized surgical site infection measure. When a measure that is better suited for the HOPD setting is fully developed, we will re-propose the measure. As previously indicated, CMS is not finalizing the surgical site infection measure for HOPDs at this time.

After consideration of the public comments we received, we are not finalizing the surgical site infection measure that we proposed to adopt for Hospital OQR Program. We intend to re-propose the surgical site infection measure though future rulemaking once measurement and operational issues for HOPDs are resolved.

b. New Chart-Abstracted Measures for the CY 2014 Payment Determination

In the CY 2011 OPPS/ASC final rule with comment period, we stated that we would not finalize five proposed NQF-endorsed diabetes care measures because we were in the process of refining the chart-abstracted numerator definitions for these measures (75 FR 72091). We also stated that we intended to again propose to adopt these measures for the CY 2014 payment determination. In the CY 2012 OPPS/ASC proposed rule (76 FR 42317 through 42319), we proposed to adopt these five diabetes care measures for the CY 2014 payment determination as chart-abstracted measures. These five measures are: (1) Hemoglobin A1c Management (NQF #0059); (2) Diabetes Measure Pair: A. Lipid Management: Low Density Lipoprotein Cholesterol (LDL–C) < 130, B. Lipid Management: LDL–C < 100 (NQF #0064); (3) Diabetes: Blood Pressure Management (NQF #0061); (4) Diabetes: Eye Exam (NQF #0055); and (5) Diabetes: Urine Protein Screening (NQF #0062). We note that these five measures are electronically specified. We hope to be able to collect such information via EHRs in the future, and in the proposed rule we solicited comments on using EHR for data collection in the future. In addition, in the CY 2012 OPPS/ASC proposed rule (76 FR 42319 through 42320), we proposed to adopt a sixth new chart-abstracted measure, Cardiac Rehabilitation Patient Referral from an Outpatient Setting (NQF #0643), for the CY 2014 payment determination.

- Five Diabetes Care Measures

For detailed descriptions of the five diabetes care measures we proposed to

adopt for the Hospital OQR Program, please refer to the CY 2012 OPPS/ASC proposed rule (76 FR 42317 through 42319).

Comment: A few commenters supported the addition of the proposed chart-abstracted measures for the CY 2014 payment determination.

Response: We thank the commenters for their support of these measures. We believe they will help assess care provided to patients seen in hospital outpatient clinics for management of chronic conditions.

Comment: Many commenters noted that the proposed addition of six chart-abstracted measures in the Hospital OQR Program for the CY 2014 payment determination does not appear to be consistent with CMS' goal to reduce burden for providers. One commenter suggested that CMS provide per case abstraction time burden in the proposal. Commenters strongly recommended that no new chart-abstracted measures should be introduced while providers are in transition to ICD–10. Many commenters were very concerned about the burden from the proposed addition of chart-abstracted measures, in terms of staff training, coordination of data submission, data quality checks, and staff resources. Commenters recommended delaying the implementation of the proposed chart-abstracted measures to the CY 2015 payment determination as the target date. Other commenters suggested that we delay the implementation for these chart-abstracted measures until NQF finishes retooling and testing the related specifications, and EHR technology can facilitate electronic data transmission.

Response: We are aware of the burden that HOPDs would face if we finalized all of the proposed chart-abstracted measures, as well as the challenges that providers may face as they adopt ICD–10. Based upon consideration of the public comments we received regarding this burden and the need to further specify these diabetes care measures for the hospital outpatient setting, we have decided not to finalize the 5 proposed diabetes care measures at this time. We intend to further refine the measures for use in the hospital outpatient setting and re-propose these measures at a future date when the denominators and numerators are more refined for the HOPD setting and they would be less burdensome for HOPDs to implement.

Comment: Many commenters strongly supported the diabetes care measure set and believed it would improve quality of care for diabetic patients with co-morbidities. However, these commenters were very concerned that data collection may be overwhelming without a clear definition of the target patient population. Commenters asserted that CMS needs to provide more precise specifications to identify the appropriate patient population inclusions and exclusions for these measures. The commenters explained that many patients that visited hospital outpatient departments do so to receive diagnostic reports, lab work, and treatments ordered by their primary care physicians. Therefore, these commenters believed that hospitals that do not have diabetes clinics should be held accountable for outpatients' diabetes lab work ordered by primary care physicians practice outside the hospital outpatient setting. Some commenters opposed the diabetes care measure set and believed they would be better suited for the PQRS Program where patients are being followed on a long-term basis whereas much of the care in the HOPD setting is episodic or even fragmented. One commenter recommended that CMS use data being submitted by HOPDs to diabetes registries instead of collecting data.

Response: Diabetes is prevalent in the Medicare population, and many patients with diabetes receive ongoing evaluation management services in hospital outpatient department clinics. These diabetes measures align with measures which are also currently in use in the PQRS and HITECH EHR Incentive Program. We also believe that both the facility and the affiliated physician(s) play a role in ensuring that their patients received quality and coordinated care. We thank the commenter for the suggestion of using registries. Based upon consideration of the public comment regarding the burden and the need to further specify these measures for the hospital outpatient setting, we have decided not to finalize these 5 diabetes care measures at this time.

Comment: A few commenters provided suggestions to modify the diabetes care measure specifications to: (1) Limit the denominator population to capture only primary care provider-based clinics that are under the OPPS system; (2) incorporate electronic lab data; (3) evaluate the appropriateness of using CPT-category II codes (not currently used in OPPS billing) or a corresponding algorithm to convey quality data codes; (4) use NPI specialty numbers to track associated clinics responsible for the diabetes care measures; and (5) include at least a minimum number of visits per patient before a patient would be included in the denominator.

Response: We thank the commenters for the valuable suggestions and will take them into consideration in refinement of the measures for the hospital outpatient setting.

After consideration of the public comment regarding burden and the need to further specify these measures for the hospital outpatient setting, we have decided not to finalize these 5 diabetes care measures at this time. We intend to further refine the measures for use in the hospital outpatient setting and re-propose these measures at a future date.

Cardiac Rehabilitation Measure: Patient Referral From an Outpatient Setting (NQF #0643)

Cardiac rehabilitation improves the quality of life, reduces modifiable cardiovascular risk factors, enhances adherence to preventable medications, and lowers morbidity and mortality.[2] Despite these benefits, cardiac rehabilitation is significantly underused by patients with heart disease and there is significant geographical variation in referral rates and lower use in women, non-whites, older patients and patients on Medicaid.[3] A recent study of Medicare beneficiaries, using 70,040 matched pairs of patients hospitalized for coronary conditions or revascularization procedures, found that mortality rates were 21 percent to 34 percent lower in cardiac rehabilitation users compared to nonusers.[4] Evidence from registries which include a cardiac rehabilitation performance measure indicated that only about 18 percent of eligible patients were referred to cardiac rehabilitation.[5] Under our regulations, 42 CFR 410.49, cardiac rehabilitation is covered for patients who have had one or more of the following: An acute myocardial infarction within the preceding 12 months, current stable angina, individuals who have undergone coronary bypass surgery, a percutaneous coronary intervention or coronary stenting, heart valve repair or replacement, or a heart-lung transplant.

In May 2010, the NQF endorsed two cardiac rehabilitation referral performance measures as part of the call

[2] Wenger, N.K.: Current status of cardiac rehabilitation. J. Am Coll Cardiol 2008; 51:1619–1631.

[3] Suaya, J.A., Shepard, D.S., Normand, S.L., *et al.:* Use of cardiac rehabilitation by Medicare beneficiaries after myocardial infarction or coronary bypass surgery. Circulation. 2007;116:1653–62.

[4] Suaya, J.A., Stason, W.B., Ades, P.A., *et al.:* Cardiac rehabilitation and survival in older coronary patients. J. Am Coll Cardiol. 2009;54:25–33.

[5] Chan, P.S., Oetgen, W.J., Buchanan, D., Mitchell, K. *et al.:* Cardiac performance measure compliance on outpatients: The American College of cardiology and National Cardiovascular data registry's PINNACLE (Practice Innovation and Clinical Excellence) program. J. Am Coll Cardiol 2010 56(1) 8–14).

for care coordination performance measures. These measures are: (1) Cardiac Rehabilitation: Patient Referral From an Inpatient Setting (NQF #0642). The percentage of patients admitted to the hospital with a qualifying cardiovascular disease (CVD) event who are referred to an early outpatient cardiac rehabilitation/secondary prevention program; and (2) Cardiac Rehabilitation: Patient Referral From an Outpatient Setting (NQF #0643)—The percentage of patients evaluated in an outpatient setting who in the previous 12 months experienced an acute myocardial infarction or chronic stable angina or who have undergone coronary artery bypass (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery (CVS), or cardiac transplantation who have not already participated in an early outpatient cardiac rehabilitation/ secondary prevention program for the qualifying event and who are referred to an early outpatient cardiac rehabilitation/secondary prevention program unless there is a documented medical or patient oriented reason why a referral was not made. We proposed to adopt the second (NQF #0643) of these measures for the CY 2014 Hospital OQR Program. The measure specifications are located in Appendix A (Pages A4 and A5) of the 2010 NQF consensus report entitled '' Preferred Practices and Performance Measures for Measuring and Reporting Care Coordination'' which is available at the following link: *http://www.qualityforum.org/Publications/2010/10/Preferred_Practices_and_Performance_Measures_for_Measuring_and_Reporting_Care_Coordination.aspx.*

This proposed measure targets patients who have experienced a qualifying cardiovascular event. These patients are commonly seen in hospital outpatient departments and, for this reason, we believe that the proposed measure is appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings as required under section 1833(t)(17)(C)(i) of the Act. The measure also is NQF-endorsed, and therefore meets the requirement that measures selected for the program ''reflect consensus among affected parties and, to the extent feasible and practicable, that these measures include measures set forth by one or more national consensus building entities'' under section 1833(t)(17)(C)(i) of the Act.

We proposed to adopt the NQF-endorsed Cardiac Rehabilitation Patient Referral from an Outpatient Setting measure for CY 2014 payment determination. The goal of this measure is to improve the delivery of cardiac care in order to reduce cardiovascular mortality and morbidity and optimize the health of patients suffering from CVD.

In the proposed rule we invited public comment on this proposed measure.

Comment: Many commenters were very supportive of the cardiac rehabilitation referral measure which they believed would encourage hospitals to take responsibility for patient care beyond the cardiovascular interventions. Commenters stated that facilities with electronic patient management systems would generate more physician referrals to cardiac rehabilitation. A commenter recommended that the measure should be included in the Hospital IQR Program as well so that the continuity of care for cardiovascular events can be better enhanced. A commenter alerted CMS that some registries already integrate both the inpatient and outpatient cardiac referral measures in their systems to collect data.

Response: We thank the commenters for the support. We agree that a similar measure in the hospital inpatient setting would be beneficial from a continuity of care perspective and we thank the commenter for the suggestion which we will consider in future Hospital IQR Program rulemaking.

Comment: Some commenters did not support this measure for various reasons. A commenter did not see the reason for hospitals to report this measure because presumably, the cardiologist in the cardiac clinic would be reporting this measure. Furthermore, the commenter stated the calculation of the percentage of patients evaluated in an outpatient setting who in the previous 12 months experienced a major cardiac event, such as heart attack, and received treatment for the event in an outpatient setting would be very burdensome. The commenter believed that only highly integrated care system with well-structured coordination like Accountable Care Organizations (ACOs) or comprehensive medical homes have the capability to compile the data needed for this measure.

Response: We understand that a cardiologist, who works in a cardiology clinic for a hospital outpatient department, may report cardiac rehabilitation referral to other reporting programs. However, we continue to believe that the measure is valuable because it encourages HOPDs to coordinate the care that their patients receive. We want to clarify that Cardiac Rehabilitation: Patient Referral From an Outpatient Setting (NQF #0643) measures the percentage of patients evaluated in an outpatient setting who, in the previous 12 months, experienced a qualifying cardiovascular event (which is defined in the NQF-endorsed measure specifications). Hospital outpatient departments are not required under the measure specifications to track whether these patients were actually following the qualifying cardiovascular event in the last 12 months. The measure focuses on the process of referring a patient to a cardiac rehabilitation or secondary prevention program. The NQF measure specification for this measure available at the link above includes the definition of a referral as ''an official communication between the healthcare provider and the patient to recommend and carry out a referral order to an early outpatient cardiac rehabilitation program.'' This includes the provision of all necessary information to the patient that would allow the patient to enroll in an early outpatient cardiac rehabilitation program. This also includes written or electronic communication between the healthcare provider or healthcare system and the cardiac rehabilitation program that includes the patient's enrollment information for the program.

Comment: A commenter believed that this measure would be very challenging and burdensome for a safety net hospital, because such a hospital usually does not have an affiliation with a cardiac rehabilitation facility, to collect patient data, since its patients do not visit the hospital on a regular basis. Another commenter viewed this measure as merely reporting whether a referral was made without regard to whether the patient ultimately could access or actually received cardiac rehabilitation services. Therefore, the commenter did not see the tie of this measure to quality improvement.

Response: We recognize that this measure does not focus on whether the patient actually enrolls in a cardiac rehabilitation or secondary prevention program. The measure focuses on the process of referring a patient to a cardiac rehabilitation or secondary prevention program. We believe that care coordination processes such as this are an indicator of high quality of care delivered to HOPD patients by hospitals including safety net hospitals.

Comment: A commenter urged delaying implementation of this measure until it is e-specified and can be reported via EHRs.

Response: We do not believe we should delay the implementation of this measure given its beneficial impact on

patient care. We thank the commenter for the input for e-measure specification and we will take this into consideration in our e-measure development.

After consideration of the public comments we received, we are finalizing the chart-abstracted Cardiac Rehabilitation Measure: Cardiac Rehabilitation Patient Referral from an Outpatient Setting measure for CY 2014 payment determination. The data collection requirements for this measure are detailed in the ''Form, Manner, and Timing'' section of this final rule with comment period.

c. New Structural Measures

In the CY 2012 OPPS/ASC proposed rule (76 FR 42320 through 42323), for the CY 2014 payment determination, we proposed to add two structural measures: (1) Safe Surgery Checklist Use; and (2) Hospital Outpatient Volume for Selected Outpatient Surgical Procedures. In general, structural measures assess the characteristics and capacity of the provider to deliver quality health care.

(1) Safe Surgery Checklist Use Measure

This proposed structural measure assesses whether a hospital outpatient department utilizes a Safe Surgery checklist that assesses whether effective communication and safe practices are performed during three distinct perioperative periods: (1) The period prior to the administration of anesthesia; (2) the period prior to skin incision; and (3) the period of closure of incision and prior to the patient leaving the operating room. The use of such checklists has been credited with dramatic decreases in preventable harm, complications and post-surgical mortality [6]. In November 2010, the New England Journal of Medicine (NEJM) published a study concluding that surgical complications were reduced by one-third, and mortality by nearly half, when a safe surgery checklist was used.[7]

We believe that effective communication and the use of safe surgical practices during surgical procedures will significantly reduce preventable surgical deaths and complications. For example, mistakes in surgery can be prevented by ensuring that the correct surgery is performed on the correct patient and at the correct place on the patient's body.[8] A safe surgery checklist would also reduce the potential for human error, which we believe would increase the safety of the surgical environment.

The safe surgery checklists of which we are aware typically include safe surgery practices corresponding to three critical perioperative periods: The period prior to the administration of anesthesia, the period prior to skin incision, and the period of closure of incision and prior to the patient leaving the operating room. Some examples of safe surgery practices that can be performed during each of these three perioperative periods are shown in the table below:

First critical point (period prior to administering anesthesia)	Second critical point (period prior to skin incision)	Third critical point (period of closure of incision and prior to patient leaving the operating room)
• Verbal confirmation of patient identity • Mark surgical site • Check anesthesia machine/medication • Assessment of allergies, airway and aspiration risk	• Confirm surgical team members and roles • Confirm patient identity, procedure, and surgical incision site • Administration of antibiotic prophylaxis within 60 minutes before incision • Communication among surgical team members of anticipated critical events • Display of essential imaging as appropriate	• Confirm the procedure • Complete count of surgical instruments and accessories • Identify key patient concerns for recovery and management of the patient

One example of a checklist that lists safe surgery practices during each of these three perioperative periods is the World Health Organization Surgical Safety Checklist, which was adopted by The World Federation of Societies of Anesthesiologists as an international standard of practice. This checklist can be found at: *http://www.who.int/*

[6] Haynes, A.B.; Weiser, T.G.; Berry, W.G. *et. al* (2009). ''A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population.''. New England Journal of Medicine. 360: 491–499.

[7] de Vries EN, Prins HA, Crolla RMPH, *et al.* Effect of a comprehensive surgical safety system on patient outcomes. N Engl J Med 2010;363: 1928–37

[8] Hospital National Patient Safety Goals. The Joint Commission Accreditation Hospital Manual, 2011. *http://www.jointcommission.org/standards_information/npsgs.aspx*

patientsafety/safesurgery/ss_checklist/en/index.html. The adoption of a structural measure that assesses Safe Surgery Checklist use would align our patient safety initiatives with those of several surgical specialty societies including: The American College of Surgeons' Nora Institute for Patient Safety, the American Society of Anesthesiologists, TJC, the National Association for Healthcare Quality and the Association of periOperative Registered Nurses (AORN). For this proposed structural measure, a hospital outpatient department would indicate whether or not it uses a safe surgery checklist for its surgical procedures that includes safe surgery practices during each of the three critical perioperative periods discussed above. The measure would assess whether the hospital uses a safe surgery checklist in the hospital outpatient department for surgical procedures, but would not require a hospital to report whether it uses a checklist in connection with any individual outpatient procedures.

The proposed Safe Surgery Checklist structural measure is not NQF-endorsed. However, we believe that consensus among affected parties can be reflected through means other than NQF endorsement including: Consensus achieved during the measure development process; consensus shown through broad acceptance and use of measures; and consensus through public comment. The proposed safe surgery checklist measure assesses the adoption of a best practice for surgical care that is broadly accepted and in widespread use among affected parties. In addition to being adopted by The World Federal of Societies of Anesthesiologists, the use of a safe surgery checklist is one of the safe surgery principles endorsed by the Council on Surgical and Perioperative Safety, which is comprised of the American Association of Nurse Anesthetists, American College of Surgeons, American Association of Surgical Physician Assistants, American Society of Anesthesiologists, American Society of PeriAnesthesia Nurses, AORN, and Association of Surgical Technologists. Two State agencies (Oregon, South Carolina), the Veterans Health Administration,[9] numerous hospital systems, State hospital associations (such as California, and South Carolina), national accrediting organizations and large private insurers have endorsed the use of a safe surgery checklist as a best practice for reducing morbidity, mortality, and medical errors.[10] [11] Because the use of a safe surgery checklist is a widely accepted best practice for surgical care, we believe that the proposed structural measure of Safe Surgery Checklist use reflects consensus among affected parties. We also note that TJC included safe surgery checklist practices among those to be used to achieve National Patient Safety Goals (NPSGs) adopted for 2011 for surgeries performed in ambulatory settings and hospitals.

For the CY 2014 payment determination, we proposed that data collection for this structural measure for hospital outpatient departments will be from July 1, 2013 through August 15, 2013 for the time period January 1, 2012 through December 31, 2012. These data will be collected via a Web-based tool available on the QualityNet Web site that is currently employed for the collection of structural measures for the Hospital IQR Program and the Hospital OQR Program. In the proposed rule we invited public comments on our proposal to add this new structural measure to the CY 2014 Hospital OQR Program measure set.

Comment: Many commenters supported the measure and were pleased that CMS cited the WHO's Surgical Safety Checklist as a reference. A commenter recommended incorporating the WHO's Surgical Safety Checklist as an Appendix in the Specifications Manual. A few commenters commended CMS' efforts to align the Safe Surgery Checklist measure in both hospital outpatient departments and ASCs to ensure quality of care across settings. Some commenters suggested that CMS adopt the measure in the hospital inpatient setting.

Some commenters appreciated the flexibility provided under the measure that would allow facilities to develop a safe surgery checklist based on their own needs and populations served. A commenter noted that a mandated specific checklist may interfere with the ability to rapidly implement new evidence-based processes. A commenter requested finalization of a generic checklist(s) that is acceptable to have data elements contained in more than one form (for example, intra-operative record, anesthesia record, etc.) as appropriate.

Response: We appreciate the support for the measure designed to assess the adoption of a best practice for surgical care to reduce preventable medical errors and mortality while giving HOPDs the flexibility to develop their own checklist that meets their needs. We chose not to finalize any specific checklist but will consider providing links to specific examples of Surgical Safety Checklists as an Appendix in the Specifications Manual as recommended by the commenter. We have proposed the same measure for ASC Quality Reporting Program and will consider its inclusion in the Hospital IQR Program, as suggested by the commenters, in the future.

Comment: Some commenters recommended that after implementation, CMS should evaluate the appropriate implementation and utilization of the use of the safe surgery checklist by providers as indicated in this measure. Commenters were concerned that the use of a surgical checklist may result in a documentation task which does not result in the improved delivery of care for which the checklist is intended.

Response: We agree with the commenters that the use of a safe surgery checklist as indicated in this measure should be implemented appropriately to achieve improved delivery rather than just create additional documentation. The use of a checklist is intended to help prevent serious medical errors involving surgical care such as anesthesia dosing errors and allergic reactions, wrong site surgery, wrong procedure or wrong patient surgery, and the retention of foreign objects in the body. During our measure maintenance process, we will review the improvement potential for this measure, like all the measures we adopted for the Hospital OQR Program, for indication of best practices, among other review criteria.

Comment: A commenter suggested that this measure should only apply to surgeries performed in an operating room setting because many hospital outpatient departments perform procedures (for example, prostate biopsy, PEG replacement, endoscopy, etc.) in procedure units where safe surgery checklist is not used routinely in procedure units.

Response: This measure applies to any facility where a surgery or other invasive procedures occurs rather than to specific surgical procedures performed in a HOPD or individual surgical patients. Therefore exclusions of this nature are not needed.

Comment: A few commenters asserted that the proposal is only a concept and

[9] Neily, J; Mills, PD, Young-Xu, Y. (2010). ''Association between implementation of a Medical Team Training Program and Surgical Mortality''. JAMA. 304 (15): 1693–1700.

[10] Haynes, AB; Weiser, TG; Berry, WR *et al.* (2009) ''A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population''. NEJM. 360:491–499.

[11] Birkmeyer, JD (2010) ''Strategies for Improving Surgical Quality—Checklists and Beyond.'' NEJM. 363: 1963–1965.

that it is not fully developed or NQF-endorsed. Additionally, one commenter noted that the introduction of this measure would create an undue burden on hospitals because Medicare National Coverage Determinations already specify no Medicare reimbursement for any adverse event from any aspects of a surgery. Furthermore, The Joint Commission surveys all accredited institutions for surgery checklists as part of its patient safety requirements. A few commenters urged CMS to seek NQF endorsement. Another commenter was skeptical that the proposed Safe Surgery Checklist attestation could be validated by CMS and therefore, does not warrant consideration as a structural measure. A commenter viewed that the managing of the processes around surgical care is what improves quality of care, not the mere use of a checklist.

Response: We disagree that this measure is only a concept and not a measure because it highlights critical elements that HOPDs could include in their checklist to avoid preventable medical errors. We believe the Safe Surgery Checklist complements the management of surgical care processes and ultimately contributes to better patient outcomes by increasing safe surgery practices and by reducing preventable human error, and minimizing complications and post-surgical mortality. To that end, we believe it warrants inclusion in the Hospital OQR Program. At this time we have not proposed to validate this measure.

We note that even though this measure is not NQF-endorsed, as we had indicated in the proposed rule, the measure reflects significant consensus among affected parties. As stated in the CY 2012 OPPS/ASC proposed rule (76 FR 42321), the adoption of this structural measure would align our patient safety initiatives with those of several surgical specialty societies including: The American College of Surgeons' Nora Institute for Patient Safety, the American Society of Anesthesiologists, TJC, the National Association for Healthcare Quality and the Association of PeriOperative Registered Nurses (AORN). Furthermore, consensus for this measure was reflected through broad acceptance and the use of measures. In addition to being adopted by the World Federation of Societies of Anesthesiologists, the use of a safe surgery checklist is one of the safe surgery principles endorsed by the Council on Surgical and Perioperative Safety. Some State agencies, State hospital associations, accrediting organizations, and the Veterans Health Administration also have endorsed the use of a safe surgery checklist as a best practice.

Although most of the measures we have adopted for the Hospital OQR Program are NQF-endorsed and we prefer to select NQF-endorsed measures for the Hospital OQR Program whenever possible, we are not required to adopt only NQF-endorsed measures for the Hospital OQR Program. We will take the comment regarding seeking endorsement of this measure under consideration.

Comment: A commenter supported the proposed Web-based tool to submit data as it was perceived as least burdensome. One commenter indicted that additional operational details of the Web-based tool should be provided, such as specification of the file format for data submission, given that the formats submitted to the QualityNet warehouse and to Medicare billing (claims data) are different.

Response: We thank the commenter, and agree that this collection method places minimal burden on HOPDs. The Web-based tool will not require uploading files to QualityNet, rather it will require entry of responses directly into a Web form. Details regarding submission deadlines are provided in the ''Form, Manner and Timing'' section of the program requirements included in this final rule with comment period.

After consideration of the public comments we received, we are finalizing the Safe Surgery Checklist Use measure for the CY 2014 payment determination. Data collection and submission requirements are shown in the ''Form, Manner and Timing'' section of the Hospital OQR Program requirements contained in this final rule.

(2) Hospital Outpatient Department Volume for Selected Outpatient Surgical Procedures Measure

There is substantial evidence in recent peer-reviewed clinical literature that volume of surgical procedures, particularly of high risk surgical procedures, is related to better patient outcomes, including decreased surgical errors and mortality.[12, 13, 14] This may be attributable to greater experience and/or surgical skill, greater comfort with and, hence, likelihood of application of standardized best practices, and increased experience in monitoring and management of surgical patients for the particular procedure. For this reason, the National Quality Forum has previously endorsed measures of total all-patient surgical volume for Isolated CABG and Valve Surgeries (NQF #0124), Percutaneous Coronary Intervention (PCI) (NQF #0165), Pediatric Heart Surgery (NQF #0340), Abdominal Aortic Aneurism Repair (NQF #357), Esophageal Resection (#0361), and Pancreatic Resection (NQF #0366). Additionally, many consumer-oriented Web sites that display health care quality information required to be reported under State law (California, New York, Texas, Washington, Florida, Illinois, Michigan, Oregon) and private organizations (Leapfrog Group, U.S. News & World Report) are reporting procedure volume, in addition to provider performance on surgical process (SCIP measures) and outcome measures (surgical site infection, Patient Safety Indicators, and Mortality), in order to provide more context to consumers choosing a health care provider. The current NQF-endorsed measures of procedure volume (noted above) relate to surgeries performed only in inpatient settings, and would not be applicable to the types of procedures approved to be performed in HOPDs and ASCs.

The table below, which shows the proportion of procedures during CY 2010 performed in hospital outpatient departments stratified by broad categories, reveals that most hospital outpatient procedures (99 percent) fall into one of 8 categories: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, and Skin.

[12] Livingston, E.H.; Cao, J ''Procedure Volume as a Predictor of Surgical Outcomes''. Edward H. Livingston, Jing Cao JAMA. 2010;304(1):95–97.

[13] David R. Flum, D.R.; Salem, L.; Elrod, J.B.; Dellinger, E.P.; Cheadle, A. Chan, L. ''Early Procedure Volume on Outcomes Following Surgery for Colon Cancer'' *JAMA. 2000; 284 (23): 3028–3035.* Maltezou, H.C., Drancourt, M.: Nosocomial influenza in children. Journal of Hospital Infection 2003; 55:83–91.

[14] Schrag, D; Cramer, L.D.; Bach, P.B.; Cohen, A.M.; Warren, J.L.; Begg, C.B '' Influence of Hospital Mortality Among Medicare Beneficiaries Undergoing Bariatric Surgical Procedures''. *JAMA. 2005;294(15):1903–1908.*

CY 2010 Hospital Outpatient Data	
Procedure Category	**% of Total Services**
Cardiovascular	75.50%
Chest	0.00%
Ear	0.20%
Endocrine	0.10%
Eye	1.70%
Gastrointestinal	5.70%
Genitourinary	2.70%
Hemic & Lymphatic	0.30%
Maternity	0.00%
Musculoskeletal	3.80%
Nervous System	2.80%
Radiology	0.10%
Respiratory	1.00%
Skin	6.20%
Total	100.00%

Because surgical volume is associated with better quality, and surgical procedures are performed in hospital outpatient departments, we believe that surgical volume is appropriate for measuring the quality of these eight categories of surgical procedures performed in an HOPD. For the CY 2014 payment determination, we proposed that HOPDs would report all-patient volume data with respect to these eight categories between the dates July 1, 2013 and August 15, 2013 with respect to the time period January 1, 2012 through December 31, 2012. In other words, under this proposal, an HOPD would report its CY 2012 all-patient volume data for these eight categories of procedures during the 45 day window of July 1, 2013 to August 15, 2013. The table below lists the specific HCPCS codes for each of the 8 procedure categories for which hospitals would be required to report the all-patient volume data. Like the other structural measures in the Hospital OQR Program, data on this proposed measure would be collected via an online Web-based tool that will be made available to HOPDs via the QualityNet Web site.

In the proposed rule we invited public comment on this proposal.

Comment: A few commenters agreed that surgical volume can be associated with quality but recommended that the volume data should always be linked to the corresponding surgical procedures and not the type of broad procedure categories as proposed. The commenters asserted that the measure as proposed without associated information on outcomes or patient-reported assessment of care may have the potential to mislead patients and Medicare about the care that providers delivered. Another commenter requested that CMS provide data that indicate a correlation between all-payer data and Medicare-specific data related to outpatient procedure volumes. A commenter requested a snapshot of how the surgical procedures volume data would be displayed on the *Hospital Compare* Web site.

Some commenters opposed the inclusion of the hospital outpatient volume for selected outpatient surgical procedures measure because of concerns regarding the categories and because of concerns regarding CPT codes. Some commenters stated that the proposed procedures are broad based categories. The commenter stated that without an associated list of individual CPT codes or families of CPT codes for these proposed surgical procedures, it would be difficult to differentiate volume variations for different procedures within the broad surgical procedure categories. Therefore, the broad-based surgical procedure volume information may be misinterpreted as overall indicator of quality for these particular services. The commenters urged CMS to provide the measure specifications for the public to review and comment prior to implementation.

Response: We appreciate the commenters' input on selected surgical categories and CPT codes. As discussed in the proposed rule, our goal for this measure is to provide consumers with useful information on surgical procedure volume in order to assist patients in making informed healthcare decisions. Based on the public comment received suggesting that the eight broad categories will not be meaningful to consumers, we will further identify groupings of key procedure types within the 8 broad categories so that they will be more meaningful to consumers. We will include these refinements in the specifications for the measure that will be in an upcoming release of the Hospital OQR Specifications Manual.

Comment: Some commenters recommended less burdensome alternatives to implement this measure as follows: (1) Implement it as a claims-based measure using the HCPCS codes or CPT codes for hospitals to count numerators and denominators; (2) place it in the HITECH EHR Incentive Program as one of the meaningful use objectives; (3) reduce the number of categories; (4) expand the submission window beyond the proposed 45-day

timeframe; (5) only collect information on the most frequently performed outpatient surgeries for all patients and for Medicare patients rather than the collection of surgical volume by body system category; or (6) use a structural measure to assess whether hospitals participate in a surgical outcomes registry to build the evidence base in this area (that is, linking high volume to better outcomes).

Response: We thank the commenters for these suggestions. This information will be submitted in aggregate counts once annually and the counts can be generated by the HOPD using administrative data that is already being collected by the HOPD in order to obtain payment for the services they render. As a result, we do not believe it would be overly burdensome for hospitals to submit this information based on all-patient data. Currently, we use a standard 45-day collection window for all of the structural measures. As previously indicated based on public comment, we will further group procedure types within the 8 broad categories so that they are more meaningful to consumers. We will include these refinements in the specifications for the measure that will be in an upcoming release of the Hospital OQR Specifications Manual.

Comment: A commenter stated that it is imperative that the volume of procedures be compared to the number of physicians performing such procedures at the facility level. The commenter stated the quality implication of a hospital reporting 1,000 procedures in a category with 50 physicians is very different from a hospital reporting 1,000 procedures with 500 physicians.

Response: We do not have information about the volume of physicians performing the procedures within each facility and did not propose to collect such information from facilities in this year's rule. We will consider this comment, as well as the feasibility and burden of HOPDs reporting this information, for future rules.

Comment: Some commenters did not support this measure based on the assertion that the measure is not NQF-endorsed, not approved by HQA, not evidence-based, not a quality measure, and does not meet The Joint Commission definition of an accountability measure. Furthermore, the commenters stated that the data are already available on many State-supported or hospital-specific Web sites, and registries. In addition, some commenters believed that data collection for this measure would create tremendous burden if the population include all patients and not just Medicare patients.

A commenter contended that the proposed measure is only a crude measurement tool to monitor surgical volume. A few commenters noted that there is a lack of evidence linking volume of surgical procedure performed in HOPDs or ASCs to quality, notwithstanding the non-HOPD- or ASC-specific literature linking volume of specific high-risk procedures to outcomes cited by CMS.

Response: We do not agree with the comments regarding the suitability of this measure. As we indicated in the proposed rule, we believe that this measure reflects significant consensus among affected parties because of evidence in the peer-reviewed literature and because this type of information is frequently displayed on consumer-oriented Web sites that feature quality information.

We do not believe that all-patient volume is burdensome to report, as hospitals could use data to generate the aggregate counts that they would submit once annually. In the Specifications Manual, we will include further reporting instructions if hospitals do not perform certain procedures.

We disagree with the concern expressed regarding the inpatient focus of the literature we cited. We believe that this literature is also relevant to HOPDs. We note that the number of Medicare-certified HOPDs has increased dramatically over the years. In addition, an increasing number of procedures that were formerly performed primarily in the inpatient setting are now being performed in outpatient settings such as HOPDs and ASCs. We believe that this growth in HOPDs and procedures performed in HOPDs underscores the importance of providing a context for beneficiaries to assess the number of selected procedures performed annually by any given HOPD.

Comment: Several commenters asked CMS to identify which procedures are considered high risk in HOPDs and ASCs. According to the commenters, high-risk procedures are generally not performed in HOPDs or ASCs.

Response: We disagree with this comment. High risk procedures are performed in HOPD facilities. For example, in 2010 there were more than 25,000 arterial transposition procedures and more than 31,000 endovascular repairs of the aorta and its branches performed in HOPDs. Further, there are risks associated with all surgical procedures, and we believe that the more often a surgery is performed in a HOPD, the greater the incentive for the HOPD to implement standardized practices that can minimize these risks. At this time, a greater number and types of surgery are being performed in HOPDs and other outpatient settings. By collecting volume of procedures, we will be able to provide information about whether facilities perform a specific procedure type, and how many per year. This information is crucial for consumers trying to make informed decisions about where to have surgery performed. Based on commenters' suggestions, we will further define key procedure types within each of the 8 broad categories in the Hospital OQR Specifications Manual so that the information will be more useful to consumers.

After consideration of the public comments we received, we are finalizing the Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures measure for the Hospital OQR Program CY 2014 payment determination. In response to concerns regarding the utility of the 8 broadly specified categories to consumers, we will further identify key procedure types within each of the 8 broad categories for hospitals to report.

In summary, in addition to the 23 measures we previously adopted for the CY 2014 payment determination in the CY 2011 OPPS/ASC final rule with comment period, we are finalizing 1 new chart-abstracted measure and 2 new structural measures. The complete measure set (26 measures) for the Hospital OQR Program CY 2014 payment determination, including the measures we adopted in the CY 2011 OPPS/ASC final rule with comment period, is set out in the table below.

BILLING CODE 4120–01–P

CY 2014 Hospital OQR Program Measure Set Reflecting Measures Previously Adopted and the Addition of 1 Chart-Abstracted Measure, and 2 Structural Measures
OP-1: Median Time to Fibrinolysis
OP-2: Fibrinolytic Therapy Received Within 30 Minutes
OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
OP-4: Aspirin at Arrival
OP-5: Median Time to ECG
OP-6: Timing of Antibiotic Prophylaxis
OP-7: Prophylactic Antibiotic Selection for Surgical Patients
OP-8: MRI Lumbar Spine for Low Back Pain
OP-9: Mammography Follow-up Rates
OP-10: Abdomen CT – Use of Contrast Material
OP-11: Thorax CT – Use of Contrast Material
OP-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data*
OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non Cardiac Low Risk Surgery *
OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)*
OP-15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache*
OP-16: Troponin Results for Emergency Department acute myocardial infarction (AMI) patients or chest pain patients (with Probable Cardiac Chest Pain) Received Within 60 minutes of Arrival **
OP-17: Tracking Clinical Results between Visits**
OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients**
OP-19: Transition Record with Specified Elements Received by Discharged Patients**
OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional**
OP-21: ED- Median Time to Pain Management for Long Bone Fracture **
OP-22: ED Patient Left Without Being Seen**
OP-23: ED- Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 minutes of Arrival **
OP-24: Cardiac Rehabilitation Patient Referral From an Outpatient Setting ***
OP-25: Safe Surgery Checklist Use***
OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures***

CY 2014 Hospital OQR Program Measure Set Reflecting Measures Previously Adopted and the Addition of 1 Chart-Abstracted Measure, and 2 Structural Measures

Procedure Category	Corresponding HCPCS Codes
Gastrointestinal	40000 through 49999, G0104, G0105,G0121,C9716, C9724, C9725, 0170T
Eye	65000 through 68999, G0186, 0124T, 0099T, 0017T, 0016T, 0123T, 0100T, 0176T, 0177T, 0186T, 0190T, 0191T, 0192T, 76510, 0099T
Nervous System	61000 through 64999, G0260, 0027T, 0213T, 0214T, 0215T, 0216T, 0217T, 0218T, 0062T
Musculoskeletal	20000 through 29999, 0101T, 0102T, 0062T, 0200T, 0201T
Skin	10000 through 19999, G0247, 0046T, 0268T, G0127, C9726, C9727
Genitourinary	50000 through 58999, 0193T, 58805
Cardiovascular	33000 through 37999
Respiratory	30000 through 32999

* New measure for the CY 2012 payment determination.

** New measure for the CY 2013 payment determination.

*** New measure for the CY 2014 payment determination.

BILLING CODE 4120–01–C

3. Hospital OQR Program Measures for the CY 2015 Payment Determination

a. Retention of CY 2014 Hospital OQR Measures for the CY 2015 Payment Determination

In general, unless otherwise specified, we retain measures from one payment determination to the next. Accordingly, in the CY 2012 OPPS/ASC proposed rule (76 FR 42323), we proposed that all of the measures we finalize for the CY 2014 payment determination continue to be used for the CY 2015 payment determination. We invited public comment on this proposal.

We did not receive any comments objecting to the retention of CY 2014 Hospital OQR Measures for the CY 2015 payment determination. Therefore, we are finalizing the retention of the 26 measures finalized for the CY 2014 payment determination for the CY 2015 payment determination.

b. Proposed NHSN HAI Measure for the CY 2015 Payment Determination

In the CY 2012 OPPS/ASC proposed rule (76 FR 42323 through 42324), for the measure set to be used for the CY 2015 payment determination, we proposed to adopt an additional HAI measure entitled Influenza Vaccination Coverage among Healthcare Personnel (HCP) (NQF #0431). This measure is currently collected by the CDC via the NHSN.

Rates of serious illness and death resulting from influenza and its complications are increased in high-risk populations such as persons over 50 years or under four years of age, and persons of any age who have underlying conditions that put them at an increased risk. HCP can acquire influenza from patients and can transmit influenza to patients and other HCP. Many HCP provide care for, or are in frequent contact with, patients with influenza or patients at high risk for complications of influenza. The involvement of HCP in influenza transmission has been a long-standing concern.[15] [16] [17]

Vaccination is an effective preventive measure against influenza, and can prevent many illnesses, deaths, and losses in productivity.[18] HCP are considered a high priority for expanding influenza vaccine use. Achieving and sustaining high influenza vaccination coverage among HCP is intended to help protect HCP and their patients and reduce disease burden and healthcare costs. Results of several studies indicate that higher vaccination coverage among HCP is associated with lower incidence of nosocomial influenza.[19] [20] [21] Such

[15] Maltezou, H.C., Drancourt, M.: Nosocomial influenza in children. Journal of Hospital Infection 2003; 55:83–91.

[16] Hurley, J.C., Flockhart, S.: An influenza outbreak in a regional residential facility. Journal of Infection Prevention 2010; 11:58–61.

[17] Salgado, C.D., Farr, B.M., Hall, K.K., Hayden, F.G.: Influenza in the acute hospital setting. The Lancet Infectious Diseases 2002; 2:145–155.

[18] Wilde, J.A., McMillan, J.A., Serwint, J., Butta, J., O'Riordan, M.A., Steinhoff, M.C.: Effectiveness of influenza vaccine in health care professionals: a randomized trial. The Journal of the American Medical Association 1999; 281:908–913.

[19] Salgado, C.D., Giannetta, E.T., Hayden, F.G., Farr, B.M.: Preventing influenza by improving the vaccine acceptance rate of clinicians. Infection Control and Hospital Epidemiology 2004;25:923–928.

[20] Potter, J., Stott, D.J., Roberts, M.A., *et al.:* Influenza vaccination of health-care workers in long-term-care hospitals reduces the mortality of elderly patients. Journal of Infectious Diseases 1997; 175:1–6.

findings have led some to call for mandatory influenza vaccination of HCP.[22] [23] [24] [25] [26]

Until recently, vaccination coverage among HCP has been well below the national Healthy People 2010 target of 60 percent,[27] but preliminary data suggest 62 percent of HCP reported receiving seasonal influenza vaccine in 2009–2010.[28] Only 37 percent reported receiving the 2009 pandemic A/H1N1 vaccine.[29]

HCP refers to all personnel working in healthcare settings who have the potential for exposure to patients and/or to infectious materials, including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or contaminated air.[30] HCP may include (but are not limited to) physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the healthcare facility, and persons (for example, clerical, dietary, housekeeping, laundry, security, maintenance, billing, and volunteers) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from HCP and patients. Settings in which HCP may work include, but are not limited to, acute care hospitals, long-term care facilities, skilled nursing facilities, rehabilitation centers, physicians' offices, urgent care centers, outpatient clinics, home health agencies, and emergency medical services.

Currently, four States have ''offer'' laws for influenza vaccination of HCP, meaning that vaccine must be offered to HCP by healthcare facilities; and three States (Alabama, California, and New Hampshire) have ''ensure'' laws for influenza vaccination of HCP, meaning that vaccination of non-immune HCP is mandatory in the absence of a specified exemption or refusal; and, additionally, numerous hospitals and other healthcare facilities have established policies requiring mandatory influenza vaccination of their HCP.[31]

Currently, no State requires that hospitals report this measure to NHSN. However, approximately 13 hospitals (including long term acute care and rehabilitation), outpatient hemodialysis centers, long term care facilities, and ambulatory surgical centers are currently reporting HCP immunization data to the NHSN. In September 2009, CDC released the Healthcare Personnel Safety (HPS) Component of the NHSN, which complements Patient Safety and Biovigilance components available in NHSN. The HPS Component replaced CDC's National Surveillance System for Health Care Workers (NaSH) and is comprised of two modules: the Blood/Body Fluid Exposure Module and the Influenza Vaccination and Management and Exposure Module.[32] Currently, participation in either module is voluntary. The current Influenza Vaccination and Management and Exposure Module may soon offer options for healthcare facilities to submit vaccination summary data. NHSN plans to partner with vendor-based surveillance systems to permit periodic data extractions into NHSN.

The modules feature basic, custom, and advanced analysis capabilities available in real-time, which allow individual healthcare facilities to compile and analyze their own data, as well as benchmark these results to aggregate NHSN estimates. The HPS Component can assist participating facilities in developing surveillance and analysis capabilities to permit the timely recognition of HCP safety problems and prompt interventions with appropriate measures. Influenza vaccination data submitted to CDC will ultimately capture regional trends on the yearly uptake of the vaccine, prophylaxis and treatment for healthcare personnel, as well as the elements within yearly influenza campaigns that succeed or require improvement. At the State and national levels, the HPS Component will aid in monitoring rates and trends.

Due to the significant impact of HCP influenza vaccination on patient outcomes, we believe this measure is appropriate for measuring the quality of care in hospital outpatient departments. Healthcare Personnel (HCP) Influenza Vaccination is one of the HAI measures that we proposed to adopt for the FY 2015 Hospital IQR Program in the FY 2012 IPPS/LTCH PPS proposed rule. This measure assesses the percentage of healthcare personnel who have been immunized for influenza during the flu season. The specifications for this measure are available at *http://www.cdc.gov/nhsn/PDFs/HSPmanual/HPS_Manual.pdf.*

The proposed HCP Influenza Vaccination measure is NQF-endorsed for the hospital setting and applies to the hospital outpatient setting. Therefore, this measure meets the requirement for measure selection under section 1833(t)(17)(C)(i) of the Act. We proposed to adopt the Influenza Vaccination Coverage among Healthcare Personnel measure that is collected by the CDC via the NHSN. The NHSN proposed reporting mechanism for this proposed HAI measure is discussed in greater detail in sections XIV.C.2.a. of the proposed rule and this final rule with comment period. We proposed that

[21] Hayward, A.C., Harling, R., Wetten, S., *et al.:* Effectiveness of an influenza vaccine programme for care home staff to prevent death, morbidity, and health service use among residents: cluster randomised controlled trial. British Medical Journal 2006; 333:1241–1246.

[22] Talbot, T.R., Bradley, S.F., Cosgrove, S.E., *et al.:* SHEA position paper: Influenza vaccination of healthcare workers and vaccine allocation for healthcare workers during vaccine shortages. Infection Control and Hospital Epidemiology 2005; 26:882–890.

[23] American College of Physicians (ACP), ACP policy on influenza vaccination of health care workers. *http://www.acponline.org/running_practice/quality_improvement/projects/adult_immunization/flu_hcw.pdf.*

[24] Greene, L.R., Cain, T.A., Dolan, S.A. *et al.:* APIC position paper: influenza immunization of healthcare personnel. Association of Professionals in Infection Control (APIC). November 2008. *http://www.apic.org/Content/NavigationMenu/PracticeGuidance/Topics/Influenza/APIC_Position_Paper_Influenza_11_7_08final_revised.pdf, http://www.apic.org/Content/NavigationMenu/PracticeGuidance/Topics/Influenza/APIC_Position_Paper_Influenza_11_7_08final_revised.pdf.*

[25] National Patient Safety Foundation (NPSF), Mandatory flu vaccinations for healthcare workers. Press Release, November 18, 2009. *http://www.npsf.org/pr/pressrel/2009-11-18.php.*

[26] Infectious Diseases Society of America (IDSA), IDSA policy on mandatory immunization of health care workers against seasonal and 2009 H1N1 influenza. Infectious Diseases Society of America (IDSA). September 30, 2009. *http://www.idsociety.org/HCWimmunization/.*

[27] Walker, F.J., Singleton, J.A., Lu, P., Wooten, K.G., Strikas, R.A.: Influenza vaccination of healthcare workers in the United States, 1989–2002. Infection Control and Hospital Epidemiology 2006; 27:257–265.

[28] *http://www.cdc.gov/mmwr/preview/mmwrhtml/rr55e209a1.htm.* Influenza Vaccination of Health-Care Personnel Recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices.

[29] Centers for Disease Control and Prevention, Interim results: Influenza A (H1N1) 2009 and Monovalent Seasonal Influenza Vaccination Coverage Among Health-Care Personnel—United States August 2009–January 2010. Morbidity and Mortality Weekly Report (MMWR); 59:357–362. Available at: *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5912a1.htm.*

[30] Adapted from: Pearson M.L., Bridges C.B., Harper S.A.: Influenza vaccination of health-care personnel: Recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP). Morbidity and Mortality Weekly Report (MMWR) 2006; 55:1–16. Available at: *http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5502a1.htm.*

[31] For additional information regarding healthcare facilities' influenza vaccine policies, please see: *http://www.immunize.org/honor%2Droll/.http://www.immunize.org/honor%2Droll/.*

[32] Available at: *http://www.cdc.gov/nhsn/hps.htmlhttp://www.cdc.gov/nhsn/hps.html.*

hospital outpatient departments use the NHSN infrastructure and protocol to report the measure for Hospital OQR purposes. We invited public comment on our proposal to adopt this HAI measure into the Hospital OQR Program for the CY 2015 payment determination.

Comment: Many commenters applauded the reporting of the influenza vaccination coverage among healthcare personnel measure in recognition of its importance in preventing transmission of influenza in hospital and ASC settings. However, commenters were concerned that the associated data collection is too labor-intensive, since the NQF specifications for denominator and numerator involve both employees and non-employees. To overcome the data collection challenges, the commenters recommended CMS/CDC testing of the NHSN–HCP module, which is being modified to accept aggregate data instead of individual level data, in inpatient settings prior to implementation in the outpatient setting. Commenters noted that the measure should not be finalized until NQF has finished its review on the proposed modifications for the denominator submitted by CDC. Furthermore, commenters remarked that delaying the measure to CY 2016 would allow HOPDs to gain experience with the revised NHSN module as well as synchronize the implementation date of this measure with that of the ASC Quality Reporting Program.

Response: We thank the commenters for their support of the measure and recognize its significance in preventing influenza transmission. CDC has submitted a revised measure proposal to NQF based on results of field testing, in its efforts to streamline data collection. The revised measure proposal reduces denominator data collection to employee healthcare personnel, defined as staff on facility payroll, and two categories of non-employee healthcare personnel: (1) Licensed independent practitioners, that is, physicians, advance practice nurses, and physician assistants, and (2) student trainees and adult volunteers. CDC has indicated that NQF's final review of the NHSN–HCP module and an endorsement decision are pending. Therefore, we are not finalizing this measure for CY 2015 payment determination in this rulemaking, but intend to propose an influenza vaccination measure for the CY 2016 payment determination.

Comment: A few commenters stated that the influenza vaccination coverage among healthcare personnel measure lacks the supporting evidence that links patients contracting influenza to ambulatory procedures.

Response: Several randomized clinical trials in healthy working-age adults have shown that influenza vaccination reduces infection, illness, antibiotic use, medical visits, and lost work days.[33] [34] Influenza vaccination also reduces influenza virus shedding and reduces transmission of influenza to others through prevention of infection. In addition, studies show that healthcare personnel continue to work while ill, including when ill with influenza.[35] Therefore, preventing influenza illness in healthcare personnel is important to reduce patient exposures to influenza-infected persons in the healthcare setting.

Although no studies have been done in the outpatient setting to assess reductions in illness among patients due to healthcare personnel vaccination, studies have been done in hospitals and nursing homes demonstrating the risk of healthcare-acquired influenza in these settings. One study in a hospital and three studies in long-term care facilities have demonstrated reductions in patient illness and mortality with healthcare personnel influenza vaccination. The evidence that influenza vaccination of healthcare personnel reduces disease in hospital and nursing home residents should be generalizable to outpatient settings based on knowledge of the benefits of influenza vaccination in working-age adults and an understanding of influenza transmission.

Comment: A commenter was concerned that hospitals may be unfairly penalized when there is a shortage of flu vaccines.

Response: We are not finalizing this measure at this time, but we intend to re-propose this measure for a future payment determination in order to allow more time for CDC to address infrastructure capacity to accept the data from an increasing number of provider types. The purpose of the measure is to track vaccination rates; therefore, in the event of a vaccination shortage, it is still important to monitor and track this measure. However, if such a measure is adopted and a large-scale vaccination shortage occurs, we will consider temporarily suspending display of the measure on *Hospital Compare.*

Comment: A commenter was concerned about potential duplicative efforts since some States already mandate vaccination of healthcare workers and public reporting of healthcare vaccination rates.

Response: We were informed by CDC that in the event that the measure is adopted in the Hospital OQR Program, it will strive to standardize the reportable quality measure at State and federal levels. Standardizing reportable healthcare quality measurements is a priority because that reduces reporting burden while preserving the opportunities to use those data for different purposes at the State and federal levels.

Comment: A commenter recommended the influenza vaccination measure for healthcare personnel be inclusive of all employees of the facility and not split out as inpatient and outpatient settings. Another commenter stated that the measure should allow healthcare personnel to choose the vaccination type or brand most appropriate for them.

Response: The measure does not specify which vaccination types or brand the healthcare personnel should receive. As stated previously, we are not finalizing this measure for the Hospital OQR Program at this time.

After consideration of the public comments we received, we are not finalizing the HCP Influenza Vaccination measure for CY 2015 payment determination in this final rule with comment period, but intend to propose a HCP Influenza Vaccination measure for the CY 2016 payment determination once measure refinements and operational issues have been addressed.

The complete measure set for the Hospital OQR Program CY 2015 payment determination is set out in the table below.

BILLING CODE 4120–01–P

[33] Bridges CB, Thompson WW, Meltzer MI, *et al.* Effectiveness and cost-benefit of influenza vaccination of healthy working adults: a randomized controlled trial. JAMA 2000; 284: 1655–63. (adults employed at a manufacturing plant).

[34] Bridges CB, Thompson WW, Meltzer MI, *et al.* Effectiveness and cost-benefit of influenza vaccination of healthy working adults: A randomized controlled trial. JAMA 2000; 284: 1655–63. (adults employed at a manufacturing plant).

[35] Wilde JA, McMillan JA, Serwint J, Butta J, O'Riordan MA, Steinhoff MC. Effectiveness of influenza vaccine in health care professionals. A randomized trial. JAMA 1999;281:908–13.

CY 2015 Hospital OQR Program Measure Set
OP-1: Median Time to Fibrinolysis
OP-2: Fibrinolytic Therapy Received Within 30 Minutes
OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
OP-4: Aspirin at Arrival
OP-5: Median Time to ECG
OP-6: Timing of Antibiotic Prophylaxis
OP-7: Prophylactic Antibiotic Selection for Surgical Patients
OP-8: MRI Lumbar Spine for Low Back Pain
OP-9: Mammography Follow-up Rates
OP-10: Abdomen CT – Use of Contrast Material
OP-11: Thorax CT – Use of Contrast Material
OP-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data*
OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non Cardiac Low Risk Surgery *
OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)*
OP-15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache*
OP-16: Troponin Results for Emergency Department acute myocardial infarction (AMI) patients or chest pain patients (with Probable Cardiac Chest Pain) Received Within 60 minutes of Arrival **
OP-17: Tracking Clinical Results between Visits**
OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients**
OP-19: Transition Record with Specified Elements Received by Discharged Patients**
OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional**
Op-21: ED- Median Time to Pain Management for Long Bone Fracture **
OP-22: ED Patient Left Without Being Seen**
OP-23: ED- Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 minutes of Arrival **
OP-24: Cardiac Rehabilitation Patient Referral From an Outpatient Setting ***
OP-25: Safe Surgery Checklist Use***
OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures***

CY 2015 Hospital OQR Program Measure Set	
Procedure Category	**Corresponding HCPCS Codes**
Gastrointestinal	40000 through 49999, G0104, G0105,G0121,C9716, C9724, C9725, 0170T
Eye	65000 through 68999, 0186, 0124T, 0099T, 0017T, 0016T, 0123T, 0100T, 0176T, 0177T, 0186T, 0190T, 0191T, 0192T, 76510, 0099T
Nervous System	61000 through 64999, G0260, 0027T, 0213T, 0214T, 0215T, 0216T, 0217T, 0218T, 0062T
Musculoskeletal	20000 through 29999, 0101T, 0102T, 0062T, 0200T, 0201T
Skin	10000 through 19999, G0247, 0046T, 0268T, G0127, C9726, C9727
Genitourinary	50000 through 58999, 0193T, 58805
Cardiovascular	33000 through 37999
Respiratory	30000 through 32999

* New measure for the CY 2012 payment determination.

** New measure for the CY 2013 payment determination.

*** New measure for the CY 2014 payment determination.

BILLING CODE 4120–01–C

D. Possible Quality Measures Under Consideration for Future Inclusion in the Hospital OQR Program

The current measure set for Hospital OQR includes measures that assess imaging efficiency patterns, care transitions, and the use of HIT. In the CY 2012 OPPS/ASC proposed rule, we proposed to add measures to the CY 2014 and CY 2015 measure sets addressing care coordination, patient safety, volume, and prevention of influenza.

In previous years' rulemakings, we have provided lists of measures that are under consideration for future adoption into the Hospital OQR measure set. Below is a list of potential measurement areas that we set out in the CY 2012 OPPS/ASC proposed rule that we are considering for future Hospital OQR payment determinations (beginning with CY 2015) for which we solicited public comment. In particular, we sought comment on the inclusion of Patient Experience of Care Measures in the Hospital OQR measure set for a future payment determination, such as existing Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys for clinicians/groups and the CAHPS Surgical Care Survey, sponsored and submitted by the American College of Surgeons (ACS) and the Surgical Quality Alliance (SQA).

We also intend to align the surgical safety measures across the HOPD and ASC settings and would seek to utilize comparable data to assess patient safety in these settings. Therefore, in the proposed rule, we sought comment on the potential submission of such measures by HOPDs via quality codes submitted on claims in the future. We also sought comment on the inclusion of measures of Anesthesia-related Complications in the Hospital OQR measurement set.

BILLING CODE 4120–01–P

Measures and Measurement Topics Under Consideration for Future Hospital OQR Program Payment Determinations Beginning with CY 2015
Measures for future development:
Procedure Specific Measures
Colonoscopy and other Endoscopy measures
Cataract Surgery measures
Cancer Care
Adjuvant Chemotherapy is Considered or Administered within 4 Months of Surgery to Patients Under Age 80 with AJCC III Colon Cancer.
Adjuvant Hormonal Therapy for Patients with Breast Cancer
Needle Biopsy to Establish Diagnosis of Cancer Precedes Surgical Excision/Resection.
Heart Failure
Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)
Heart Failure: Left Ventricular Ejection Fraction Assessment
Heart Failure: Combination Medical Therapy for Left Ventricular Systolic Dysfunction
Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction
Heart Failure: Counseling regarding Implantable Cardioverter-Defibrillator (ICD) Implantation for Patients with Left Ventricular Systolic Dysfunction on Combination Medical Therapy
Heart Failure: Patients with Left Ventricular Systolic Dysfunction on Combination Medical Therapy
Heart Failure: Symptom Management
Heart Failure: Symptom and Activity Assessment
Heart Failure: Patient Education
Heart Failure: Overuse of Echocardiography
Heart Failure: Post-Discharge Appointment for Heart Failure Patients
Surgical Safety
Patient Fall
Patient Burn
Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
Hospital Transfer/Admission
Patient Experience-of-Care
Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys for clinicians/groups
CAHPS Surgical Care Survey

Measures and Measurement Topics Under Consideration for Future Hospital OQR Program Payment Determinations Beginning with CY 2015
Anesthesia Related Complications
Death
Cardiac Arrest
Perioperative Myocardial Infarction
Anaphylaxis
Hyperthermia
Transfusion Reaction
Stroke, Cerebral Vascular Accident, or Coma following anesthesia
Visual Loss
Medication Error
Unplanned ICU admission
Patient intraoperative awareness
Unrecognized difficult airway
Reintubation
Dental Trauma
Perioperative aspiration
Vascular access complication, including vascular injury or pneumothorax
Pneumothorax following attempted vascular access or regional anesthesia
Infection following epidural or spinal anesthesia
Epidural hematoma following spinal or epidural anesthesia
High Spinal
Postdural puncture headache
Major systemic local anesthetic toxicity
Peripheral neurologic deficit following regional anesthesia
Infection following peripheral nerve block
Additional Measurement Topics
NQF Serious Reportable Events in Healthcare
Medication Reconciliation
Chemotherapy
Post-discharge follow up
Post-discharge ED visit within 72 hours
Breast cancer detection rate

BILLING CODE 4120–02–C

We invited public comment on these measures and other topics that we might consider proposing to adopt beginning with the Hospital OQR Program CY 2015 payment determination. We also sought suggestions and rationales to support the adoption of measures and topics for the Hospital OQR Program which do not appear in the table above.

We received many comments on measures and measurement topics considered for the future. We describe them as follows:

○ Cancer care

Comment A commenter noted that the cancer care measures listed are duplicative measures of those used in the PQRS. A commenter did not support the Needle Biopsy to Establish

Diagnosis of Cancer Precedes Surgical Excision/Resection measure because many cancers do not have needle biopsy as an option for diagnosis.

Response: We thank the commenters for their views and will consider them during future measure selection activity.

○ Heart failure

Comment: A few commenters supported the heart failure measures on the list. Two commenters noted the Overuse of echocardiography, Left ventricular ejection fraction assessment, and the Patients with left ventricular systolic dysfunction on combination medical therapy have inherent fundamental incompatibilities, given that the first measure would likely prohibit the use of echocardiography while the latter two measures would presumably encourage the use of echocardiography. The commenters were specifically concerned that the first measure may have unintended consequences of deterring physicians from ordering echocardiography to identify potential heart failure patients.

Response: We thank the commenters for the valuable suggestions and will take them into consideration in our future measure review and selection activity.

○ Patient experience-of-care

Comment: Many commenters strongly supported the inclusion of patient experience of care measures listed.

Response: We thank the commenters for this input and will consider them during future measure selection activity.

○ Anesthesia related complication measures

Comment One commenter requested that CMS collaborate with anesthesiologists and CRNAs to revise the list of anesthesia-related complications to codify the definitions of anesthesia related complications.

Response: We thank the commenter for this input and will consider it during future measure selection activity.

○ Additional measure topics

Comment A commenter believed the Medication reconciliation measure is inappropriate for ED setting since emergency room patients may not have the ability to accurately report current medications taken and the data collection process may cause a delay in patient care. A commenter was concerned that the Post discharge follow-up and the post discharge ED visit within 72 hours measure may lead to unintended consequences if not constructed prudently, given there are many variables affecting a patient's return to an ED. A commenter supported the listed Breast cancer detection rate measure for future consideration.

Response: We thank the commenters for these suggestions and support, and will take them into consideration during our future measure selection activity.

E. Payment Reduction for Hospitals That Fail To Meet the Hospital OQR Program Requirements for the CY 2012 Payment Update

1. Background

Section 1833(t)(17)(A) of the Act, which applies to subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act), requires that hospitals that fail to report data required to be submitted on the measures selected by the Secretary, in the form and manner, and at a time, required by the Secretary under section 1833(t)(17) of the Act, incur a 2.0 percentage point reduction to their OPD fee schedule increase factor, that is, the annual payment update factor. Section 1833(t)(17)(A)(ii) of the Act specifies that any reduction applies only to the payment year involved and will not be taken into account in computing the applicable OPD fee schedule increase factor for a subsequent payment year.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68769 through 68772), we discussed how the payment reduction for failure to meet the administrative, data collection, and data submission requirements of the Hospital OQR Program affected the CY 2009 payment update applicable to OPPS payments for HOPD services furnished by the hospitals defined under section 1886(d)(1)(B) of the Act to which the program applies. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program requirements. All other hospitals paid under the OPPS receive the full OPPS payment update without the reduction.

The national unadjusted payment rates for many services paid under the OPPS equal the product of the OPPS conversion factor and the scaled relative weight for the APC to which the service is assigned. The OPPS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPPS payment rate for services with the following status indicators (listed in Addendum B to this final rule with comment period, which is available via the Internet on the CMS Web site): ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''V,'' ''U,'' or ''X.'' In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68770), we adopted a policy that payment for all services assigned these status indicators would be subject to the reduction of the national unadjusted payment rates for applicable hospitals, with the exception of services assigned to New Technology APCs with assigned status indicator ''S'' or ''T,'' and brachytherapy sources with assigned status indicator ''U,'' which were paid at charges adjusted to cost in CY 2009. We excluded services assigned to New Technology APCs from the list of services subject to the reduced national unadjusted payment rates because the OPD fee schedule increase factor is not used to update the payment rates for these APCs.

In addition, section 1833(t)(16)(C) of the Act, as amended by section 142 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275), specifically required that brachytherapy sources be paid during CY 2009 on the basis of charges adjusted to cost, rather than under the standard OPPS methodology. Therefore, the reduced conversion factor also was not applicable to CY 2009 payment for brachytherapy sources because payment would not be based on the OPPS conversion factor and, consequently, the payment rates for these services were not updated by the OPD fee schedule increase factor. However, in accordance with section 1833(t)(16)(C) of the Act, as amended by section 142 of the MIPPA, payment for brachytherapy sources at charges adjusted to cost expired on January 1, 2010. Therefore, in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60641), we finalized our CY 2010 proposal, without modification, to apply the reduction to payment for brachytherapy sources to hospitals that fail to meet the quality data reporting requirements of the Hospital OQR Program for brachytherapy services furnished on and after January 1, 2010.

The OPD fee schedule increase factor is an input into the OPPS conversion factor, which is used to calculate OPPS payment rates. To implement the requirement to reduce the OPD fee schedule increase factor for hospitals that fail to meet reporting requirements, we calculate two conversion factors: a full market basket conversion factor (that is, the full conversion factor), and a reduced market basket conversion factor (that is, the reduced conversion factor). We then calculate a reduction ratio by dividing the reduced conversion factor by the full conversion factor. We refer to this reduction ratio as the ''reporting ratio'' to indicate that it

applies to payment for hospitals that fail to meet their reporting requirements. Applying this reporting ratio to the OPPS payment amounts results in reduced national unadjusted payment rates that are mathematically equivalent to the reduced national unadjusted payment rates that would result if we multiplied the scaled OPPS relative weights by the reduced conversion factor. To determine the reduced national unadjusted payment rates that applied to hospitals that failed to meet their quality reporting requirements for the CY 2010 OPPS, we multiply the final full national unadjusted payment rate in Addendum B to the CY 2010 OPPS/ASC final rule with comment period by the CY 2010 OPPS final reporting ratio of 0.980 (74 FR 60642).

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68771 through 68772), we established a policy that the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would each equal the product of the reporting ratio and the national unadjusted copayment or the minimum unadjusted copayment, as applicable, for the service. Under this policy, we apply the reporting ratio to both the minimum unadjusted copayment and national unadjusted copayment for those hospitals that receive the payment reduction for failure to meet the Hospital OQR Program reporting requirements. This application of the reporting ratio to the national unadjusted and minimum unadjusted copayments is calculated according to § 419.41 of our regulations, prior to any adjustment for a hospital's failure to meet the quality reporting standards according to § 419.43(h). Beneficiaries and secondary payers thereby share in the reduction of payments to these hospitals.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68772), we established the policy that all other applicable adjustments to the OPPS national unadjusted payment rates apply in those cases when the OPD fee schedule increase factor is reduced for hospitals that fail to meet the requirements of the Hospital OQR Program. For example, the following standard adjustments apply to the reduced national unadjusted payment rates: the wage index adjustment; the multiple procedure adjustment; the interrupted procedure adjustment; the rural sole community hospital adjustment; and the adjustment for devices furnished with full or partial credit or without cost. We believe that these adjustments continue to be equally applicable to payments for hospitals that do not meet the Hospital OQR Program requirements. Similarly, outlier payments will continue to be made when the criteria are met. For hospitals that fail to meet the quality data reporting requirements, the hospitals' costs are compared to the reduced payments for purposes of outlier eligibility and payment calculation. This policy conforms to current practice under the IPPS. We continued this policy in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60642), and in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72099). For a complete discussion of the OPPS outlier calculation and eligibility criteria, we refer readers to section II.G. of this final rule with comment period.

2. Reporting Ratio Application and Associated Adjustment Policy for CY 2012

In the CY 2012 OPPS/ASC proposed rule (76 FR 42327 through 42328), we proposed to continue our established policy of applying the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for the full CY 2012 annual payment update factor. For the CY 2012 OPPS, the proposed reporting ratio was 0.980, calculated by dividing the proposed reduced conversion factor of $68.052 by the proposed full conversion factor of $69.420. The final CY 2012 OPPS reporting ratio is 0.980, calculated by dividing the reduced conversion factor of $68.616 by the full conversion factor of $70.016. We proposed to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. For the CY 2012 OPPS, we proposed to apply the reporting ratio, when applicable, to all HCPCS codes to which we have assigned status indicators ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''U,'' ''V,'' and ''X'' (other than new technology APCs to which we have assigned status indicators ''S'' and ''T''). We proposed to continue to exclude services paid under New Technology APCs. We proposed to continue to apply the reporting ratio to the national unadjusted payment rates and the minimum unadjusted and national unadjusted copayment rates of all applicable services for those hospitals that fail to meet the Hospital OQR Program reporting requirements. We also proposed to continue to apply all other applicable standard adjustments to the OPPS national unadjusted payment rates for hospitals that fail to meet the requirements of the Hospital OQR Program. Similarly, we proposed to continue to calculate OPPS outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements.

We invited public comments on these proposals. We did not receive any public comments on our CY 2012 proposal to apply the HOP QDRP reduction in the manner described in the paragraph above and, therefore, are finalizing our proposal, without modification.

Therefore, for the CY 2012 OPPS, we are applying a reporting ratio of 0.980 to the national unadjusted payments, minimum unadjusted copayments, and national unadjusted copayments for all applicable services for those hospitals failing to meet the HOP QDRP reporting requirements. This reporting ratio applies to HCPCS codes assigned status indicators ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''U,'' ''V,'' or ''X,'' excluding services paid under New Technology APCs. All other applicable standard adjustments to the OPPS national unadjusted payment rates for hospitals that fail to meet the requirements of the HOP QDRP will continue to apply. We continue to calculate OPPS outlier eligibility and outlier payment based on the reduced rates for those hospitals that fail to meet the reporting requirements.

F. Extraordinary Circumstances Extension or Waiver for CY 2012 and Subsequent Years

In our experience, there have been times when hospitals have been unable to submit required quality data due to extraordinary circumstances that are not within their control. It is our goal to not penalize hospitals for such circumstances and we do not want to unduly increase their burden during these times. Therefore, in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60046 through 600647), we adopted a process for hospitals to request and for CMS to grant extensions or waivers with respect to the reporting of required quality data when there are extraordinary circumstances beyond the control of the hospital. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72103), we retained these procedures with some modifications. For CY 2012 and subsequent years, we proposed to retain these procedures with one modification. In the CY 2012 OPPS/ASC proposed rule (76 FR 42328), we proposed to extend these procedures to the submission of medical record documentation for purposes of complying with our validation

requirement for the Hospital OQR Program.

Under this process, in the event of extraordinary circumstances, such as a natural disaster, not within the control of the hospital, for the hospital to receive consideration for an extension or waiver of the requirement to submit quality data or medical record documentation for one or more quarters, a hospital would submit to CMS a request form that would be made available on the QualityNet Web site. The following information should be noted on the form:

- Hospital CCN;
- Hospital Name;
- CEO and any other designated personnel contact information, including name, email address, telephone number, and mailing address (must include a physical address, a post office box address is not acceptable);
- Hospital's reason for requesting an extension or waiver;
- Evidence of the impact of the extraordinary circumstances, including but not limited to photographs, newspaper and other media articles; and
- A date when the hospital would again be able to submit Hospital OQR data and/or medical record documentation, and a justification for the proposed date.

The request form would be signed by the hospital's CEO. A request form would be required to be submitted within 45 days of the date that the extraordinary circumstance occurred.

Following receipt of such a request, CMS would—

(1) Provide a written acknowledgement using the contact information provided in the request, to the CEO and any additional designated hospital personnel, notifying them that the hospital's request has been received;

(2) Provide a formal response to the CEO and any additional designated hospital personnel using the contact information provided in the request notifying them of our decision; and

(3) Complete our review of any CY 2012 request and communicate our response within 90 days following our receipt of such a request.

We note that we might also decide to grant waivers or extensions to hospitals that have not requested them when we determine that an extraordinary circumstance, such as an act of nature (for example, hurricane) affects an entire region or locale. If we make the determination to grant a waiver or extension to hospitals in a region or locale, we would communicate this decision to hospitals and vendors through routine communication channels, including but not limited to emails and notices on the QualityNet Web site.

In the proposed rule we invited public comment on this proposal to retain our existing process for granting extraordinary circumstances extensions or waivers, and to extend this process to the submission of medical record documentation, for the Hospital OQR Program.

Comment: Several commenters supported the proposal to continue the existing process for granting extraordinary circumstances extensions or waivers and to extend this process to the submission of medical record documentation for the Hospital OQR Program. One commenter noted direct experience with medical record documentation destroyed by a recent disaster.

Response: We thank these commenters for supporting our proposal to extend our process for granting extraordinary circumstances extensions or waivers to the submission of medical record documentation.

After consideration of the public comments we received, we are finalizing our proposal without modification; to continue the existing process for granting extraordinary circumstances extensions or waivers, to extend this process to the submission of medical record documentation for the Hospital OQR Program, and to use this process for CY 2012 and subsequent years.

G. Requirements for Reporting of Hospital OQR Data for CY 2013 and Subsequent Years

To participate in the Hospital OQR Program, hospitals must meet administrative, data collection and submission, and data validation requirements (if applicable). Hospitals that do not meet Hospital OQR Program requirements, as well as hospitals not participating in the Program and hospitals that withdraw from the Program, will not receive the full OPPS payment rate update. Instead, in accordance with section 1833(t)(17)(A) of the Act, those hospitals will receive a reduction of 2.0 percentage points to their OPD fee schedule increase factor for the applicable payment year. We established the payment determination requirements for the CY 2012 payment update in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72099 through 72106).

In the CY 2012 OPPS/ASC proposed rule (76 FR 42328 through 42333), with respect to the payment determinations for CY 2013 and subsequent years, we proposed to implement the requirements listed below. Most of these requirements are the same as the requirements we implemented for the CY 2012 payment determination, with some proposed modifications.

1. Administrative Requirements for CY 2013 and Subsequent Years

To participate in the Hospital OQR Program, we proposed that several administrative steps be completed. These steps are the same as those we finalized for the CY 2012 payment determination and would require the hospital to:

- Identify a QualityNet security administrator who follows the registration process located on the QualityNet Web site (*http://www.QualityNet.org*) and submits the information to the appropriate CMS-designated contractor. All CMS-designated contractors would be identified on the QualityNet Web site. The same person may be the QualityNet security administrator for both the Hospital IQR Program and the Hospital OQR Program. Based on our experience, we believe that the QualityNet security administrator typically fulfills a variety of tasks related to the hospital's ability to participate in the Hospital OQR Program, such as: Creating, approving, editing and/or terminating QualityNet user accounts within the organization; monitoring QualityNet usage to maintain proper security and confidentiality measures; and serving as a point of contact for information regarding QualityNet and the Hospital OQR Program. However, the main purpose of the QualityNet Administrator is to serve as a contact for security purposes. Because of CMS information systems security requirements, the hospital would be required to maintain a current QualityNet security administrator for as long as the hospital participates in the Program. While only a single QualityNet security administrator would be required for Program purposes, we suggest to hospitals that it may be beneficial to have more than one QualityNet security administrator for back-up purposes.
- Register with QualityNet, regardless of the method used for data submission.
- Complete and submit an online participation form if this form (or a paper Notice of Participation form) has not been previously completed, if a hospital has previously withdrawn, or if the hospital acquires a new CCN. For Hospital OQR Program purposes, hospitals that share the same CCN would be required to complete a single online participation form. At this time, the participation form for the Hospital OQR Program is separate from the

participation form required for the Hospital IQR Program and completing a form for each program is required. Agreeing to participate includes acknowledging that the data submitted to the CMS-designated contractor would be submitted to CMS, shared with one or more other CMS contractors that support the implementation of the Hospital OQR Program, and be publicly reported.

We proposed to retain the procedures and update the deadlines for submitting the participation form which we established in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72100):

Hospitals with Medicare acceptance dates on or after January 1 of the year prior to the annual payment update affected: For the CY 2013 and subsequent years payment updates, we proposed that any hospital that has a Medicare acceptance date on or after January 1 of the year prior to the annual payment update affected (for example, 2012 would be the year prior to the affected CY 2013 annual payment update), including a new hospital and hospitals that have merged, must submit a completed participation form no later than 180 days from the date identified as its Medicare acceptance date on the CMS Certification and Survey Provider Enhanced Reporting (CASPER) system. Hospitals typically receive a package notifying them of their new CCN after they receive their Medicare acceptance date. The Medicare acceptance date is the earliest date that a hospital can receive Medicare payment for the services that it furnishes. Completing the participation form would include supplying the name and address of each hospital campus that shares the same CCN.

The use of the Medicare acceptance date as beginning the timeline for Hospital OQR Program participation allows us to monitor more effectively hospital compliance with the requirement to complete a participation form because a hospital's Medicare acceptance date is readily available to CMS through its data systems. In addition, providing an extended time period to register for the program would allow newly functioning hospitals sufficient time to get their operations fully functional before having to collect and submit quality data.

We are aware that Medicare acceptance dates may be back-dated; we had experience with reported occurrences as such over the past year. In that event, we would consider a hospital's request to allow additional time to elect to participate.

Hospitals with Medicare acceptance dates before January 1 of the year prior to the affected annual payment update: For the CY 2013 and subsequent years payment update, we proposed that any hospital that has a Medicare acceptance date before January 1 of the year prior to the affected annual payment update (for example, 2012 would be the year prior to the affected CY 2013 annual payment update) that is not currently participating in Hospital OQR and wishes to participate in the Hospital OQR Program must submit a participation form by March 31 of the year prior to the affected annual payment update. We proposed a deadline of March 31, because we believe it would give hospitals sufficient time to decide whether they wish to participate in the Hospital OQR Program, as well as put into place the necessary staff and resources to timely report data for first quarter of the year's services. This requirement would apply to all hospitals whether or not the hospital billed for payment under the OPPS.

For the CY 2013 and subsequent years payment updates, we proposed that any Hospital OQR-participating hospital that wants to withdraw may do so at any time from January 1 to November 1 of the year prior to the affected annual payment update. A hospital that withdraws during this time period for any annual payment update would not be able to later sign up to participate for that payment update, would receive a 2.0 percentage point reduction to its OPD fee schedule increase factor for that year, and would be required to submit a new participation form in order to participate in any future year of the Hospital OQR Program. We note that once a hospital has submitted a participation form, it is considered to be an active Hospital OQR Program participant until such time as the hospital submits a withdrawal form to CMS or is designated as closed in the CMS CASPER system.

In the proposed rule we invited public comment on these proposed Hospital OQR Program administrative requirements for the CY 2013 and subsequent years' payment determinations.

Comment: Some commenters supported requiring hospital outpatient departments to report quality data and the 2.0 percent reduction for hospitals that do not successfully report quality data to CMS.

Response: We thank these commenters for supporting hospital outpatient quality data reporting under the Hospital OQR Program and the use of the 2.0 percentage point reduction for hospitals that do not successfully report quality data to CMS.

Comment: Some commenters supported the proposed administrative requirements for the Hospital OQR Program in general.

Response: We thank these commenters for supporting our proposed administrative Hospital OQR Program requirements.

After consideration of the public comments we received, we are finalizing our proposals for Hospital OQR Program administrative requirements without modification.

2. Form, Manner, and Timing of Data Submission for CY 2013 and Subsequent Years

In the CY 2012 OPPS/ASC proposed rule (76 FR 42329 through 42332), we proposed that, to be eligible to receive the full OPD fee schedule increase factor for any payment determination, hospitals must comply with our submission requirements for chart-abstracted data, population and sampling data, claims-based measure data, and structural quality measure data, including all-patient volume data:

a. CY 2013 and CY 2014 Data Submission Requirements for Chart-Abstracted Measure Data Submitted Directly to CMS

In the CY 2012 OPPS/ASC proposed rule (76 FR 42329 through 42330), with respect to the proposed chart-abstracted measures for which hospitals would submit data directly to CMS, we proposed for CY 2013 and CY 2014 that participating hospitals submit chart-abstracted data for each applicable quarter by the deadline posted on the QualityNet Web site; there must be no lapse in data submission. For the CY 2013 Hospital OQR Program, we proposed that the applicable quarters would be as follows: 3rd quarter CY 2011, 4th quarter CY 2011, 1st quarter CY 2012, and 2nd quarter CY 2012. Hospitals that did not participate in the CY 2012 Hospital OQR Program, but would like to participate in the CY 2013 Hospital OQR Program, and that have a Medicare acceptance date on the CASPER system before January 1, 2012, would begin data submission with respect to 1st quarter CY 2012 encounters using the CY 2013 measure set that was finalized in this final rule with comment period. For those hospitals with Medicare acceptance dates on or after January 1, 2012, data submission must begin with the first full quarter following the submission of a completed online participation form.

For the CY 2014 Hospital OQR Program, we proposed that the

applicable quarters for previously finalized measures would be as follows: 3rd quarter CY 2012, 4th quarter CY 2012, 1st quarter CY 2013, and 2nd quarter CY 2013. With respect to our proposed additional measures for CY 2014 (5 Diabetes measures and 1 Cardiac Rehabilitation measure), the applicable quarters would be 1st quarter CY 2013 and 2nd quarter CY 2013. Hospitals that did not participate in the CY 2013 Hospital OQR Program, but would like to participate in the CY 2014 Hospital OQR Program, and that have a Medicare acceptance date on the CASPER system before January 1, 2013, would begin data submission with respect to 1st quarter CY 2013 encounters using the CY 2014 measure set that we are finalizing in this final rule with comment period. For those hospitals with Medicare acceptance dates on or after January 1, 2013, data submission must begin with the first full quarter following the submission of a completed online participation form.

We proposed that hospitals must submit all required data according to the data submission schedule that is made available on the QualityNet Web site (*https://www.QualityNet.org*). This Web site meets or exceeds all current HIPAA requirements. Submission deadlines would be, in general, approximately 4 months after the last day of each calendar quarter. Thus, for example, the proposed submission deadline for data for services furnished during the first quarter of CY 2012 (January–March, 2012) would be on or around August 1, 2012. The actual submission deadlines would be posted on the *http://www.QualityNet.org* Web site.

We proposed that hospitals submit chart-abstracted data to the OPPS Clinical Warehouse using either the CMS Abstraction and Reporting Tool for Outpatient Department (CART–OPD) measures or the tool of a third-party vendor that meets the measure specification requirements for data transmission to QualityNet.

We proposed that hospitals must collect Hospital OQR data from outpatient hospital encounters to which the required measures apply. In previous rulemakings, we have used various terms for describing the unit of care for outpatient hospital reporting, including encounter, episode, episode of care, and discharge. We note that for outpatient hospital services, the term encounter is explicitly used and defined in the Medicare Benefit Policy Manual (Pub. 100–02), Chapter 6, Section 20.3, which states ''A hospital outpatient 'encounter' is a direct personal contact between a patient and a physician, or other person who is authorized by State licensure law and, if applicable, by hospital or CAH staff bylaws, to order or furnish hospital services for diagnosis or treatment of the patient.'' For Medicare outpatient services, the terms episode and episode of care also are used. When discussing inpatient services, the Medicare Benefit Policy Manual specifically refers to discharges; the term encounter is not used in reference to inpatient services. Thus, for the Hospital OQR Program, we are examining encounters, episodes, or episodes of care and will use these terms in connection with the Hospital OQR Program.

We will make every effort to ensure that data elements common to both inpatient and outpatient settings are defined consistently for purposes of quality reporting (such as ''time of arrival'').

We proposed that hospitals must submit quality data using the CCN under which the care was furnished.

To be accepted into the OPPS Clinical Warehouse and to meet data submission requirements, data submissions, at a minimum, must be timely, complete, and accurate. Data submissions are considered to be ''timely'' when data are successfully accepted into the OPPS Clinical Warehouse on or before the reporting deadline. A ''complete'' submission would be determined based on whether the data satisfy the sampling criteria that are published and maintained in the Hospital OQR Specifications Manual, and must correspond to both the aggregate number of encounters submitted by a hospital and the number of Medicare claims the hospital submits for payment; requirements for utilizing the option of sampling are discussed below.

We strongly recommend that hospitals review OPPS Clinical Warehouse feedback reports and the Hospital OQR Provider Participation Reports that are accessible through their QualityNet accounts. These reports enable hospitals to verify whether the data they or their vendors submitted were accepted into the OPPS Clinical Warehouse and the date/time that such acceptance occurred. We also note that irrespective of whether a hospital submits data to the OPPS Clinical Warehouse itself or uses a vendor to complete the submissions, the hospital is responsible for ensuring that Hospital OQR requirements are met.

Comment: One commenter requested clarification on data submission dates for the chart-abstracted measures OP–16, OP–18 through OP–21, and OP–23 due to statements in the CY 2011 OPPS/ASC final rule with comment period that data collection for these measures would be due in August 2012, whereas, in the CY 2012 OPPS/ASC proposed rule, the proposed timing for data collection for the CY 2013 payment determination is to begin July 1, 2011.

Response: In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72090), we finalized 23 quality measures for the CY 2013 payment determination, which included OP–16 through OP–23. We stated in that final rule that data submission of the new chart-abstracted measures for the CY 2013 payment determination will be due in August 2012. We also stated that collection for OP–16: Troponin results for Emergency Department acute myocardial infarction (AMI) patients or chest pain patients (with Probable Cardiac Chest Pain) Received Within 60 minutes of Arrival would begin with January 1, 2012 discharges (75 FR 72083).

However, in the CY 2012 OPPS/ASC proposed rule, we proposed changes to the form and manner for data collection for the chart-abstracted measure OP–22: Left Without Being Seen (76 FR 42332). We are finalizing this proposal below in section XIV.G.2.g. of this final rule with comment period.

OP–16, OP–18 through OP–21, and OP–23 are chart-abstracted measures for which data are submitted directly to CMS. We proposed the form and manner for submitting chart-abstracted data for these measures for the CY 2013 payment determination in the CY 2012 OPPS/ASC proposed rule (76 FR 42329 through 42330).

As discussed above, we have in this final rule with comment period finalized our proposal to modify the collection mechanism for OP–22: Left Without Being Seen. With respect to the CY 2013 payment determination, hospitals must submit data on this measure between July 1, 2012 and August 15, 2012 with respect to the period January 1, 2011 through December 31, 2011.

Comment: One commenter appreciated the discussion related to the harmonization of terminology around the use of the terms encounters, episodes, and episodes of care as consistent definitions are vital to data accuracy.

Response: We thank this commenter for their appreciation of the discussion related to harmonization of this terminology.

Comment: Some commenters supported the proposed data submission requirements for the Hospital OQR Program in general.

Response: We thank these commenters for their support of our proposed data submission requirements.

After consideration of the public comments we received, we are finalizing our proposals, without modification, regarding CY 2013 and CY 2014 data submission requirements for chart-abstracted measure data for OP–16, OP–18 through OP–21, and OP–23 submitted directly to CMS. Specifically, for the CY 2013 Hospital OQR Program, the applicable quarters will be as follows: 3rd quarter CY 2011, 4th quarter CY 2011, 1st quarter CY 2012, and 2nd quarter CY 2012. Submission deadlines will be, in general, approximately 4 months after the last day of each calendar quarter. Thus, for example, the proposed submission deadline for data for services furnished during the first quarter of CY 2012 (January to March, 2012) will be on or around August 1, 2012.

b. Eligibility To Voluntarily Sample and Data Submission Exception for Low Patient Volume for CY 2013 and Subsequent Years

If a hospital has a sufficiently large number of eligible encounters with respect to a measure, the hospital has the option to sample those encounters and submit data only for these sampled encounters, rather than submitting data on all of the eligible encounters. This sampling scheme, which includes the minimum number of encounters that a hospital must have in order to sample, is set out in the Hospital OQR Specifications Manual at least 3 months in advance of each data submission deadline. We note that sampling is not required and hospitals may submit more cases than the minimum set by our sampling scheme and may submit up to all of their cases if they desire to do so. We changed the notification timeframe for this sampling scheme to at least 3 months from at least 4 months to be consistent with the Hospital OQR Specifications Manual release schedule. If a hospital chooses to sample for a particular quarter, the hospital must meet the sampling requirements for the required chart-abstracted measures that quarter.

In addition, to reduce the burden on hospitals that treat a low number of patients but otherwise meet the submission requirements for a particular quality measure, we proposed to continue our policy that hospitals that have five or fewer encounters (both Medicare and non-Medicare) for any measure included in a measure topic in a quarter would not be required to submit patient level data for the entire measure topic for that quarter. Even if hospitals would not be required to submit patient level data because they have five or fewer encounters (both Medicare and non-Medicare) for any measure included in a measure topic in a quarter, we note that they may voluntarily do so.

We did not receive any public comments on our proposal for voluntary sampling and data submission exception for low patient volume for CY 2013 and subsequent years; therefore, we are finalizing our proposal without modification.

c. Population and Sampling Data Requirements Beginning With the CY 2013 Payment Determination and for Subsequent Years

During the past three years of the Hospital OQR Program, the submission of population and sampling data was not required, though hospitals could submit, on a voluntary basis, the aggregate numbers of outpatient encounters which are eligible for submission under the Hospital OQR Program and sample size counts. These aggregated numbers of outpatient encounters represent the number of outpatient encounters in the universe of all possible cases eligible for data reporting under the Hospital OQR Program. For the CY 2012 payment update, we proposed, but did not adopt, a policy to require submission of this population and sample size data.

In the CY 2012 OPPS/ASC proposed rule (76 FR 42330 through 42331), we proposed that beginning with the CY 2013 payment determination, hospitals must submit on a quarterly basis, aggregate population and sample size counts for Medicare and non-Medicare encounters for the measure populations for which chart-abstracted data must be submitted.

Under this proposal, a hospital would submit on a quarterly basis an aggregate population and sample size count with respect to each measure regardless of whether any patients met the inclusion criteria for the measure population. For example, if a hospital did not treat any patients who met the inclusion criteria for a specific measure, the hospital would still be required to submit a zero for its quarterly aggregate population and sample count to meet the requirement.

Our analysis of third quarter CY 2010 outpatient hospital submitted data shows that for hospitals that submitted abstracted data for encounters, at least 99 percent of these providers voluntarily reported both population and sampling data. Data completeness was also assessed by comparing reported Medicare cases to submitted claim counts, minimum encounter count thresholds based on reported population sizes, and minimum sample size thresholds based on reported population sizes. We found that less than 10 percent of hospitals differed significantly in their Medicare self-reported encounters versus Medicare claim counts in the Clinical Warehouse, and less than 20 percent did not meet case count or sample size minimum thresholds. Based upon this analysis, we believe that hospitals have had sufficient time to become familiar with Hospital OQR data reporting and have developed data systems necessary to support this proposed requirement; in fact, recent data suggest that the vast majority of hospitals have done so.

We proposed that the deadlines for the reporting of aggregate numbers of outpatient hospital encounters and sample size counts would be the same as those for reporting data for chart-abstracted measures, and these deadlines would be posted on the data submission schedule that would be available on the QualityNet Web site. Hospitals would be permitted to submit this information prior to the deadline; this would allow us to advise hospitals regarding their incomplete submission status as appropriate and give hospitals sufficient time to make appropriate revisions before the data submission deadline.

We stated that we plan to use the aggregate population and sample size data to assess data submission completeness to the OPPS Clinical Warehouse and adherence to sampling requirements for Medicare and non-Medicare patients.

Comment: One commenter was concerned that only 80 percent of hospitals are able to submit outpatient quality data meeting requirements for case count and sampling minimums aggregate population and sample size data. This commenter believed that this should be of concern to CMS because the commenter believed that the 20 percent of hospitals not meeting the case count or sampling minimum requirements are ones that have systematic issues such as ''complex outpatient services,'' high volume or services, and/or have some clinics that have patients who should have data reported to CMS under the Hospital OQR Program, while some other clinics owned by the hospital do not that make it difficult for them to accurately determine what minimum number of cases or cases sampled are to be submitted to meet program requirements.

Response: The percent of hospitals that show evidence of having issues with meeting sampling thresholds is less than 20 percent: more precisely, 17.3 percent in the Hospital OQR data

examined. Over 99 percent of hospitals are voluntarily reporting aggregate population and sampling data. However, due to data accuracy concerns that may exist for this small set of reporting hospitals, we have decided to not finalize this requirement for the CY 2013 payment determination.

After consideration of the public comments we received, we have decided to not finalize our proposal to require the reporting of population and sample size data and instead will continue our policy of accepting the submission of this information on a voluntary basis for the CY 2013 payment determination.

d. Claims-Based Measure Data Requirements for the CY 2013 and CY 2014 Payment Determinations

In the CY 2012 OPPS/ASC proposed rule (76 FR 42331), for the claims-based measures, we proposed to calculate the measures using the hospital's Medicare claims data as specified in the Hospital OQR Specifications Manual; no additional data submission is required for hospitals. For the CY 2013 and CY 2014 payment updates, we would utilize paid Medicare FFS claims for services furnished from January 1, 2010 to December 31, 2010 and January 1, 2011 to December 31, 2011, respectively.

We did not receive any comments on our proposal regarding the time periods for Medicare FFS claims for calculating claims-based measures for the CY 2013 and CY 2014 payment determinations; therefore, we are finalizing these proposals without modification.

e. Structural Measure Data Requirements for the CY 2013 and CY 2014 Payment Determinations

In the CY 2012 OPPS/ASC proposed rule (76 FR 42331), for the CY 2013 payment determination, we proposed that hospitals would be required to submit data on the structural measures, including OP–17: Tracking Clinical Results between Visits, between July 1, 2012 and August 15, 2012 with respect to the time period of January 1, 2011 to December 31, 2011.

As discussed above, we proposed to adopt two new structural measures for the CY 2014 payment determination, OP–31: Safe Surgery Checklist Use, and OP–32: Hospital Outpatient Department Volume for Selected Outpatient Surgical Procedures. We proposed that for the CY 2014 payment determination, hospitals would be required to submit data on all structural measures between July 1, 2013 and August 15, 2013 with respect to the time period from January 1, 2012 to December 31, 2012.

Comment: One commenter requested clarification on data submission dates for the structural measure OP–17: Tracking Clinical Results between Visits, due to statements in the CY 2011 OPPS/ASC final rule with comment period that data collection for this measure would start January 1, 2012, whereas, in the CY 2012 OPPS/ASC proposed rule, CMS proposed that the submission of data for CY 2013 payment determinations would begin July 1, 2011.

Response: In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72090), we finalized 23 quality measures for the CY 2013 payment determination, which included the structural measure OP–17: Tracking Clinical Results between Visits. We stated that hospitals would be required to begin submitting data on OP–17 via a Web-based tool on the QualityNet Web site in July 2012 for the time period January 1, 2012 through June 2012.

In the CY 2012 OPPS/ASC proposed rule, we proposed a modification to the timeframe for data collection. We stated that for all of the proposed structural measures, including OP–17: Tracking Clinical Results between Visits, hospitals would be required to submit data between July 1, 2012 and August 15, 2012 with respect to the time period of January 1, 2011 to December 31, 2011 (76 FR 42331).

After consideration of the public comment we received on our proposal regarding structural measure data requirements for the CY 2013 and CY 2014 payment determinations; we are finalizing our proposals, with modification. With respect to structural measures for the CY 2013 payment determination, hospitals will be required to submit data between July 1, 2012 and August 15, 2012 with respect to the time period from January 1, 2012 to June 30, 2012.

f. Data Submission Deadlines for the NHSN HAI Surgical Site Infection Measure for the CY 2014 Payment Determination

As discussed above, we proposed to adopt a new HAI measure for the CY 2014 payment determination: surgical site infection. We proposed to use the data submission and reporting standard procedures that have been set forth by CDC for NHSN participation in general and for submission of this measure to NHSN. We refer readers to the CDC's NHSN Web site (*http://www.cdc.gov/nhsn*) for detailed data submission and reporting procedures. We believe that these procedures are feasible because they are already widely used by over 4,000 hospitals reporting HAI data to the NHSN. Our proposal seeks to reduce hospital burden by aligning CMS data submission and reporting procedures with NHSN procedures currently used by hospitals, including hospitals complying with 28 State HAI reporting requirements. The submission timeframes for the CY 2014 payment determination that we proposed to use for the proposed HAI measure are shown below. Hospitals would be required to submit their quarterly data to the NHSN for Hospital OQR purposes according to the schedule shown in the table below (any updates to this schedule made by CMS will be posted on the QualityNet Web site).

Proposed Submission Timeframe for the Proposed Surgical Site Infection Measure for the CY 2014 Payment Determination

CY 2013 Infection Events	CDC-NHSN Collection and Quarterly Report	Final Submission Deadline for Hospital OQR Program CY 2014 Payment Determination
Q1 (Jan 1 to Mar 31, 2013)	January 31st to August 1st	August 1, 2013
Q2 (Apr 1 to Jun 30, 2013)	April 30th to November 1st	November 1, 2013

Hospitals would have until the Hospital OQR final submission deadline to submit their quarterly data to NHSN. After the final Hospital OQR Program submission deadline has occurred for each CY 2013 quarter to be used toward the CY 2014 payment determination, we will obtain the hospital-specific calculations generated by the NHSN for the Hospital OQR Program.

Comment: Many commenters stated their belief that data collection on NHSN measures by outpatient hospitals should be deferred. Commenters cited issues related to NHSN capacity, lack of experience with NHSN measures, and applicability to outpatient procedures of the NHSN Surgical Site Infection measure.

Response: We thank the commenters for their input. As discussed above, we are not finalizing the collection of any NHSN measures at this time. Thus, we are not finalizing our proposals regarding data submission deadlines for these measures at this time.

g. Data Submission Requirements for OP–22, ED-Patient Left Without Being Seen, for the CY 2013 and CY 2014 Payment Determinations

In the CY 2012 OPPS/ASC proposed rule (76 FR 42328 through 42333), with respect to OP–22: ED-Patient Left Without Being Seen, we proposed that hospitals would be required to submit data once for each of the CY 2013 and CY 2014 payment determinations via a Web-based tool located on the QualityNet Web site. For the CY 2013 payment determination, hospitals would be required to submit data between July 1, 2012 and August 15, 2012 with respect to the time period from January 1, 2011 to December 31, 2011. For the CY 2014 payment determination, hospitals would be required to submit data between July 1, 2013 and August 15, 2013 with respect to the time period of January 1, 2012 to December 31, 2012.

We invited public comment on these proposals for data collection and submission requirements and these comments are discussed in section XIV.B.2.a., above, of this final rule with comment period.

After consideration of the public comments we received, for OP–22: ED-Patient Left Without Being Seen we are finalizing our proposal on the form and manner of data collection, with a modification. Specifically, as proposed we are finalizing that for the CY 2013 payment determination, numerator and denominator counts will be collected for this measure and that these data are to be submitted to CMS via a Web-based tool from July 1, 2012 to August 15, 2012. However, based on the comments we received, we are modifying the time frames so that data collection will be prospective, and will begin for the time period from January 1, 2012 to June 30, 2012.

3. Hospital OQR Program Validation Requirements for Chart-Abstracted Measure Data Submitted Directly to CMS: Data Validation Approach for the CY 2013 Payment Determination

a. Randomly Selected Hospitals

In the CY 2012 OPPS/ASC proposed rule (76 FR 42332), similar to our approach for the CY 2012 payment determination (75 FR 72103 through 72106), we proposed to validate chart-abstracted data submitted directly to CMS from randomly selected hospitals for the CY 2013 payment determination. To reduce hospital burden and to facilitate our efforts to reallocate resources in the event that we finalize the targeting proposal discussed below, for the CY 2013 payment determination, we proposed to reduce the number of randomly selected hospitals from 800 to 450. We have found that hospitals are consistently reporting high accuracy rates for chart-abstracted measures and that variation among hospitals is relatively low. We believe that this low level of variation between hospitals will allow us to reduce the sample size while not diminishing our ability to make statistical inferences from the sample. Thus, we believe that we can safely reduce sample size and still have sufficient case numbers for purposes of validation. Because these 450 hospitals will be selected randomly, every Hospital OQR Program participating hospital will be eligible each year for validation selection. To be eligible for random selection for validation, a hospital must be coded as open in the CASPER system at the time of selection and must have submitted at least 10 encounters to the OPPS Clinical Warehouse during the data collection period for the CY 2013 payment determination. In our proposed rule, we mistakenly stated that a hospital must be coded as open in the OSCAR system; this system has been replaced by CASPER. We proposed this 10 encounter minimum so that we have a sufficient sample size for calculating a statistically valid validation score.

Comment: Several commenters supported the proposal to reduce the number of hospitals randomly selected for validation from 800 to 450. One of these commenters applauded this proposal, and encouraged continued reductions in the number of hospitals selected for validation as hospital accuracy increased. One commenter believed that the total number of hospitals (up to 500) will remain adequate to assess the reporting accuracy of various types of hospitals.

One commenter expressed concern at the severe reduction in the number of hospitals sampled for validation seemingly without justification. One commenter strongly opposed this proposal and believed that this reduced CMS' burden at the expense of validity of data publicly reported on *Hospital Compare.* One commenter opposed the proposed reduction and believed that the number of hospitals selected for validation should be increased.

Response: We thank all of these commenters for their views on the number of hospitals that should be selected for validation. Our proposal attempts to balance the burden to hospitals and cost to us with ensuring the validity of data made publicly available on *Hospital Compare*. As we stated, we have observed high levels of data accuracy, we believe that we can reduce the number of hospitals selected for validation for the CY 2013 payment determination without compromising the accuracy of the data. Under this proposal a sample of approximately 21,600 randomly selected records would be selected for validation each year, and records submitted by up to 50 additional targeted hospitals would also be validated (discussed below).

Comment: One commenter believed that the minimum number of cases a hospital should have to be subject to selection for validation should be 25 cases rather than 10.

Response: We considered larger threshold values for hospitals to be selected for validation. However, we concluded that because measure data submitted by hospitals with small case counts in the denominator currently are published on *Hospital Compare,* we have sought to select a minimum number as a threshold for validation. We have selected an absolute minimum threshold of 10 cases for validation selection in order for a sufficient sample size for calculating a statistically valid validation score.

Comment: Several commenters noted that CMS proposed separate and specific procedures for data validation of another NHSN measure under the Hospital IQR Program and requested that CMS discuss its plans for validation of data submitted through the NHSN for the Hospital OQR Program. Some of these commenters requested that in discussing such procedures, CMS provide more detail on how hospital outpatient departments would submit a list of patients and what format should

be used. One commenter noted the importance of robust and accurate data and encouraged CMS to explicitly discuss its intended plan to validate data submitted on the NHSN measures.

Response: We thank the commenters for their suggestions and agree that separate and specific procedures for validation of NHSN measure data are warranted. We intend to learn from our experiences with validating NHSN measure data under the Hospital IQR Program and apply these lessons to our future proposals for validating NHSN measure data under the Hospital OQR Program.

After consideration of the public comments we received, we are finalizing our proposals for validation without modification.

b. Use of Targeting Criteria for Data Validation Selection for CY 2013

(1) Background

In the CY 2011 OPPS/ASC proposed rule (75 FR 46381), we stated that we were considering building upon what we proposed as a validation approach for the Hospital OQR Program. We noted that we were considering, in addition to selecting a random sample of hospitals for validation purposes, selecting targeted hospitals based on criteria designed to measure whether the data these hospitals have reported raises a concern regarding data accuracy. Because hospitals had gained little experience with validation under the Hospital OQR at that time, we noted that we were considering this approach for possible use beginning with the CY 2013 payment determination. Examples of targeting criteria suggested for inclusion:

- Abnormal data patterns identified such as consistently high Hospital OQR measure denominator exclusion rates resulting in unexpectedly low denominator counts;
- Whether a hospital had previously failed validation;
- Whether a hospital had not been previously selected for validation for 2 or more consecutive years;
- Whether a hospital had low submitted case numbers relative to population sizes; or
- Whether a hospital had any extreme outlier values for submitted data elements.

We invited comment on whether, in addition to random sampling for validation, we should use targeted validation and, if so, what criteria for targeting we should adopt.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72106) we responded to the comments we received and noted that for the CY 2013 payment determination, Hospital OQR Program data reporting will have been completed for four payment determinations: CYs 2009, 2010, 2011, and 2012. Further, hospitals will have had the opportunity to learn from the validation process. We also stated that we intended to propose to implement validation targeting criteria for CY 2013 and subsequent years in the CY 2012 OPPS/ASC proposed rule.

(2) Targeting Criteria for Data Validation Selection for CY 2013

In the CY 2012 OPPS/ASC proposed rule (76 FR 42332), in addition to proposing to randomly selecting 450 hospitals for validation, we proposed to select up to an additional 50 hospitals based upon targeting criteria. A hospital could be selected for validation based on targeting criteria if it:

- Fails the validation requirement that applies to the CY 2012 payment determination; or
- Has an outlier value for a measure based on the data it submits. We proposed to define an ''outlier value'' for purposes of this targeting as a measure value that appears to deviate markedly from the measure values for other hospitals. For a normally distributed variable, nearly all values of the variable lie within 3 standard deviations of the mean; very few values lie past the 3 standard deviation mark. One definition of an outlier is a value that exceeds this threshold.[36] In order to target very extreme values, we proposed to target hospitals that greatly exceed this threshold because such extreme values strongly suggest that the data submitted is inaccurate. Specifically, we proposed to select hospitals for validation if their measure value for a measure is greater than 5 standard deviations from the mean, placing the expected occurrence of such a value outside of this range at 1 in 1,744,278. If more than 50 hospitals meet either of the above targeting criteria, then up to 50 would be selected randomly from this pool of hospitals.

Comment: Several commenters supported the use of extreme outliers as a criterion for selecting hospitals for validation. Some commenters supported using data quality concerns for targeting hospitals for validation selection.

Response: We thank these commenters for their support of our extreme outlier proposal and the use of data quality concerns for targeting hospitals for validation selection. We note that in our proposal we used a standard normal distribution for the selected outlier threshold. We have also examined data submitted under the Hospital OQR Program and found the 5 standard deviation threshold suitable for detecting extreme values for targeting hospitals based upon data quality concerns.

After consideration of the public comments we received, we are finalizing our proposal without modification.

c. Encounter Selection

In the CY 2012 OPPS/ASC proposed rule (76 FR 42332 through 42333), for each selected hospital (random or targeted), we proposed to validate up to 48 randomly selected patient encounters (12 per quarter; 48 per year) from the total number of encounters that the hospital successfully submitted to the OPPS Clinical Warehouse. If a selected hospital has submitted less than 12 encounters in one or more quarters, only those encounters available would be validated. For each selected encounter, a designated CMS contractor would request that the hospital submit the supporting medical record documentation that corresponds to the encounter.

We continue to believe that validating a larger number of encounters per hospital for fewer hospitals at the measure level has several benefits. We believe that this approach is suitable for the Hospital OQR Program because it will: (1) Produce a more reliable estimate of whether a hospital's submitted data have been abstracted accurately; (2) provide more statistically reliable estimates of the quality of care delivered in each measured hospital as well as at a national level; and (3) reduce overall burden, for example, in submitting validation documentation, because hospitals most likely will not be selected to undergo validation each year, and a smaller number hospitals per year will selected.

For all selected hospitals, we would not be selecting cases stratified by measure or topic; our interest is whether the data submitted by hospitals accurately reflects the care delivered and documented in the medical record, not what the accuracy is by measure or whether there are differences by measure or topic. We proposed to validate data for April 1, 2011 to March 31, 2012 encounters as this provides a full year of the most recent data possible to use for purposes of completing the validation in time to make the CY 2013 payment determinations.

[36] Ruan, Da, Chen, Guoguing, Kerre, Etienne E., and Wets, Geert, (2010), *Intelligent Data Mining: Techniques and Applications, Studies in Computational Intelligence,* Vol. 5, Page 318.

Comment: One commenter requested that CMS re-evaluate the sampling requirements for the Hospital OQR Program to better align them with the Hospital IQR Program and requested a reduction in sample size requirements to reduce burden on hospitals.

Response: We interpret the commenter as referring to the Hospital IQR Program sampling requirements for validation which stratify by measure and/or topic. As we have stated, we are interested in whether the data submitted by hospitals accurately reflects the care delivered and documented in the medical record, not what the accuracy is by measure or whether there are differences by measure or topic. In addition, by not stratifying by measure and/or topic, it is possible to sample fewer cases and maintain precision for reliability estimates for validation purposes.

Comment: One commenter opposed the proposal to continue the CY 2012 policy of sampling up to 12 records per quarter from hospitals selected for validation, stating their belief that this number should be reduced as burden to hospitals should be reduced, not just the burden to CMS. One commenter believed that validating a larger number of cases from a sample of hospitals has advantages over sampling a smaller number of cases from a pool of all hospitals.

Response: We thank the commenters for their views on the number of cases to be sampled from hospitals selected for validation. In setting a sample size we are attempting to balance burden to hospitals with data accuracy; sentiments mirrored in the comments received. We discussed our basis for the selection of up to 12 records per quarter or 48 per year in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72104), and the CY 2012 OPPS/ASC proposed rule (76 FR 42332 through 42333).

After consideration of the public comments we received, we are finalizing our proposals without modification.

d. Validation Score Calculation

In the CY 2012 OPPS/ASC proposed rule (76 FR 42333), for the CY 2013 payment determination, we proposed to use the validation calculation approach finalized for the CY 2012 payment determination with validation being done for each selected hospital. Specifically, we proposed to conduct a measures level validation by calculating each measure within a submitted record using the independently abstracted data and then comparing this to the measure reported by the hospital; a percent agreement would then be calculated. We would also compare the measure category for quality measures with continuous units of measurement, such as time, so that for these measures, both the category and the measure would need to match.

To receive the full OPPS OPD fee schedule increase factor for CY 2013, we proposed that hospitals must attain at least a 75 percent reliability score, based upon the proposed validation process. We proposed to use the upper bound of a two-tailed 95 percent confidence interval to estimate the validation score. If the calculated upper limit is above the required 75 percent reliability threshold, we would consider a hospital's data to be ''validated'' for payment purposes. Because we are more interested in whether the measure has been accurately reported, we would continue to focus on whether the measure data reported by the hospital matches the data documented in the medical record as determined by our reabstraction. We proposed to calculate the validation score using the same methodology we finalized for the CY 2012 payment determination (75 FR 72105). We also proposed to use the same medical record documentation submission procedures that we also finalized for the CY 2012 payment determination (75 FR 72104) with one modification.

We proposed to shorten the time period given to hospitals to submit medical record documentation to the CMS contractor from 45 calendar days to 30 calendar days. This proposed change in submission timeframe will align the process with requirements in 42 CFR 476.78(b)(2), which allow 30 days for chart submission in the context of QIO review. We proposed this deadline of 30 days also to reduce the time for data validation completion to increase timeliness of providing hospitals with feedback on their abstraction accuracy.

Comment: Many commenters opposed the proposal to reduce the time for hospitals to submit medical record documentation for validation. Some of these commenters cited burden as an issue. Some commenters expressed concern that the shortened timeframe would not allow adequate time to review records before submission for validation purposes. One commenter stated that hospitals also have records they are required to prepare for Recovery Audit Contractor (RAC) purposes. One commenter believed that this proposal would be a burden on medical and quality staff if a hospital had been selected for both outpatient and inpatient hospital quality reporting.

Response: We thank these commenters for expressing their concerns regarding this proposal. Based on these comments, we have decided to not finalize our proposal to reduce the time for hospitals to submit medical record documentation and, instead, due to issues of burden as well as consistency with other CMS programs (for example, the RAC, PERM, and CERT programs), we will retain our existing policy. Under this existing policy, the CMS contractor must receive the requested documentation by 45 calendar days from the date of the request as documented in the request letter. Other details of this policy, including the issuance of a second request letter if the hospital does not respond to the initial request within 30 days are detailed in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72104).

Comment: Some commenters agreed with reducing the time from 45 days to 30 days if the timeliness of feedback was improved.

Response: We thank these commenters for supporting our proposal to reduce the time to submit medical records for validation from 45 days to 30 days if timeliness of feedback could be improved. We agree that improved timelines of feedback is important for quality improvement.

After consideration of the public comments we received, we have decided to not finalize our proposal to reduce the time for hospitals to submit medical record documentation. As stated above, we will retain the medical record return policy that we finalized in the CY 2011 OPPS/ASC final rule for the Hospital OQR Program CY 2012 payment determination. We did not receive any comments on our proposal regarding validation score calculation. Therefore, we are finalizing this proposal without modification.

4. Additional Data Validation Conditions Under Consideration for CY 2014 and Subsequent Years

We continue to consider building upon our validation approach of targeting hospitals to address data quality concerns and to ensure that our payment decisions are made using accurate data. Thus, in the CY 2012 OPPS/ASC proposed rule (76 FR 42333), we requested public comment on the following additional targeting criteria to select hospitals for validation:

- Whether a hospital that was open under its current CCN and had not been selected for validation in the previous 3 years. This is consistent with validation targeting criteria we recently proposed to implement for the CY 2015 Hospital

IQR Program (76 FR 25920 through 25921).

- Whether a hospital had submitted a low number of encounters relative to population sizes; or
- Whether a hospital reported significant numbers of ''Unable to Determine'' data elements.

In the proposed rule we welcomed public comment on these proposals, and noted that we were specifically interested in receiving public comments on definitions of low numbers relative to population sizes and what would constitute significant numbers of ''Unable to Determine'' data elements.

Comment: Several commenters supported the idea of selecting eligible hospitals for validation if not selected in the previous 3 years, or, in other words, at least once every 4 years for validation. One commenter suggested that the time allowance for targeting a hospital for validation due to non-selection be increased from 3 years to 4 years.

Response: We appreciate the commenters' support. Regarding the suggestion that the time allowance for targeting a hospital for validation due to non-selection be increased from three years to four, if the time was increased to four years, the maximum number of years that a hospital could avoid being selected for validation would be 5 years. We believe that this timeframe is too long for a hospital that has submitted quality measure information to go without their data being validated.

Comment: One commenter expressed concerns about the criteria for how to define low numbers relative to population size and significant numbers of ''unable to determine'' data elements. The commenter stated that without a quality strategy for outpatient care, it is difficult to evaluate a low number of encounters relative to population or significant numbers of ''unable to determine.'' Another commenter suggested that statistical testing be used to determine thresholds for these proposed criteria.

Response: We thank these commenters for their thoughts on how to define low numbers relative to population size and significant numbers of ''unable to determine'' data elements in formulating these factors as targeting criteria for validation. We will take these views under consideration as we develop future proposals on these issues. We thank the commenters for all their views on these proposed criteria and will take them into account as we consider future proposals.

H. Hospital OQR Reconsideration and Appeals Procedures for CY 2013 and Subsequent Years

When the Hospital IQR Program was initially implemented, it did not include a reconsideration process for hospitals. Subsequently, we received many requests for reconsideration of those payment decisions and, as a result, established a process by which participating hospitals would submit requests for reconsideration. We anticipated similar concerns with the Hospital OQR Program and, therefore, in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66875), we stated our intent to implement for the Hospital OQR Program a reconsideration process modeled after the reconsideration process we implemented for the Hospital IQR Program. In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68779), we adopted a reconsideration process that applied to the CY 2010 payment decisions. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60654 through 60655), we continued this process for the CY 2011 payment update. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72106 through 72108), we continued this process for the CY 2012 payment update with some modification.

In the CY 2012 OPPS/ASC proposed rule (76 FR 42333 through 42334), we proposed to continue this process for the CY 2013 payment determination and subsequent years. Under this proposed process, a hospital seeking reconsideration must—

- Submit to CMS, via QualityNet, a Reconsideration Request form that will be made available on the QualityNet Web site; this form must be submitted by February 3 of the affected payment year (for example, for the CY 2013 payment determination, the request must be submitted by February 3, 2013) and must contain the following information:
  - Hospital CCN.
  - Hospital Name.
  - CMS-identified reason for not meeting the requirements of the affected payment year's Hospital OQR Program as provided in any CMS notification to the hospital.
  - Hospital basis for requesting reconsideration. This must identify the hospital's specific reason(s) for believing it met the affected year's Hospital OQR Program requirements and should receive the full OPD fee schedule increase factor.
  - CEO and any additional designated hospital personnel contact information, including name, email address, telephone number, and mailing address (must include physical address, not just a post office box).
  - A copy of all materials that the hospital submitted to comply with the requirements of the affected year's Hospital OQR Program. Such material might include, but does not need to be limited to, the applicable Notice of Participation form or completed online registration form, and measure data that the hospital submitted via QualityNet.
- Paper copies of all the medical record documentation that it submitted for the initial validation (if applicable). We proposed that hospitals would submit this documentation to a designated CMS contractor which would have authority to review patient level information. We would post the address where hospitals are to send this documentation on the QualityNet Web site.
- To the extent that the hospital is requesting reconsideration on the basis that CMS has determined it did not meet an affected year's validation requirement, the hospital must provide a written justification for each appealed data element classified during the validation process as a mismatch. Only data elements that affect a hospital's validation score would be eligible to be reconsidered. We would review the data elements that were labeled as mismatched as well as the written justifications provided by the hospital, and make a decision on the reconsideration request.

We note that, consistent with our policy for CY 2012 reconsiderations, reconsideration request forms would not need to be signed by the hospital's CEO.

Following receipt of a request for reconsideration, CMS would—

- Provide an email acknowledgement, using the contact information provided in the reconsideration request, to the CEO and any additional designated hospital personnel notifying them that the hospital's request has been received.
- Provide a formal response to the hospital CEO and any additional designated hospital personnel, using the contact information provided in the reconsideration request, notifying the hospital of the outcome of the reconsideration process.

We intend to complete any reconsideration reviews and communicate the results of these determinations within 90 days following the deadline for submitting requests for reconsideration.

We also proposed to apply the same policies that we finalized for the CY 2012 payment determination regarding the scope of our review when a hospital requests reconsideration because it

failed our validation requirement. These policies are as follows:

- If a hospital requests reconsideration on the basis that it disagrees with a determination that one or more data elements were classified as mismatches, we would only consider the hospital's request if the hospital timely submitted all requested medical record documentation to the CMS contractor each quarter under the validation process.
- If a hospital requests reconsideration on the basis that it disagrees with a determination that one or more medical records it submitted during the quarterly validation process was classified as an invalid record selection (that is, the CMS contractor determined that one or more medical records submitted by the hospital did not match what was requested, thus resulting in a zero validation score for the encounter(s)), our review would initially be limited to determining whether the medical documentation submitted in response to the designated CMS contractor's request was the correct documentation. If we determine that the hospital did submit the correct medical documentation, we would abstract the data elements and compute a new validation score for the encounter. If we conclude that the hospital did not submit the correct medical record documentation, we would not further consider the hospital's request.
- If a hospital requests reconsideration on the basis that it disagrees with a determination that it did not submit the requested medical record documentation to the CMS contractor within the proposed 30 calendar day timeframe, our review would initially be limited to determining whether the CMS contractor received the requested medical record documentation within 30 calendar days, and whether the hospital received the initial medical record request and reminder notice. If we determine that the CMS contractor timely received paper copies of the requested medical record documentation, we would abstract data elements from the medical record documentation submitted by the hospital and compute a validation score for the hospital. If we determine that the hospital received two letters requesting medical documentation but did not submit the requested documentation within the 30 calendar day period, we would not further consider the hospital's request.

If a hospital is dissatisfied with the result of a Hospital OQR reconsideration decision, the hospital would be able to file an appeal under 42 CFR Part 405, Subpart R (PRRB appeal).

In the proposed rule we invited public comment on our proposed CY 2013 Hospital OQR Program reconsideration and appeals procedures.

Comment: Some commenters supported our proposal to continue for CY 2013 and subsequent years' payment determinations our program reconsideration and appeals procedures currently in place.

Response: We thank these commenters for their support of our Hospital OQR Program reconsideration and appeals procedures.

Comment: One commenter encouraged CMS to be more prescriptive than, as stated in the proposal, the intention of having reconsideration reviews completed and communication of the results of these determinations to hospitals within 90 days given that hospitals were not allowed this leeway in submission timeframes.

Response: We believe that the commenter is stating a desire for a commitment that we will complete reconsideration reviews and communicate decisions results to hospitals in 90 day days or less after the submission deadline timeframe. As reconsideration requests can involve extensive research and information review, among other time consuming processes, often the full 90 day time-frame is necessary to complete the process in a thorough manner. In some more complex cases, the 90 days may not be enough. Note that, when the reconsideration process can be completed in a shorter time-frame, we can and have communicated the results in less than 90 days. We intend where possible to complete any reconsideration requests and to communicate the results of our decision within 90 days.

After consideration of the public comments we received, we are finalizing our proposals without modification.

I. Electronic Health Records (EHRs)

Starting with the FY 2006 IPPS final rule, we have encouraged hospitals to take steps toward the adoption of EHRs (also referred to in previous rulemaking documents as electronic medical records) that will allow for reporting of clinical quality data from EHRs to a CMS data repository (70 FR 47420 through 47421). We sought to prepare for future EHR submission of quality measures by sponsoring the creation of electronic specifications for quality measures under consideration for the Hospital IQR Program. Through the EHR Incentive Programs, we expect that the submission of quality data through EHRs will provide a foundation for establishing the capacity of hospitals to send, and for CMS, in the future, to receive, quality measures via hospital EHRs for Hospital IQR and OQR Program measures. We expect the Hospital IQR and Hospital OQR Programs to transition to the use of certified EHR technology, for measures that otherwise require information from the clinical record. This would allow us to collect data for measures without the need for manual chart abstraction.

In the FY 2012 IPPS/LTCH PPS proposed rule (75 FR 25894), we identified FY 2015 as a potential transition date to move to EHR-based submission and phase out manual chart abstraction. We also anticipate such a transition for hospital outpatient measures, although likely somewhat after the transition for hospital inpatient measures. This is a result of the fact that the clinical quality measures in the EHR Incentive Program currently are primarily aligned with the Hospital IQR Program, rather than the Hospital OQR Program. Our goals are to align the hospital quality reporting programs, to seek to avoid redundant and duplicative reporting of quality measures for hospitals, and to rely largely on EHR submission for measures based on clinical record data.

Comment: A commenter recommended that prior to CY 2015, CMS offer a voluntary test period of at least one year and omit public reporting, in order to allow hospitals to submit data, refine electronic submission process to ensure accuracy and validity of data flows. The commenter was also concerned about the potential inaccurate calculations generated from certified EHRs and urged CMS not to publicly report the Stage 1 clinical quality measure (CQM) data reported and not to use them as a baseline for future quality reporting programs, such as a value-based purchasing program.

Response: We understand that hospitals need to gain experience in electronic data submission. The 2012 Medicare EHR Incentive Program Electronic Reporting Pilot (2012 Electronic Reporting Pilot) (discussed below) that we proposed is voluntary and last for one year. This Pilot would provide eligible hospitals and CAHs the opportunity to report clinical quality measures using certified EHR technology. We thank the commenter for the feedback on certified EHR technology and we will communicate that to the ONC for further evaluation. We also note that at present, CQMs reported through attestation under the EHR Incentive Program are not publicly

reported and we do not plan to publish the CQMs reported through the 2012 Electronic Reporting Pilot. The only information that we expect to make publicly available are the names of hospitals that have received an incentive payment under the EHR Incentive Program. We will provide further education and outreach to stakeholders on the reporting process for the 2012 Electronic Reporting Pilot in FY 2012. For hospitals that may be concerned about the accuracy of the results calculated by their certified EHR technology, we would suggest that they contact their vendors about these issues.

Comment: A commenter requested clarification regarding the validation of quality measures submitted through certified EHR technology after manual chart-abstraction is phased out.

Response: For reporting clinical quality measures under the EHR Incentive Program, the eligible hospital or CAH must attest to the output that is generated from its certified EHR technology. We are still in the process of developing validation strategy for quality measures submitted through certified EHR technology after manual chart-abstraction is phased out.

Comment: A commenter stated that CMS must ensure that the electronic measure is comparable to the original manual chart-abstracted measure. The commenter noted that any potential electronic retooling of the measures must not undermine the scientific basis and data integrity of the measures.

Another commenter suggested that for easy understanding by healthcare professionals, the e-specifications for EHR submission of quality measures should be written in simple language while maintaining the accuracy of data element definitions. The commenter believed it is critical for CMS to create measure specifications to ensure discrete data are applicable to measures without contradicting documentation in ''free text'' and ''scanned document'' areas of the medical record.

Response: We agree that electronic measures should be comparable to the original manual chart-abstracted measures and we thank the commenter for the suggestions on the creation of user-friendly e-specifications that align with medial record documentations. We are collaborating with the NQF, measure stewards, and the ONC to develop the accurate, easy to understand, and medical-record compatible electronic specifications while maintaining the integrity of the measures as endorsed.

Comment: Some commenters discussed their CQM reporting experience for Stage 1 meaningful use. Commenters indicated that extra efforts were required to manipulate the certified EHR products to generate accurate quality data. For this reason, some commenters had misgivings about the testing of the e-measure specifications. In addition, commenters were concerned whether corrections or updates, such as new medications to treat patients with stroke, were communicated and adopted timely by vendors. Some commenters did not believe EHR vendors have the capacity to keep up with the constant changes in electronic measures and related specifications. Moving forward, some commenters requested that CMS establish a transparent process to manage specification updates to quality measures, as well as a mechanism through which vendors and providers can provide feedback on problematic measures. The commenters noted that the existing CQMs require a level of clinical documentation and the use of coded data fields that are far more extensive than other Stage 1 Meaningful Use objectives.

Response: We thank the commenters for the feedback. We are continuing to work with ONC to resolve the identified concerns. Generally, the e-measure specifications we adopt undergo rigorous development processes and e-specification updates and new specifications are timely communicated to vendors. We thank the commenters for their suggestions on the transparent process to manage updates and will take them into consideration for future planning.

Comment: Commenters recommended that CMS conduct a different pilot program to field test the measures used in the HITECH EHR Incentive Program for the purpose of determining the ability of vendors and hospitals to accurately capture the necessary data in the required formats to generate, valid, reliable and comparable quality measures directly from the EHRs.

Response: CMS agrees that it is important to obtain input from the vendors, providers, and measure stewards about the electronic specifications. We thank the commenters for the suggestions for a pilot program to test measures in the field. Currently, we are working with the various stakeholders to define this process.

Comment: A commenter requested clarification whether the information related to the Hospital IQR Program contained in CMS' FAQ (Answer ID10589: ''CMS does not require any additional information beyond what is generated from certified EHR technology in order to satisfy the requirement for submitting CQM information'') also applies to e-measures in the Hospital OQR Program. If it does, the amount of data obtained from e-measures will differ in the Hospital IQR and Hospital OQR Programs.

Response: The reporting requirements are separate for each program. At this time there are different and separate reporting requirements for the EHR Incentive Program, the Hospital IQR Program, and the Hospital OQR Program.

J. 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs

1. Background

In the CY 2012 OPPS/ASC proposed rule (76 FR 42334 through 42336), we proposed changes to the methods by which eligible hospitals and CAHs would report clinical quality measures for the 2012 payment year and subsequent years for the Medicare EHR Incentive Program. Specifically, we proposed that for the 2012 payment year and subsequent years, eligible hospitals and CAHs may continue to report clinical quality measure results as calculated by certified EHR technology by attestation, as for the 2011 payment year. Alternatively, for the 2012 payment year, eligible hospitals and CAHs would be able to participate in a proposed 2012 Electronic Reporting Pilot. We proposed to revise our regulations at § 495.8(b)(2)(ii) and proposed to add § 495.8(b)(2)(vi), which would reflect these proposals for reporting CQMs through attestation and the 2012 Electronic Reporting Pilot.

2. Electronic Reporting Pilot

Section 1886(n)(3)(B)(ii) of the Act provides authority for the Secretary to accept information on CQMs electronically on a pilot basis. We proposed that eligible hospitals and CAHs participating in the Medicare EHR Incentive Program may meet the CQM reporting requirement of the EHR Incentive Program for payment year 2012 by participating in an Electronic Reporting Pilot. We proposed that participation in this Electronic Reporting Pilot would be voluntary and that eligible hospitals and CAHs may continue to attest to the results of CQMs calculated by certified EHR technology as they did for the 2011 payment year.

We encouraged participation in the proposed Electronic Reporting Pilot in view of our desire to adequately pilot electronic submission of CQMs and to move to a system of reporting where eligible hospitals and CAHs can qualify for CQM reporting for both the Hospital IQR and Hospital OQR Programs, and

the EHR Incentive Program. We strongly encouraged eligible hospitals and CAHs to participate in the proposed Electronic Reporting Pilot as it provides opportunities to test the interoperability and functionality of the certified EHR technology that they have implemented. We believe that the participation of eligible hospitals and CAHs in the proposed Electronic Reporting Pilot would help advance EHR-based reporting in the Hospital IQR and Hospital OQR Programs.

Eligible hospitals and CAHs would need to be registered in order to participate in the proposed Electronic Reporting Pilot. Eligible hospitals and CAHs wishing to participate in the proposed Electronic Reporting Pilot for the CQMs would register by indicating their desire and intent to participate in the proposed Electronic Reporting Pilot as part of the attestation process for the Medicare EHR Incentive Program. We proposed that eligible hospitals and CAHs that participate in the proposed Electronic Reporting Pilot and meet its submission requirements would satisfy the requirements for reporting clinical quality measures under the Medicare EHR Incentive Program. Such eligible hospitals and CAHs would therefore not need to attest to the results of clinical quality measures calculated by certified EHR technology. As described below, for the purpose of the proposed Electronic Reporting Pilot, CMS would calculate the results of the clinical quality measures for eligible hospitals and CAHs based on patient level data submitted for Medicare patients. The proposed Electronic Reporting Pilot would require eligible hospitals and CAHs to submit information on the same 15 CQMs that were listed in Table 10 of the final rule for the Medicare and Medicaid EHR Incentive Programs (75 FR 44418 through 44420) and such information would be obtained from the certified EHR technology used by the eligible hospital or CAH.

We proposed that electronic submission of the 15 CQMs through this proposed Electronic Reporting Pilot would be sufficient to meet the core objective for reporting CQMs for the Medicare EHR Incentive Program for the 2012 payment year. Since the reporting of CQMs is only one of the 14 core meaningful use objectives for eligible hospitals and CAHs for the Medicare EHR Incentive Program, an eligible hospital or CAH that chooses to participate in the proposed Electronic Reporting Pilot would still be required to meet and attest to the other core and menu set objectives and their associated measures using the attestation module for the program on the CMS Web site.

We stated that after the eligible hospital or CAH had attested and CMS had received electronic submission of the CQMs from an eligible hospital or CAH participating in the proposed Electronic Reporting Pilot, CMS would determine whether the eligible hospital or CAH has successfully met all the requirements for the Medicare EHR Incentive Program. We expect this determination would be made within 2 months after the end of the payment year and not later than November 30, 2013. Eligible hospitals and CAHs that do not meet the reporting requirements through the Electronic Reporting Pilot may meet such requirement through attestation. We proposed that eligible hospitals and CAHs, alternatively, may attest, but still participate in the proposed Electronic Reporting Pilot.

Comment: A commenter requested more clarification on the purpose of this Pilot, which appears to duplicate other quality measurement programs.

Response: The specific purpose of the 2012 Electronic Reporting Pilot is to provide a method for eligible hospitals and CAHs to electronically report the clinical quality measures for the EHR Incentive Program. We recognize that there may be some overlap between the 2012 Electronic Reporting Pilot and other quality reporting programs but we expect electronic reporting will be aligned and harmonized across Medicare quality reporting programs over time.

Comment: Some commenters strongly supported the proposed 2012 Electronic Reporting Pilot, which they perceived as a great opportunity for hospitals to test interoperability and functionality of their certified EHR technology while allowing CMS to evaluate the compatibility of electronic measure specifications and chart-abstracted data. Commenters recommended that CMS should be flexible with the implementation timelines for the pilot to ensure the viability and successful functionality of this new reporting method.

Response: We appreciate the commenters' support of the proposed 2012 Electronic Reporting Pilot. If the proposed timelines for the Electronic Reporting Pilot are not feasible for an eligible hospital or CAH, attestation would continue to be an acceptable method for reporting the clinical quality measures for the 2012 payment year.

Comment: Some commenters believed that the 2012 Electronic Reporting Pilot would be instrumental in shaping and facilitating the mechanisms for electronic reporting by eligible hospitals and CAHs in the near future. A commenter asked CMS to clarify the options for attestation and participation in the 2012 Electronic Reporting Pilot.

Response: We thank the commenters for their support. As we stated in the proposed rule, the 2012 Electronic Reporting Pilot would be an alternative to reporting CQMs by attestation for the 2012 payment year. Eligible hospitals and CAHs may choose to report CQMs by attestation and voluntarily participate in the 2012 Electronic Reporting Pilot simultaneously. We will provide more education and outreach to stakeholders on the reporting process for the 2012 Electronic Reporting Pilot in 2012.

Comment: A commenter recommended making the 2012 Electronic Reporting Pilot a viable option for all hospitals, including safety net hospitals, so that CMS can gauge the unique challenges to electronic reporting by a diverse group of hospitals. Another commenter suggested CMS should allow all hospitals to participate in the 2012 Electronic Reporting Pilot regardless of whether they participated in the EHR Incentive Program. A commenter recommended providing an additional incentive for 2012 Electronic Reporting Pilot participants to increase participation.

Response: We plan to engage a variety of hospitals and vendors in the testing of the submission of patient level reports for the clinical quality measures required in the pilot. The submitter will not be required to register in the registration and attestation module before submitting the test files. More information about the testing period will be available in 2012. Although we appreciate the commenter's recommendation, the amounts of the incentive payments are limited by statute and we do not have the authority to award additional amounts for participation in the 2012 Electronic Reporting Pilot.

Comment: One commenter requested delaying the 2012 Electronic Reporting Pilot until 2013.

Response: Based on the amount of support from public comments and our desire to advance the electronic reporting of quality measures, we have decided to implement the Electronic Reporting Pilot for the 2012 payment year as proposed. We recognize that the 2012 Electronic Reporting Pilot may not be suitable for all eligible hospitals and CAHs. To that end, we anticipate only those eligible hospitals and CAHs that are most ready to transmit clinical quality measure information from their certified EHR technology would participate in the 2012 Electronic Reporting Pilot. Participation in the pilot is not required to be a meaningful

user of certified EHR technology. Eligible hospitals and CAHs that are not interested in participating in the pilot would report the clinical quality measures by attestation as was required for the 2011 payment year. We refer readers to the discussion of the reporting method for the 2011 payment year in the HITECH EHR Incentive Program final rule (75 FR 44430 through 44431).

Comment: A commenter requested a detailed analysis of the incapability of the PQRI 2009 Registry XML Specification content exchange standard in conveying aggregate hospital quality measures data from EHRs. The commenter also suggested CMS consult with hospitals and vendors on the need to move to electronic reporting from the current attestation model, given relative costs and benefits.

Response: We suggest that the commenter should contact the Office of the National Coordinator for Health Information Technology (ONC) with any questions or concerns about the PQRI 2009 Registry XML Specification content exchange standard. ONC's Web site address is *http://healthit.hhs.gov*. We appreciate the suggestion to consult with hospitals and vendors about the need to move from the current attestation model to electronic reporting and will take it into consideration for future planning.

After consideration of the public comments we received, we are finalizing as proposed the voluntary 2012 Electronic Reporting Pilot for eligible hospitals and CAHs participating in the Medicare EHR Incentive Program for the 2012 payment year. Eligible hospitals and CAHs also may choose to attest to the results of CQMs calculated by certified EHR technology as for the 2011 payment year. We also are revising our regulations at § 495.8(b)(2) as proposed. Successful electronic submission of the 15 CQMs required for eligible hospitals and CAHs through this 2012 Electronic Reporting Pilot will be sufficient to meet the core objective of reporting hospital CQMs to CMS under the Medicare EHR Incentive Program for the 2012 payment year.

3. CQM Reporting Under the Electronic Reporting Pilot

In the CY 2012 OPPS/ASC proposed rule (76 FR 42336), we proposed that eligible hospitals and CAHs participating in the proposed 2012 Electronic Reporting Pilot must submit CQM data on all 15 CQMs listed in Table 10 of the final rule (75 FR 44418 through 44420) to CMS via a secure portal and based on data obtained from the eligible hospital or CAH's certified EHR technology.

We proposed that eligible hospitals and CAHs participating in the proposed Electronic Reporting Pilot would: (1) Submit CQM data on Medicare patients only; (2) submit Medicare patient-level data from which CMS may calculate CQM results using a uniform calculation process, rather than aggregate results calculated by the eligible hospital or CAH's certified EHR technology; (3) submit one full Federal fiscal year of CQM data, regardless of the eligible hospital or CAH's year of participation in the Medicare and Medicaid EHR Incentive Programs; and (4) use electronic specifications for transmission as specified by CMS, which we expected would be Quality Data Reporting Architecture (QRDA) Level I. (We note that we used the term ''Level 1'' in the CY 2012 OPPS/ASC proposed rule (76 FR 42336). ''Level 1'' is used interchangeably with the term ''Category I'' to denote patient-level data. In order to be consistent with the Implementation Guide for Clinical Document Architecture Release 2, we are using the term ''Category 1'' instead of the term ''Level I'' in this final rule with comment period.)

As noted previously, for the proposed 2012 Electronic Reporting Pilot, CQM data on which the eligible hospital or CAH's submission is based would be obtained from certified EHR technology. However, the functionality of reporting these CQMs to CMS would not rely on the certification process. We proposed that eligible hospitals and CAHs participating in the proposed Electronic Reporting Pilot would report CQMs based on a pilot measurement period of one full Federal fiscal year (October 1, 2011 through September 30, 2012), regardless of whether the eligible hospital or CAH is in its first year of participation in the Medicare and Medicaid EHR Incentive Programs. The period for submitting information on CQMs under the proposed 2012 Electronic Reporting Pilot would be October 1, 2012 through November 30, 2012, which is the 60 days following the close of the measurement period. The CQM reporting format would be as specified by CMS, which we expected would be QRDA Category I. We proposed to offer a test period beginning July 1, 2012, which would allow eligible hospitals, CAHs, or their designee to submit CQM reports to CMS with the requirements that would be used in the proposed 2012 Electronic Reporting Pilot.

Comment: Some commenters stated that if QRDA Category I is going to be implemented, vendors will need time to develop, test, and deploy this functionality. Commenters urged CMS to provide a Web site for vendors to test their implementation of the transmission standard and a sample set of test data to ensure that the results are consistent.

Response: We will provide a test period before and during the submission period as well as additional education and outreach to the industry in advance to assist 2012 Electronic Reporting Pilot participants with transmitting electronic quality measure data. We thank the commenters for the suggestions for sample test data and will take that into consideration should the Pilot be extended beyond the one-year time frame.

Comment: A commenter supported the collection of patient-level data. Another commenter was concerned about the significant resource and system burden from the submission of patient-level data. Furthermore, the structure and content of the patient-level data elements were not clear to the commenter. The commenter urged CMS to accept the submission of aggregate-level data which can be compiled from certified EHR technology. Additionally, a commenter was concerned that QRDA is not a sufficiently well-tested and mature standard, compared to the PQRI XML format (contained in the certified EHR technology), which the commenter believed is well-tested for submission of aggregate quality measure data. The commenter strongly urged CMS to strive to modify the PQRI XML format for suitability for electronic transmission of patient-level quality measure data for the 2012 Electronic Reporting Pilot.

Response: We do not believe there will be additional burdens from the submission of patient-level data because eligible hospitals are already submitting patient-level data to CMS under the Hospital IQR Program. Also, we anticipate that the certified EHR technology vendors will work with the requirements necessitated by the Pilot to serve the best interest of hospitals. We will strive to ensure that hospitals participating in the Pilot are provided with the resources needed to understand the structure and content of the patient-level data elements. One important purpose of the 2012 Electronic Reporting Pilot is to test the QRDA Category I format for the transmission of patient-level CQM data. Therefore, we do not intend to modify the PQRI XML format for suitability to transmit patient-level data.

Comment: A commenter stated that the proposed 2012 Electronic Reporting Pilot seems to require a reporting period of one full year, while the reporting

period for eligible hospitals and CAHs not participating in the pilot is only 90 days. The commenter requested standardizing the reporting period to 90 days for both the 2012 Electronic Reporting Pilot participants and non-participants to level the playing field, based on concerns that requiring one full year of data would delay the receipt of incentive payments for eligible hospitals and CAHs that are in their first payment year. The commenter strongly believed that the proposed one-year measurement period is a disincentive for provider participation in the pilot, as eligible hospitals and CAHs would have to complete one whole year of data collection before receiving their EHR incentive payment.

Response: We understand the commenter's concerns. However, for testing purposes, we believe the pilot measurement period should be one full year for consistency with the EHR reporting period that is required for eligible hospitals and CAHs beginning in their second payment year under the Medicare EHR Incentive Program. Eligible hospitals and CAHs should note that the 2012 Electronic Reporting Pilot is voluntary. Hospitals that begin Stage 1 in FY 2012 would have a 90-day reporting period if they choose to report CQMs by attestation. We encourage participation in the 2012 Electronic Reporting Pilot because we believe it is a valuable learning process as we move to electronic submission of CQMs.

Comment: Some commenters recommended that CMS should only collect numerator, denominator, and exclusionary data. Commenters also requested CMS to provide explanation why aggregate data submission is not piloted.

Response: We still collect numerator, denominator, and exclusion data from eligible hospitals and CAHs who choose to report CQMs by attestation. The reason we collect patient-level data in the 2012 Electronic Reporting Pilot is to align with the data reported to the Hospital IQR Program, as part of our efforts to reduce burdens on the hospitals that participate in that program.

Comment: A few commenters assumed that CMS intends to test the use of the HL7 Standard QRDA Category I, which has been developed to support reporting on quality data from EHRs, and may use it for the future. Based on this assumption, some commenters requested CMS to collaborate with ONC to remove the PQRI 2009 Registry content exchange standards from the certification requirements, as they will not be used.

Response: Because this is a pilot and is meant to test alternative ways for electronic reporting to take place, we do not believe it is necessary or appropriate to collaborate with ONC to remove the PQRI 2009 XML Registry specification as the basis of certification.

Comment: One commenter was concerned that the collection of patient-level data would not comply with the HIPAA requirements.

Response: The HIPAA Privacy Rule at 45 CFR 164.512(a) permits disclosures of protected health information that are required by law, including regulation. Eligible hospitals and CAHs that choose to participate in the 2012 Electronic Reporting Pilot would be required to submit patient-level data.

Comment: A commenter recommended the collection of all-payer data, instead of just Medicare data, in order to advance the utilization of all-payer database.

Response: We thank the commenter for the suggestion. The pilot is designed to collect Medicare patient data. We will analyze the Medicare patient data we receive in this 2012 Electronic Reporting Pilot and evaluate the feasibility of collecting all-payer data in the future.

Comment: A commenter was concerned about the significant resource and system burden from the submission of patient-level data using QRDA. The commenter questioned CMS' ability to receive and analyze the huge amount of patient-level data and was concerned that the huge QRDA Category I files may slow down CMS' data processing. Some commenters recommended that CMS and other measure vendors work with HL7 to create, ballot, and test a generic standard (perhaps QRDA Category II) conformable to NQF's Quality Data Model and the Model and the Health Quality Measure Format (HQMF) standard that would allow for computer-to-computer interoperable exchange of discrete data.

Response: We thank the commenters for their valuable input. QRDA Category I will be piloted in the 2012 Electronic Reporting Pilot, but it may not be the eventual transmission format used for all EHR CQM reporting. We will use the 2012 Electronic Reporting Pilot experience to evaluate the level of complexity, effort, and burden created by this transmission format. This analysis will be considered in future program designs.

Comment: A commenter was concerned about the potential security risks of patient data and urged CMS to build a security protection mechanism modeled after the Quality Improvement Organization (QIO) warehouse system. Some commenters recommended that CMS should require providers to submit their patient-level data to a QIO Clinical Data Warehouse, which would then transmit quality data to CMS.

Response: We have security standards in place to receive patient-level data in the Hospital IQR and OQR Programs. We will continue to utilize secure data transmission standards in all reporting programs at CMS. We also note that certified EHR technology is a requirement of participation in the pilot, and that a core objective of meaningful use addresses security validation.

Comment: A commenter suggested that the 2012 Electronic Reporting Pilot also test electronic measures and not just transmission of quality data to CMS. The commenter also encouraged CMS to solicit feedback from participants and non-participants of the 2012 Electronic Reporting Pilot.

Response: The 2012 Electronic Reporting Pilot will test file submission while certified EHR technology is certified for its ability to electronically calculate CQM specifications required by CMS. We welcome feedback from participants and non-participants in the 2012 Electronic Reporting Pilot.

After consideration of the public comments we received, we are finalizing our proposals for reporting CQM data under the 2012 Electronic Reporting Pilot. Among other requirements, eligible hospitals and CAHs participating in the 2012 Electronic Reporting Pilot must: (1) Submit CQM data on Medicare patients only; (2) submit Medicare patient-level data from which CMS may calculate CQM results using a uniform calculation process, rather than aggregate results calculated by the eligible hospital or CAH's certified EHR technology; (3) submit one full Federal fiscal year of CQM data, regardless of the eligible hospital or CAH's year of participation in the Medicare and Medicaid EHR Incentive Programs; and (4) use QRDA Category I format data transmission.

K. ASC Quality Reporting Program

1. Background

Section 109(b) of the MIEA TRHCA amended section 1833(i) of the Act by re-designating clause (iv) as clause (v) and adding new clause (iv) to paragraph (2)(D) and by adding new paragraph (7). Section 1833(i)(2)(D)(iv) of the Act authorizes, but does not require, the Secretary to implement the revised ASC payment system ''in a manner so as to provide for a reduction in any annual update for failure to report on quality measures in accordance with paragraph (7).'' Section 1833(i)(7)(A) of the Act

states that the Secretary may provide that any ASC that does not submit quality measures to the Secretary in accordance with paragraph (7) will incur a 2.0 percentage point reduction to any annual increase provided under the revised ASC payment system for such year. It also specifies that a reduction for one year cannot be taken into account in computing any annual increase factor for a subsequent year.

Section 1833(i)(7)(B) of the Act provides that, ''[e]xcept as the Secretary may otherwise provide,'' the hospital outpatient quality data provisions of subparagraphs (B) through (E) of section 1833(t)(17) of the Act shall apply to ASCs in a similar manner to the manner in which they apply under these paragraphs to hospitals under the Hospital OQR Program and any reference to a hospital, outpatient setting, or outpatient hospital services is deemed a reference to an ASC, the setting of an ASC, or services of an ASC, respectively. Section 1833(t)(17)(B) of the Act requires that hospitals submit quality data in a form and manner, and at a time, that the Secretary specifies.

Section 1833(t)(17)(C)(i) of the Act requires the Secretary to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings, that these measures reflect consensus among affected parties and, to the extent feasible and practicable, that these measures include measures set forth by one or more national consensus building entities. Section 1833(t)(17)(C)(ii) of the Act allows the Secretary to select measures that are the same as (or a subset of) the measures for which data are required to be submitted under the Hospital IQR Program.

Section 1833(t)(17)(D) of the Act gives the Secretary the authority to replace measures or indicators as appropriate, such as where all hospitals are effectively in compliance or the measures or indicators have been subsequently shown not to represent the best clinical practice. Section 1833(t)(17)(E) of the Act requires the Secretary to establish procedures for making data submitted under the Hospital OQR Program available to the public. Such procedures include providing hospitals with the opportunity to review their data before these data are released to the public. For a more detailed discussion of the provisions in section1833(t)(17) of the Act, please see the CY 2011 OPPS/ASC final rule with comment period (75 FR 72064 through 72065) and this final rule with comment period.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66875), the CY 2009 OPPS/ASC final rule with comment period (73 FR 68780), the CY 2010 OPPS/ASC final rule with comment period (74 FR 60656), and the CY 2011 OPPS/ASC final rule with comment period (75 FR 72109), we did not implement a quality data reporting program for ASCs. We determined that it would be more appropriate to allow ASCs to acquire some experience with the revised ASC payment system, which was implemented for CY 2008, before implementing new requirements, such as public reporting of quality measures. However, in these rules, we indicated that we intend to implement the provisions of section 109(b) of the MIEA–TRHCA in the future.

In preparation for proposing an ASC Quality Reporting Program, in the CY 2011 OPPS/ASC proposed rule, we solicited public comment on the following measures under consideration for ASC quality data reporting: (1) Patient Fall in the ASC; (2) Patient Burn; (3) Hospital Transfer/Admission; (4) Wrong Site, Side, Patient, Procedure, Implant; (5) Prophylactic IV Antibiotic Timing; (6) Appropriate Surgical Site Hair Removal; (7) Surgical Site Infection; (8) Medication Administration Variance (MAV); (9) Medication Reconciliation; and (10) VTE Measures: Outcome/Assessment/ Prophylaxis (75 FR 46383).

In addition to preparing to propose implementation of an ASC Quality Reporting Program, HHS developed a plan to implement a value-based purchasing (VBP) program for payments under the Medicare program under title XVIII of the Act for ASCs as required by section 3006(f) of the Affordable Care Act, as added by section 10301(a) of the Affordable Care Act. We also submitted a Report to Congress, as required by section 3006(f)(4) of the Affordable Care Act, entitled ''Medicare Ambulatory Surgical Center Value-Based Purchasing Implementation Plan'' that contains this plan. This report is found on our Web site at: *http://www.cms.gov/ASCPayment/downloads/C_ASC_RTC%202011.pdf*. Currently, we do not have express statutory authority to implement an ASC VBP program. Should there be legislation to authorize CMS to implement an ASC VBP program, we will develop the program and propose it through rulemaking.

In the CY 2012 OPPS/ASC proposed rule (76 FR 42336 through 42349), we proposed to implement the ASC Quality Reporting Program beginning with the CY 2014 payment determination, with data collection beginning in CY 2012 for most of the measures to be used for the CY 2014 payment determination.

Comment: One commenter stated that it was unclear if there are any payment penalties for not participating in ASC quality data reporting and that if there are payment penalties, how would they be calculated. Several commenters stated their belief that the payment penalty for non-reporting or not meeting reporting requirements be lowered for at least the initial payment penalty year, recommending a 0.4 percentage point reduction for CY 2014, rather than a 2 percentage point reduction. Some of these commenters noted that a 0.4 percentage point reduction is consistent with the Hospital IQR Program.

Response: The payment reduction for not participating in ASC quality reporting is set by statute. Section 1833(i)(7)(A) of the Act states that the Secretary may provide that any ASC that does not submit quality measures to the Secretary as specified will incur a 2.0 percentage point reduction to any annual increase provided under the revised ASC payment system for such year. We intend to propose in the CY 2013 OPPS/ASC proposed rule the method for how these payment penalties will be calculated. We note that although the payment reduction under the Hospital IQR Program was initially a 0.4 percentage point reduction to the applicable percentage increase, the payment reduction has, since FY 2007, been 2.0 percentage points. (Beginning with FY 2015, the payment reduction will be one-quarter of the applicable percentage increase (determined without regard to sections 1886(b)(3)(B)(ix), (xi), or (xii) of the Act).)

Comment: Many commenters appreciated CMS' plan to implement an ASC Quality Reporting Program but strongly urged CMS to delay the start of required data submission from the proposed January 1, 2012 to October 1, 2012 at the earliest, in order for ASCs to have sufficient time to prepare and adapt to the new reporting procedures. A few commenters noted that a new quality reporting program warrants at least 6 months of advance notice to providers, who would have to make substantive changes to data elements and operation systems. Commenters cited the example of ASCs' inexperience in reporting data using Quality Data Codes (QDCs) as well as reporting to NHSN as efforts that would require tremendous time, training and resources to initiate.

Many commenters believed it would be prudent for CMS to allow ASCs to submit quality data initially on a trial basis for a time period from January 1,

2012 through September 30, 2012. Commenters asserted that ASCs need this trial period to test their systems and resolve any problems that may arise.

Response: We thank the commenters for their support for the ASC Quality Reporting Program. We strongly believe this program is an important milestone in the alignment of quality of care across HOPDs and ASC settings. We acknowledge the new challenges faced by ASCs in preparation for this quality reporting program. Based on public comments, we will delay required data submission until October 1, 2012 for the CY 2014 payment determination. More information regarding measure submission timeframes and other program requirements can be found in the ''Form, Manner and Timing'' section of this final rule with comment period.

After consideration of the public comments we received, we are finalizing the ASC Quality Reporting Program, with data collection to begin on October 1, 2012.

2. ASC Quality Reporting Program Measure Selection

a. Timetable for Selecting ASC Quality Measures

In the CY 2012 OPPS/ASC proposed rule (76 FR 42337), we proposed to adopt measures for three CY payment determinations for the ASC Quality Reporting Program in this rulemaking. We proposed to adopt measures for the CYs 2014, 2015, and 2016 payment determinations. We stated, to the extent that we finalize some or all of the measures for future payment determinations, we would not be precluded from adopting additional measures or changing the list of measures for future payment determinations through annual rulemaking cycles so that we may address changing program needs arising from new legislation or from changes in HHS and CMS priorities. Under this approach, in the CY 2013 or CY 2014 rulemaking cycle, we could propose any additions or revisions to the measures we adopted in the CY 2012 rulemaking cycle for the CY 2014 payment determination or for future payment determinations. This is consistent with our approach to proposing measures for multiple payment determinations for the Hospital IQR and Hospital OQR Programs. We believe this proposed process will assist ASCs in planning, meeting future reporting requirements, and implementing quality improvement efforts. We also would have more time to develop, align, and implement the infrastructure necessary to collect data on the measures and make payment determinations. This flexibility would enable us to adapt the program to support changes in HHS and CMS priorities and any new legislative requirements. In the proposed rule, we invited public comments on this proposal.

Comment: A few commenters supported the multi-year approach which is perceived as great opportunities for ASCs to gain understanding of measure specifications, data collection and data submission methodologies while CMS develops needed infrastructure to collect quality data on ASCs.

Response: We thank the commenters for the support of the multi-year proposals for ASC quality measures.

After consideration of the public comments we received, we are finalizing our proposal to adopt quality measures for the CY 2014, CY 2015, and CY 2016 payment determinations. We discuss the quality measures that we are finalizing for these CYs below.

b. Considerations in the Selection of Measures for the ASC Quality Reporting Program

Section 1833(i)(7)(B) of the Act states that section 1833(t)(17)(C) of the Act shall apply with respect to ASC services in a similar manner in which they apply to hospitals for the Hospital OQR Program, except as the Secretary may otherwise provide. The requirements at section 1833(t)(17)(C)(i) of the Act state that measures developed shall ''be appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings and that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.''

In selecting proposed measures for the ASC Quality Reporting Program and other quality reporting programs, we have focused on measures that have a high impact on and support HHS and CMS priorities for improved health care outcomes, quality, safety, efficiency and satisfaction for patients. Our goal for the future is to expand any measure set adopted for ASC quality reporting to address these priorities more fully and to align ASC quality measure requirements with those of other reporting programs as appropriate, including the Hospital OQR Program, the Hospital IQR Program, the PQRS, and reporting requirements implemented under the HITECH Act so that the burden for reporting will be reduced. In general, we prefer to adopt measures that have been endorsed by the NQF because it is a national multi-stakeholder organization with a well-documented and rigorous approach to consensus development. However, as we have noted in previous rulemaking for the Hospital OQR Program (75 FR 72065), the requirement that measures reflect consensus among affected parties can be achieved in other ways, including through the measure development process, through broad acceptance and use of the measure(s), and through public comment.

In developing this and other quality reporting programs, as well as the Hospital VBP Program, we applied the following principles for the development and use of measures. In the proposed rule, we invited public comment on these principles in the ASC quality reporting context.

- Pay-for-reporting, public reporting, and value-based purchasing programs should rely on a mix of standards, process, outcomes, and patient experience of care measures, including measures of care transitions and changes in patient functional status. Across all programs, we seek to move as quickly as possible to the use of primarily outcome and patient experience measures. To the extent practicable and appropriate, outcome and patient experience measures should be adjusted for risk or other appropriate patient population or provider/supplier characteristics.
- To the extent possible and recognizing differences in payment system maturity and statutory authorities, measures should be aligned across public reporting and payment systems under Medicare and Medicaid. The measure sets should evolve so that they include a focused core set of measures appropriate to the specific provider/supplier category that reflects the level of care and the most important areas of service and measures for that provider/supplier.
- The collection of information should minimize the burden on providers/suppliers to the extent possible. To this end, we will continuously seek to align our measures with the adoption of meaningful use standards for HIT, so that data can be submitted and calculated via certified EHR technology with minimal burden.
- To the extent practicable and feasible, and within the scope of our statutory authorities for various quality reporting and value-based purchasing programs, measures used by CMS should be endorsed by a national, multi-stakeholder organization. Measures should be aligned with best practices among other payers and the needs of the end users of the measures.

We believe that ASC facilities are similar, insofar as the delivery of surgical and related nonsurgical services, to HOPDs. Similar standards and guidelines can be applied between hospital outpatient departments and ASCs with respect to surgical care improvement, given that many of the same surgical procedures are provided in both settings. Measure harmonization assures that comparable care in different settings can be evaluated in similar ways, which further assures that quality measurement can focus more on the needs of a patient with a particular condition rather than on the specific program or policy attributes of the setting in which the care is provided. In general, our goal is to adopt harmonized measures that assess the quality of care given across settings and providers/suppliers and to use the same measure specifications based on clinical evidence and guidelines for the care being assessed regardless of provider/supplier type or setting. This harmonization goal is also supported by a commenter to the CY 2011 OPPS/ASC proposed rule, who recommended CMS align ASC quality measures with State and other Federal requirements (75 FR 72109).

Our CY 2014 measure proposals for ASCs align closely with those discussed in the Report to Congress entitled ''Medicare Ambulatory Surgical Center Value-Based Purchasing Implementation Plan'' and with those proposed for future consideration in the CY 2011 OPPS/ASC proposed rule (75 FR 46383). Furthermore, the measures that we proposed for ASCs fall into the parameter of our stated framework for the ASC Quality Reporting Program, discussed above. The initial measure set that we proposed for the CY 2014 payment determination addresses outcome measures and infection control process measures. Six of the eight initial measures that we proposed for the CY 2014 payment determination are recommended by the ASC Quality Collaborative (ASC QC) and are NQF-endorsed. The seventh measure that we proposed is appropriate for measuring ambulatory surgical care, is NQF-endorsed, is currently in use in the PQRS, and is similar to a measure that is being used in the Hospital OQR Program, and therefore aligns across settings in which outpatient surgery is performed. We proposed collecting these seven measures via ''quality data codes'' to be placed on Part B claims submitted by ASCs for Medicare fee-for-service patients beginning January 1, 2012. The eighth measure we proposed for the CY 2014 payment determination is an outcome measure of surgical site infection to be submitted in 2013 via the CDC's NHSN. Similarly, hospital inpatient departments will begin reporting this measure to the CDC under the Hospital IQR Program in 2012, and we also proposed that hospital outpatient departments begin reporting this measure to the CDC under the Hospital OQR Program in 2013. Thus, this measure would be aligned across quality reporting programs for facilities performing surgery.

Comment: Several commenters supported all the proposed NQF-endorsed measures for ASCs and also believed that all ASC quality reporting measures should be NQF-endorsed, regardless of the measures' endorsement by other national multi-stakeholder organizations. Some commenters noted that ASC measures should focus on facility-level data and not physician-level data.

Response: Under section 1833(i)(7)(B) and (t)(17)(C)(i) of the Act, except as the Secretary may otherwise provide, the Secretary must develop measures that reflect consensus among affected parties and, to the extent feasible and practicable, must include measures set forth by a national consensus building entity. Whenever possible, we strive to adopt NQF-endorsed measures because these measures will meet these requirements, as discussed above. However, we believe that the requirement that measures reflect consensus among affected parties can be achieved in other ways, including through the measure development process, through broad acceptance and use of the measure, and through public comments. Further, it may not be feasible or practicable to adopt an NQF-endorsed measure, such as when an NQF-endorsed measure does not exist. Section 1833(t)(17)(C)(i) of the Act does not require that each measure we adopt for the ASC Quality Reporting Program be endorsed by a national consensus building entity, or by the NQF specifically. Further, section 1833(i)(7)(B) of the Act states that section 1833(t)(17) of the Act, which contains this requirement, applies to the ASC Quality Reporting Program, except as the Secretary may otherwise provide. Under this provision, the Secretary has further authority to adopt measures that do not reflect consensus among affected parties and are not endorsed by a national consensus building entity. We wish to clarify that these measures would be submitted by facilities, not physicians, and that the data for the measures will be displayed at the facility level.

Comment: A commenter stated that several distinct factors should be considered in the selection of measures for ASCs: (1) The diversity in the case mix across ASCs (that is, a single subspecialty ASC (for example, endoscopy centers) versus a ''multi-specialty'' ASC may require exemptions based on case mix or low volume); (2) Hospital OQR Program measure specifications may not be relevant for all ASCs; (3) the reporting burden for most ASCs which are classified as small business; and (4) the use of EHRs in ASCs is not widespread.

Response: We have considered these factors in selecting measures for the ASC Quality Reporting Program. In general, we have sought to select measures that are broadly applicable to ASCs, given the diversity in case mix and ASC specialty. The majority of the measures selected for CY 2014, CY 2015 and CY 2016 for this program are applicable regardless of the types of procedures performed at a particular facility. We will consider the usefulness of specialty-specific measures as well as exemptions based on case mix or low volume for ASCs as we gain experience with the measures we are adopting and as we develop future measures. We also sought to align the ASC measures with measures selected for other settings/providers that perform surgeries, such as HOPDs. However, we acknowledge that not all procedures that are performed in HOPDs are performed in ASCs, and hence that some Hospital OQR measures may not be as relevant for ASCs or may need to be tailored to the types of procedures approved to be performed in ASCs. We also understand that most ASCs are small businesses for which data collection burden or EHR adoption may pose challenges. Therefore, in order to reduce burden, we proposed and are finalizing only claims-based measures for the first year of the program and adding only structural measures in the second year of the program.

Comment: A few commenters were disappointed that no patient experience of care measures were proposed for ASCs. The commenters encouraged CMS to facilitate voluntary patient experience of care measures for ASCs.

Response: We are considering a patient experience of care survey for the ASC Quality Reporting Program, and will also consider the operational feasibility of allowing voluntary reporting of such a measure in the future.

3. ASC Quality Measures for the CY 2014 Payment Determination

a. Claims-Based Measures Requiring Submission of Quality Data Codes (QDCs) Beginning January 1, 2012

In the CY 2012 OPPS/ASC proposed rule (76 FR 42338 through 42342), we proposed to adopt seven NQF-endorsed claims-based measures, six of which were developed by the ASC QC. The ASC QC is a cooperative effort of organizations and companies formed in 2006 with a common interest in ensuring that ASC quality data is measured and reported in a meaningful way. Stakeholders in the ASC QC include ASC corporations, ASC associations, professional societies and accrediting bodies that focus on ASC quality and safety. The ASC QC initiated a process of standardizing ASC quality measure development through evaluation of existing nationally endorsed quality measures to determine which could be directly applied to the outpatient surgery facility setting. The ASC QC in its ASC Quality Measure Implementation Guide version 1.4 states that ''it focused on outcomes and processes that ASC facilities could influence or impact, outcomes that ASC facilities would be aware of given their limited contact with the patient, and outcomes that would be understandable and important to key stakeholders in ASC care, including patients, providers and payers.''

The ASC QC developed and pilot-tested five facility-level measures (Patient Burn; Patient Fall in the ASC; Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; Hospital Transfer/Admission, and Prophylactic IV Antibiotic Timing) for feasibility and usability. On November 15, 2007, these five measures were endorsed by the NQF. On September 25, 2008, a sixth ASC QC-developed facility-level measure, ''Appropriate Surgical Site Hair Removal'' was NQF-endorsed as ''Ambulatory Surgery Patients with Appropriate Method of Hair Removal.'' Of the six ASC QC measures, the Prophylactic IV Antibiotic Timing and Ambulatory Surgery Patients with Appropriate Method of Hair Removal measures are infection control process measures, and the rest are outcome measures. All six of these measures were listed as under consideration in the CY 2011 OPPS/ASC proposed rule (75 FR 46383). We proposed these six measures for use in the CY 2014 payment determination.

The seventh claims-based measure we proposed for the CY 2014 payment determination is Selection of Prophylactic Antibiotic: First OR Second Generation Cephalosporin. This measure was developed by the AMA's Physician Consortium for Performance Improvement, a national, diverse, physician-led group that identifies, develops, and promotes implementation of evidence-based clinical performance measures that reflect best practices. This measure is NQF-endorsed. It is an infection control process measure and is currently adopted in the Hospital IQR Program and the PQRS.

We proposed to collect all seven measures using the claims-based quality data codes (QDCs) data collection mechanism. We proposed to require ASCs to report on ASC claims a quality data code (QDC) to be used for reporting quality data. We proposed that an ASC would need to add a QDC to any claim involving a proposed claims-based quality measure. We stated that CMS is in the process of developing QDCs for each proposed claims-based quality measure and the QDC would be a CPT Category II code or a HCPCS Level II G-code if an appropriate CPT code is not available. We stated that more information on the QDCs that would be associated with the proposed quality measures will be provided in this CY 2012 OPPS/ASC final rule with comment period. Additionally, we proposed to create a new ASC payment indicator ''M5'' (Quality measurement code used for reporting purposes only; no payment made) for assignment to the QDC to clarify that no payment is associated with the QDC for that claim. We stated that, if one or more of these measures are finalized as proposed, an ASC would need to begin submitting these QDCs on any Medicare Part B claims pertaining to the measures on January 1, 2012.

For the first six measures listed, the ASC QC measures specifications can be found at *http://www.ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pdf.*[37] For the seventh measure, the specifications can be found on the PQRS Web site at: *http://www.cms.gov/pqrs/downloads/2011_PhysQualRptg_MeasuresGroups_SpecificationsManual_033111.pdf?agree=yes&next=Accept.*

Comment: Commenters generally supported most of the proposed measures for CY 2014 and requested harmonization of the measures with the Hospital OQR Program as appropriate, so that comparative quality data is available to consumers. A commenter requested that CMS provide measure benchmarks for ASCs to assess how they stack up against their peers.

Response: We thank the commenters for the support of our intent to align and harmonize measures across Hospital OQR and ASC Quality Reporting Programs to keep consumers better informed when making outpatient care decisions. When publicly displaying measures, we provide State and national averages whenever possible for comparative purposes. For the Hospital IQR Program, we provide benchmarks using the Achievable Benchmarks of Care methodology at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228768205297*. We also provide such benchmarks for the Hospital OQR measures at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228768205213*. However, such information is provided for informational purposes and quality improvement purposes and should not be interpreted as performance standards.

Comment: Several commenters believed that the number of measures proposed for ASCs is excessive and recommended that CMS adopt three patient safety measures initially to allow ASCs more time to gain experience with quality reporting.

Response: We are mindful of the potential burden on ASCs when we contemplated measures for ASCs. We determined that the initial adoption of claims-based measures would ease the data collection burden on ASCs while providing sufficient time for ASCs to gain experience with quality reporting. To that end, instead of proposing chart-abstracted measures, we proposed seven claims-based measures and 1 NHSN-based reporting measure for the first year of ASC Quality Reporting Program. As discussed below, in this final rule with comment period, we are finalizing only five of the seven claims-based measures we proposed for CY 2014 payment determination. In addition, we are delaying the data collection until October 1, 2012 for the claims-based measures for the CY 2014 payment determination.

Comment: Several commenters supported the submission of QDCs on administrative claims which they believed are less burdensome, given that ASCs already submit a CMS–1500 form for each Medicare beneficiary served. A few commenters were concerned about the potential burden caused by the use CPT II codes—QDCs and questioned why CMS cannot adopt the same data

[37] ASC Quality Measures: Implementation Guide Version 1.4, ASC Quality Collaboration, December 2010.

collection code process used in Hospital OQR Program claims-based measures. Some commenters were very concerned that proposed method of collection via QDCs has not been tested for the ASC setting. One commenter believed that the PQRS experienced problems using QDCs.

Response: We agree with the commenters that stated that QDCs are a low-burden method of collecting quality data. The information needed for the current claims-based measures used in the Hospital OQR Program can be captured using solely ICD–9 codes and CPT–I codes placed on claims submitted to CMS. This is not the case for the ASC quality measures, because the type of information needed to assess whether numerator events occurred for these measures (and for some of the measures, events that help define the denominator) are not captured in these two coding systems. This type of information can be captured using the CPT–II and G-codes that would be placed on claims in addition to the ICD–9 codes and CPT–I codes used to capture diagnoses and procedure codes.

The other method that could have been used to collect information for these measures is submission of retrospectively chart-abstracted data elements to CMS separately from claims. However, we determined that this method of data collection for these measures may be more burdensome for ASCs than submitting CPT–II codes and G-codes on the claims for these measures in addition to the ICD–9 and CPT–I codes that they submit to CMS for payment purposes. In order to submit quality data using CPT–II and HCPCS codes, ASCs would need to add the appropriate QDCs for measure numerators and denominators on Medicare Part B claim forms. Based on the public comments we received, we are deferring the start date of required submissions of QDCs for the ASC Quality Reporting Program to October 1, 2012.

The QDCs are a means of data collection for quality measures that is already in use in PQRS. PQRS has received quality measure information via QDCs reported via claims since the program's inception in 2007. From 2007 through 2008, there were instances where QDCs were reported incorrectly and therefore deemed invalid due to a number of reasons. These reasons included: diagnosis mismatch; gender mismatch; reporting the QDC on a denominator code not contained within the measure; and reporting an invalid modifier (PQRS uses 1P, 2P, 3P and 8P modifiers to represent performance exclusions and performance not met instances). However, in recent reporting years, we have seen the QDC errors decrease to a very low percentage (less than 1 percent errors are QDC-related) attributed to providers' progressive experience with QDCs, our education and outreach efforts, as well as our streamlining of diagnosis-specific QDCs. Therefore, we believe that over time, ASCs will have the same success as PQRS with QDC-based measures.

Comment: For future options for data submission, a commenter suggested using ASC-specific registry which is under consideration for development by registry developers.

Response: We thank the commenter for the suggestion. In our search for future quality measures for ASCs, we will consider ASC-specific registry-based measures.

The seven proposed claims-based measures are discussed in more detail below:

(1) Patient Burns (NQF #0263)

The ASC Quality Measures: Implementation Guide Version 1.4 states that every patient receiving care in an ASC setting has the potential to experience a burn during an episode of care, given the multitude of factors that could pose risks for patient burns in the surgical and procedural settings. The Guide cited a recent publication from the ECRI Institute that relates an increased risk of burns associated with newer electrosurgical devices due to their application of higher electrical current for longer time intervals. Other common sources of burns in a surgical setting include chemical and thermal sources, and radiation, scalds, and fires. Clinical practice guidelines for reducing the risk of burns have been established by the American Society of Anesthesiologists (ASA) and Association of Operating Room Nurses (AORN).

This NQF-endorsed measure assesses the percentage of ASC admissions experiencing a burn prior to discharge. The specifications for this NQF-endorsed measure developed by the ASC QC can be found at: *http://www.ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pdf*. The ASC QC in their ASC Quality Measure Implementation Guide version 1.4 defines a ''burn'' for purposes of this measure as ''[u]nintended tissue injury caused by any of the six recognized mechanisms: scalds, contact, fire, chemical, electrical or radiation (for example, warming devices, prep solutions, and electrosurgical unit or laser).'' We believe that this measure would allow stakeholders to develop a better understanding of the incidence of these events and further refine means to ensure prevention.

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. We believe that this measure is appropriate to measure quality in ASCs since they serve surgical patients who may face the risk of burns during ambulatory surgical procedures. Furthermore, we believe that this measure meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it was developed by the ASC QC and is endorsed by the NQF.

In the proposed rule, we invited public comment on our proposal to adopt this measure for the CY 2014 payment determination using the claims-based QDC data collection mechanism for ASC services furnished for Medicare patients from January 1, 2012 through December 31, 2012 (76 FR 42339). While the NQF-endorsed specification for this measure includes all ASC admissions, our proposal to use information submitted on claims to calculate these measures requires that we restrict the measure population to the population for which CMS receives claims. Therefore, for this program, we would need to calculate the measures based on claims submitted for ASC services furnished to Medicare fee-for-service beneficiaries. NQF has indicated to us that our proposal to use Medicare Part B claims submitted by ASCs to calculate the measure consistently with the measure specification is an appropriate application of the NQF-endorsed measure to a subset of patients who are part of the broader population to which the measure applies. As stated in the CY 2012 OPPS/ASC proposed rule, if this measure is finalized, ASCs would need to place QDCs relevant to this measure on Medicare Part B claims beginning January 1, 2012 in order to report this measure for purposes of the CY 2014 payment determination.

Comment: Several commenters supported the proposed measure, but noted that this measure does not apply to GI ASCs since the risk of burn in conjunction with endoscopic procedures is rare and minor.

Response: We thank the commenters for the support of the measure. The denominator for the NQF-endorsed

measure is all ASC admissions. NQF has indicated to us that our proposal to use Medicare Part B claims submitted by ASCs to calculate the measure consistently with the measure specification is an appropriate application of the NQF-endorsed measure. Therefore, the measure is applicable to all Medicare Part B ASC admissions It addresses ''[u]nintended tissue injury caused by any of the six recognized mechanisms: scalds, contact, fire, chemical, electrical or radiation (for example, warming devices, prep solutions, and electrosurgical unit or laser).'' Although patient burns may be rare in GI ASCs, we believe that inclusion of the measure in the ASC Quality Reporting Program will help ensure that such burns never happen. We refer commenters to the specifications for this measure for more information.

After consideration of the public comments we received, we are finalizing this measure for the CY 2014 payment determination with data collection to begin on October 1, 2012 (as discussed in section XIV.K.1. of this final rule with comment period).

(2) Patient Fall (NQF #0266)

Falls, particularly in the elderly, can cause injury and loss of functional status, and falls in healthcare settings can be prevented through assessment of risk, care planning, and patient monitoring. Healthcare settings are being called upon to report patient falls and to take steps to reduce the risk of falls. The ASC QC indicates in their ASC quality measure implementation guide the use of anxiolytics, sedatives, and anesthetic agents may put patients undergoing outpatient surgery at increased risk for falls. Guidelines and best practices for the prevention of falls, and management of patients after falls have been made available by the Agency for Healthcare Research and Quality (*http://www.ahrq.gov/qual/transform.htm*), and the National Center for Patient Safety (*http://www.patientsafety.gov*).

This NQF-endorsed measure assesses the percentage of ASC admissions experiencing a fall in the ASC. The specifications for this NQF-endorsed measure developed by the ASC QC can be found at: *http://www.ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pdf*.

The ASC QC in its ASC Quality Measure Implementation Guide version 1.4 defines a ''fall'' as ''a sudden, uncontrolled, unintentional, downward displacement of the body to the ground or other object, excluding falls resulting from violent blows or other purposeful actions'', which is consistent with the definition set forth by the National Center for Patient Safety.

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. We believe that this measure is appropriate to measure quality in ASCs because it was specifically developed to measure quality of surgical care furnished by ASCs, as measured by patient falls. Furthermore, we believe that this measure meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it was developed by the ASC QC and is NQF-endorsed.

In the proposed rule, we invited public comment on our proposal to adopt this measure for the CY 2014 payment determination using the claims-based QDC data collection mechanism for ASC services furnished for Medicare fee-for-service beneficiaries from January 1, 2012 through December 31, 2012 (76 FR 42339). While the NQF-endorsed specification for this measure includes all ASC admissions, our proposal to use information submitted on claims to calculate the measures requires that we restrict the measure population to the population for which CMS receives claims. Therefore, for this program, we would need to calculate the measures based on claims submitted for ASC services furnished to Medicare fee-for-service beneficiaries. NQF has indicated to us that our proposal to use Medicare Part B claims submitted by ASCs to calculate the measure consistently with the measure specification is an appropriate application of the NQF-endorsed measure to a subset of patients who are part of the broader population to which the measure applies. As stated in the CY 2012 OPPS/ASC proposed rule, if this measure is finalized, ASCs would need to place QDCs relevant to this measure on Medicare Part B claims beginning January 1, 2012 in order to report this measure for purposes of the CY 2014 payment determination.

Comment: All the commenters who commented on this measure supported the proposed measure but were concerned about the proposed data collection starting on January 1, 2012.

Response: We thank the commenters for the support of the measure. As stated in XIV.K.1. of this final rule with comment period, we are delaying the beginning of the data collection until October 1, 2012.

After consideration of the public comments we received, we are finalizing this measure for the CY 2014 payment determination with data collection to begin on October 1, 2012.

(3) Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267)

Surgeries and procedures performed on the wrong site/side, and wrong patient can result in significant impact on patients, including complications, serious disability or death. While the prevalence of such serious errors may be rare, such events are considered serious reportable events, and are included in the NQF's *Serious Reportable Events in Healthcare 2006 Update*.[38] The Joint Commission has issued a Universal Protocol to prevent such serious surgical errors.[39] The proposed NQF-endorsed measure assesses the percentage of ASC admissions experiencing a wrong site, wrong side, wrong patient, wrong procedure, or wrong implant. The ASC QC in its *ASC Quality Measures:* Implementation Guide Version 1.4 defines ''wrong'' as ''not in accordance with intended site, side, patient, procedure or implant.'' The specifications for this NQF-endorsed measure developed by the ASC QC can be found at: *http://www.ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pdf*.

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. We believe that this measure is appropriate to measure quality in ASCs because the measure assesses the quality of surgical care provided in ASCs as measured by the percentage of surgical errors. Furthermore, we believe that this measure meets the consensus

[38] *http://www.qualityforum.org/Publications/2007/03/Serious_Reportable_Events_in_Healthcare%E2%80%932006_Update.aspx*

[39] Joint Commission. Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery. Available at *http://www.jointcommission.org/standards_information/up.aspx*. Last accessed December 14, 2010.

requirement and the requirement that it be set forth by a national consensus building entity because it was developed by the ASC QC and is endorsed by the NQF.

In the proposed rule we invited public comment on our proposal to adopt this measure for the CY 2014 payment determination using the claims-based QDC data collection mechanism for ASC services furnished for Medicare patients from January 1, 2012 through December 31, 2012 (76 FR 42340). While the NQF-endorsed specification for this measure includes all ASC admissions, our proposal to use information submitted on claims to calculate these measures requires that we restrict the measure population to the population for which CMS receives claims. Therefore, for this program, we would need to calculate the measures based on claims submitted for ASC services furnished to Medicare fee-for-service beneficiaries. NQF has indicated to us that our proposal to use Medicare Part B claims submitted by ASCs to calculate the measure consistently with the measure specification is an appropriate application of the NQF-endorsed measure to a subset of patients who are part of the broader population to which the measure applies. As stated in the CY 2012 OPPS/ASC proposed rule, if this measure is finalized, ASCs would need to place QDCs relevant to this measure on Medicare Part B claims beginning January 1, 2012 in order to report this measure for purposes of the CY 2014 payment determination.

Comment: All of the commenters who commented on this measure supported the proposed measure. However, some commenters indicated that this measure may not apply to GI ASCs since the risk of performing wrong site, wrong side, wrong patient, wrong procedure, and wrong implant in ASC endoscopic procedures is rare (for example, confusion over an upper GI endoscopy and colonoscopy, or a single procedure in one encounter versus both an upper endoscopy and colonoscopy in the same encounter). Also, commenters were concerned about the proposed data collection starting on January 1, 2012.

Response: We thank the commenters for the support of the measure. As discussed above, this measure is applicable to all Medicare Part B ASC admissions. Although this type of mishap may be rare, we believe that inclusion of the measure in the ASC Quality Reporting Program will help ensure they will never happen. Note that, as stated in section XIV.K.1. of this final rule with comment period, we are delaying the beginning of the data collection until October 1, 2012.

After consideration of the public comments we received, we are finalizing this measure for the CY 2014 payment determination with data collection to being on October 1, 2012.

(4) Hospital Transfer/Admission (NQF #0265)

The transfer or admission of a surgical patient from an outpatient setting to an acute care setting can be an indication of a complication, serious medical error, or other unplanned negative patient outcome. While acute intervention may be necessary in these circumstances, a high rate of such incidents may indicate suboptimal practices or patient selection criteria. The proposed NQF-endorsed measure assesses the rate of ASC admissions requiring a hospital transfer or hospital admission upon discharge from the ASC. The ASC QC defines ''hospital transfer/admission'' as ''any transfer/admission from an ASC directly to an acute care hospital, including hospital emergency room.''

The specifications for this NQF-endorsed measure developed by the ASC QC measure can be found at: *http://www.ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pdf.* The ASC QC believes that this ''measure would allow ASCs to assess their guidelines for procedures performed in the facility and patient selection if transfers/admissions are determined to be at a level higher than expected. If commonalities are found in patients who are transferred or admitted, guidelines may require revision.''

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. We believe this measure is appropriate to measure quality in ASCs because it assesses outpatient surgical care quality in the form of the rate of surgical outpatients needing acute care interventions. Furthermore, we believe that this measure meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it was developed by the ASC QC and is endorsed by the NQF.

In the proposed rule we invited public comment on our proposal to adopt this measure for the CY 2014 payment determination using the claims-based QDC data collection mechanism for ASC services furnished for Medicare patients from January 1, 2012 through December 31, 2012 (76 FR 42340). While the NQF-endorsed specification for this measure includes all ASC admissions, our proposal to use information submitted on claims to calculate these measures requires that we restrict the measure population to the population for which CMS receives claims. Therefore, for this program, we would need to calculate the measures based on claims submitted for ASC services furnished to Medicare fee-for-service beneficiaries. NQF has indicated to us that our proposal to use Medicare Part B claims submitted by ASCs to calculate the measure consistently with the measure specification is an appropriate application of the NQF-endorsed measure to a subset of patients who are part of the broader population to which the measure applies. As stated in the CY 2012 OPPS/ASC proposed rule, if the measure is finalized, ASCs would need to place QDCs relevant to this measure on Medicare Part B claims beginning January 1, 2012 in order to report this measure for purposes of the CY 2014 payment determination.

Comment: All of the commenters who commented on this measure supported the proposed measure. However, one commenter noted that the measure should be expanded to include patients who return home after ASC procedure, but are then admitted to a hospital shortly after for a procedure-related issue. The commenter urged CMS to create methods to track the adverse outcomes of these patients.

Response: We thank the commenters for their support. We also thank the commenter for the suggestion, and will consider it in future measure development and refinement.

After consideration of the public comments we received, we are finalizing this measure for the CY 2014 payment determination with data collection to begin on October 1, 2012 (as discussed in section XIV.K.1. of this final rule with comment period).

(5) Prophylactic Intravenous (IV) Antibiotic Timing (NQF #0264)

Timely preoperative administration of intravenous antibiotics to surgical patients is an effective practice in reducing the risk of developing a surgical site infection, which in turn is associated with reduced health care burden and cost, and better patient outcomes.[40] [41] [42] The measurement of

[40] Classen, D. *et al.*: The timing of prophylactic administration of antibiotics and the risk of surgical wound infection. NEJM. 1992;326(5):281–286.

Continued

timely antibiotic administration for surgical patients is occurring in the Hospital IQR Program, Hospital OQR Program and the PQRS. The NQF-endorsed ASC QC measure assesses the rate of ASC patients who received IV antibiotics ordered for surgical site infection prophylaxis on time. The specifications for this NQF-endorsed measure developed by the ASC QC measure can be found at: *http://www.ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pdf*.

The ASC QC measure implementation guide defines ''antibiotic administered on time'' as ''[a]ntibiotic infusion … initiated within one hour prior to the time of the initial surgical incision or the beginning of the procedure (e.g., introduction of endoscope, insertion of needle, inflation of tourniquet) or two hours prior if vancomycin or fluoroquinolones are administered.'' The measure also defines ''prophylactic antibiotic'' as ''an antibiotic prescribed with the intent of reducing the probability of an infection related to an invasive procedure. For purposes of this measure, the following antibiotics are considered prophylaxis for surgical site infections: Ampicillin/sulbactam, Aztreonam, Cefazolin, Cefmetazole, Cefotetan, Cefoxitin, Cefuroxime, Ciprofloxacin, Clindamycin, Ertapenem, Erythromycin, Gatifloxacin, Gentamicin, Levofloxacin, Metronidazole, Moxifloxacin, Neomycin and Vancomycin.'' All prophylactic IV antibiotics administered for surgical site infection would need to have their infusion initiated within the one hour time frame, except for vancomycin or fluoroquinolones, where infusion must be initiated within the two hours time frame. The ASC QC Guide states that ''[i]n cases involving more than one antibiotic, all antibiotics must be given within the appropriate time frame in order for the case to meet criteria.'' The timing of the antibiotic starts at the time the antibiotic is initiated with a preoperative order.

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. We believe this measure is appropriate to measure quality in ASCs because it assesses the quality of care for surgical patients in an outpatient setting as measured by timely antibiotic administration. Furthermore, we believe that this measure meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it was developed by the ASC QC and is endorsed by the NQF.

In the proposed rule, we invited public comment on our proposal to adopt this measure for the CY 2014 payment determination using the claims-based QDCs data collection mechanism for ASC services furnished for Medicare patients from January 1, 2012 through December 31, 2012 (76 FR 42341). While the NQF-endorsed specification for this measure includes all ASC admissions with a preoperative order for a prophylactic IV antibiotic for prevention of surgical site infection, our proposal to use information submitted on claims to calculate these measures requires that we restrict the measure population to the population for which CMS receives claims. Therefore, for this program, we would need to calculate the measures based on claims submitted for ASC services furnished to Medicare fee-for-service beneficiaries. NQF has indicated to us that our proposal to use Medicare Part B claims submitted by ASCs to calculate the measure consistently with the measure specification is an appropriate application of the NQF-endorsed measure to a subset of patients who are part of the broader population to which the measure applies. As stated in the CY 2012 OPPS/ASC proposed rule, if the measure is finalized, ASCs would need to place QDCs relevant to this measure on Medicare Part B claims beginning January 1, 2012 in order to report this measure for purposes of the CY 2014 payment determination.

Comment: A few commenters opposed the measure and believed that this measure is not applicable to ASC GI endoscopic centers. A few commenters considered the proposed data collection to begin on January 1, 2012 unreasonable.

Response: The measure assesses whether an antibiotic is given on time prior to a procedure if it was ordered. We note that the specifications for the measure list endoscopy as one of the examples of procedures. As stated in section XIV.K.1. of this final rule with comment period, we are delaying the beginning of data collection until October 1, 2012 for the CY 2014 payment determination.

Comment: A few commenters did not believe this measure is burdensome since it is a claims-based measure, but urged that CMS provide training to ASCs regarding when to enter the specific QDCs appropriately. A commenter asked for clarification whether the proposed QDC-codes should be reported with every claim for an ASC procedure or only if the adverse event has occurred. One commenter suggested that CMS provide education to ASCs regarding whether QDCs need to be reported with every claim, or only for those where an adverse event occurred.

Response: We also do not believe submitting QDCs on claims is burdensome. In order to submit quality data using CPT–II and HCPCS codes, ASCs would need to add the appropriate QDCs for measure numerators and denominators on Medicare Part B claim forms. We intend to provide education and outreach on data submission for the reporting program, and we will publish details about the QDCs and whether they will need to be submitted for numerators and denominators in the ASC Quality Reporting Program Specifications Manual. We anticipate releasing this manual in second quarter 2012.

Comment: One commenter noted that CMS incorrectly stated that the NQF-endorsed specification for this measure includes all ASC admissions. The commenter stated that the NQF specification limits the denominator to all ASC admissions with a pre-operative order for a prophylactic IV antibiotic for the prevention of surgical site infection.

The commenter recommended giving the public the opportunity to comment on the QDC descriptors that CMS develops in the future. Specifically, the commenter requested the following corrections: (1) The required timing of antibiotics begins with the initiation of the IV antibiotic, not the pre-operative order; and (2) the specifications limit the denominator to all ASC admissions with a preoperative order for IV antibiotics, not all ASC admissions. The commenter believed that three QDCs are needed to describe: (1) Timely administration; (2) untimely administration; and (3) circumstances where no prophylactic was ordered.

Response: The commenter is correct, the denominator for the NQF-endorsed measure is all ASC admissions with a pre-operative order for a prophylactic IV antibiotic for prevention of surgical site

[41] Silver, A. *et al.*: Timeliness and use of antibiotic prophylaxis in selected inpatient surgical procedures. The Antibiotic Prophylaxis Study Group. Am J Surg. 1996;171(6):548–552.

[42] Dounis, E., Tsourvakas, S., Kalivas, L., and Giamacellou, H.: Effect of time interval on tissue concentrations of cephalosporins after tourniquet inflation. Highest levels achieved by administration 20 minutes before inflation. Acta Orthop Scand. 1995;66(2):158–60.

infections. NQF has indicated to us that our proposal to use Medicare Part B claims submitted by ASCs to calculate the measure consistently with the measure specification is an appropriate application of the NQF-endorsed measure. We correctly described the measure initially but then did not state it completely when describing the application of the measure to a subset of patients. As the commenter stated, the assessment of appropriateness of timing begins with the initiation of IV antibiotics relative to the initial surgical incision or the beginning of the procedure. We will ensure these aspects of the measure are clarified in the Specifications Manual CMS issues for this program.

Comment: A commenter recommended the discontinuation of this measure once the proposed surgical site infection measure is implemented to include additional ASC procedures.

Response: We thank the commenter for the suggestion. As discussed in section XIV.K.3.b. below, for the ASC Quality Reporting Program, we are not finalizing the surgical site infection measure in this rulemaking.

After consideration of the public comments we received, we are finalizing this measure for the CY 2014 payment determination with data collection to begin on October 1, 2012 (as discussed in section XIV.K.1 of this final rule with comment period).

(6) Ambulatory Surgery Patients With Appropriate Method of Hair Removal (NQF #0515)

The ASC QC[43] cited evidence that ''[r]azors can cause microscopic cuts and nicks to the skin, not visible to the eye. Use of razors prior to surgery increases the incidence of wound infection when compared to clipping, depilatory use or no hair removal at all.''[44] A 1999 guideline issued by the CDC suggests that if hair must be removed from a surgical site, that it preferably be done with clippers rather than razors in order to minimize cuts and nicks to the skin which may increase the risk of a surgical site infection.[45] In 2002, the Association of Operating Room Nurses published similar guidelines for appropriate hair removal.[46] While a similar measure is being considered for retirement from the Hospital IQR Program because it displays a high degree of performance with little variability or room for improvement, we believe that there is significant variability in practice and the level of adherence to this guideline in outpatient surgical settings such as ASCs is not known. Therefore, we believe that this measure is still appropriate for use in the ASC setting. In the CY 2012 OPPS/ASC proposed rule (76 FR 42341 through 42342), we proposed to adopt the NQF-endorsed measure to capture the percentage of ASC admissions with appropriate surgical site hair removal. The specifications for this NQF-endorsed measure developed by the ASC QC can be found at: *http://www.ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pdf*. Read together, sections 1833(i)(7)(B) and 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. We believe this measure is appropriate to measure quality in ASCs because it assesses quality of surgical care performed in ASCs, as measured by appropriate surgical site hair removal. Furthermore, we believe that this measure meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it was developed by the ASC QC and is endorsed by the NQF.

In the proposed rule, we invited public comment on our proposal to adopt this measure for the CY 2014 payment determination using the claims-based QDC data collection mechanism for ASC services furnished for Medicare patients from January 1, 2012 through December 31, 2012 (76 FR 42341). While the NQF-endorsed specification for this measure includes all ASC admissions with surgical site hair removal, our proposal to use information submitted on claims to calculate these measures necessitates that we restrict the measure population to the population for which CMS receives claims. Therefore, for this program, we would need to calculate the measures based on claims submitted for ASC services furnished to Medicare fee-for-service beneficiaries. NQF indicated to us that our proposal to use Medicare Part B claims submitted by ASCs to calculate the measure consistently with the measure specification is an appropriate application of the NQF-endorsed measure to a subset of patients who are part of the broader population to which the measure applies. As stated in the CY 2012 OPPS/ASC proposed rule, if the measure is finalized, ASCs would need to place QDCs relevant to this measure on Medicare Part B claims beginning January 1, 2012 in order to report this measure for purposes of CY 2014 payment determination.

Comment: A few commenters stated that the measure does not apply to endoscopy centers. Several commenters opposed this measure because they stated that there is no conclusive clinical evidence that clipping, rather than other hair removal techniques, reduces surgical site infections across a broad spectrum of surgical procedures. Furthermore, the scrotal surgery exclusion does not appear to be present in the ASC specifications. Two commenters found it confusing that CMS has currently suspended this measure from the Hospital IQR Program due to the measure's ''topped-out'' status.

Response: CMS agrees with these comments, and is not finalizing this measure for the ASC Quality Reporting Program. A recently published systematic review by Alexander JW *et al.* (Annals of Surgery.2001;253(6):1082–1093) also indicates that not removing hair is associated with the least probability of infection.

Comment: One commenter indicated that CMS incorrectly stated that the NQF-endorsed specification for this measure includes all ASC admissions. The commenter clarified that the NQF specifications limit the denominator to all ASC admissions with surgical site hair removal. A commenter noted that the public should have the opportunity to comment on the descriptors CMS develops. The commenter believed that a correction that needs to be made in the rule: the specifications limit the denominator to all ASC admissions with surgical site hair removal, not all ASC admissions. Additionally, the commenter believed that a set of three QDCs would be needed to describe: (1) Appropriate hair removal; (2) inappropriate hair removal; and (3) circumstances where no hair was removed or other exclusions.

Response: As discussed above, we are not finalizing this measure for the ASC Quality Reporting Program.

After consideration of the public comments we received, we are not

[43] ASC QC Quality measures: Implementation Guide version 1.4. ASC Quality Collaboration. December 2010.

[44] Seropian, R., Reynolds, B.M.: Wound infections after preoperative depilatory versus razor preparation. Am J Surg.1971 Mar;121(3):251–4.

[45] *http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/SSI.pdf.*

[46] Association of Operating Room Nurses. Recommended practices for skin preparation of patients. AORN J. 2002 Jan;75(1):184–7.

finalizing this measure for CY 2014 payment determination.

(7) Selection of Prophylactic Antibiotic: First OR Second Generation Cephalosporin (NQF #0268)

Surgical outcomes are affected by the selection of appropriate antibiotics. Current guidelines indicate that first or second generation cephalosporins are effective for prevention of surgical site infections in most cases. The goal of this proposed measure is to ensure safe, cost-effective, broad spectrum antibiotics are used as a first line prophylaxis unless otherwise indicated. This measure was developed by the AMA's Physician Consortium for Performance Improvement, a national, diverse, physician-led group that identifies, develops, and promotes implementation of evidence-based clinical performance measures that reflect best practices. This measure received NQF endorsement under a 2008 project entitled ''Hospital Care: Specialty Clinician Performance Measures,'' and it assesses the percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for cefazolin or cefuroxime for antimicrobial prophylaxis. While we recognize that this measure is not specifically endorsed for the ASC setting, we believe that this measure is highly relevant for use in ASCs because it assesses adherence to best practices for use of prophylactic antibiotics for outpatient surgical patients. Accordingly, we proposed to adopt an application of this NQF-endorsed measure for use in the ASC Quality Reporting Program. The measure specifications for this proposed measure can be found at: *http://www.cms.gov/pqrs/downloads/2011_PhysQualRptg_MeasuresGroups_SpecificationsManual_033111.pdf?agree=yes&next=Accept.*

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. We believe this measure is appropriate for measurement of quality care in an ASC because it specifically assesses quality care, as measured by adherence to best practices for prophylactic antibiotics provided for outpatient surgical patients. We believe that consensus among affected parties can be reflected through means other than NQF endorsement, including consensus achieved during the measure development process; consensus shown through broad acceptance and use of measures; and consensus through public comment.

The measure development process employed the same process used by the American Medical Association Physician Consortium for Performance Improvement (AMA–PCPI). The AMA PCPI is a consortium of physicians dedicated to improving patient safety by developing evidence based performance measures, promoting the implementation of effective and relevant clinical performance improvement activities, and advancing the science of clinical performance measurement and improvement. The AMA–PCPI develops many measures for the PQRS program. The AMA–PCPI development process for this measure is a consensus-based process that involves stakeholder input, including surgeons performing procedures in outpatient settings such as ASCs. Because of this, we believe this measure meets the requirement of reflecting consensus among affected parties.

Further, it is not feasible or practicable to adopt an NQF-endorsed measure of prophylactic antibiotic selection specifically for ASCs because there is no such NQF-endorsed measure. We note that section 1833(t)(17) of the Act does not require that each measure we adopt for the ASC Quality Reporting Program be endorsed by a national consensus building entity, or by the NQF specifically. Further, section 1833(i)(7)(B) of the Act states that section 1833(t)(17) of the Act, which contains this requirement, applies to the ASC Quality Reporting Program, except as the Secretary may otherwise provide. Under this provision, the Secretary has further authority to adopt measures that are not NQF-endorsed or measures that have not been endorsed for the ASC setting.

The proposed adoption of this measure in the ASC Quality Reporting Program also is consistent with our goal to align measures across settings, as it is also used in the PQRS, and a similar measure (NQF #0528) has been implemented in the Hospital OQR Program and the Hospital IQR Program.

In the proposed rule, we invited public comment on our proposal to adopt this measure for the CY 2014 payment determination using the claims-based QDC data collection mechanism for ASC services furnished for Medicare patients from January 1, 2012 through December 31, 2012 (76 FR 42342). While the NQF-endorsed specification for this measure includes all surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for cefazolin OR cefuroxime for antimicrobial prophylaxis, our proposal to use information submitted on claims to calculate these measures requires that we restrict the measure population to the population for which CMS receives claims. Therefore, for this program, we would need to calculate the measures based on claims submitted for ASC services furnished to Medicare fee-for-service beneficiaries. NQF has indicated to us that our proposal to use Medicare Part B claims submitted by ASCs to calculate the measure consistently with the measure specification is an appropriate application of the NQF-endorsed measure to a subset of patients who are part of the broader population to which the measure applies. As stated in the CY 2012 OPPS/ASC proposed rule, if the measure is finalized, ASCs would need to place QDCs relevant to this measure on Medicare Part B claims beginning January 1, 2012 in order to report this measure for purposes of the CY 2014 payment determination.

Comment: Several commenters expressed various concerns regarding this measure: A commenter believed this is a physician-level measure and not an ASC-level measure. Therefore, the commenter suggested that CMS report the antibiotic selection data submitted by physicians for this measure by place of service (POS) and aggregate physician performance data across surgical settings, including hospital inpatient and outpatient settings, and ASC setting.

A commenter believed that this measure does not represent the most prevalent area of services provided by ASCs. A commenter stated that data collection for this measure is very burdensome. One commenter requested clarification on what procedure codes would allow for the best comparison since very few codes in the current denominator set are relevant to the ASC setting (according to the commenter, ASCs only accounted for 0.16 percent of total Medicare procedures in 2009). A commenter asked that CMS clarify and educate ASCs as to whether the proposed QDC-codes should be reported with every claim for an ASC procedure or only if the adverse event has occurred. A commenter stated that this measure should be phased out after the surgical site infection measure has been

expanded to include additional ASC procedures. Given the NQF's endorsement for this measure is non-ASC-specific, another commenter encouraged CMS to seek NQF endorsement specific to the ASC setting to ensure accuracy in data collection and implementation.

Response: We agree that the measure may not address the most prevalent procedures performed by ASCs and we will need to examine how the measure may be modified in order to capture those procedures most commonly performed in ASCs. Therefore, we are not finalizing this measure for the CY 2014 payment determination at this time.

After consideration of the public comments we received, we are not finalizing the selection of prophylactic antibiotic: first OR second generation cephalosporin measure for ASCs for the CY 2014 payment determination.

b. Surgical Site Infection Rate (NQF #0299)

HAIs are among the leading causes of death in the United States. CDC estimates that as many as 2 million infections are acquired each year in hospitals and result in approximately 90,000 deaths.[47] It is estimated that more Americans die each year from HAIs than from auto accidents and homicides combined. HAIs not only put the patient at risk, but also increase the days of hospitalization required for patients and add considerable health care costs. HAIs are largely preventable for surgical patients through application of perioperative best practices such as those listed in the CDC's Surgical Site Infection prevention guidelines. Therefore, many health care consumers and organizations are calling for public disclosure of HAIs, arguing that public reporting of HAI rates provides the information health care consumers need to choose the safest hospitals, and gives hospitals an incentive to improve infection control efforts. This proposed measure is currently collected by the NHSN as part of State-mandated reporting and surveillance requirements for hospitals in some States. Additionally, data submission for this measure through EHRs may be possible in the near future.

This measure is NQF-endorsed and we proposed to adopt it for the CY 2014 Hospital OQR Program. It also has been adopted for the FY 2014 Hospital IQR Program. Because we proposed the same measure for Hospital OQR Program, we refer readers to the discussion of this measure in sections XIV.C.2.a. of the proposed rule and this final rule with comment period. The measure specifications can be found at *http://www.cdc.gov/nhsn/psc.html*. The NQF describes this measure as the ''percentage of surgical site infection events occurring within thirty days after the operative procedure if no implant is left in place, or [within] one year if an implant is in place in patients who had an NHSN operative procedure performed during a specified time period and the infection appears to be related to the operative procedure.''

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. Increasingly, surgical procedures are being performed in hospital outpatient department settings and ASCs. We believe this measure is appropriate for measuring quality of care in ASCs because it applies to outcomes for surgical patients undergoing procedures that are performed in ASCs.

Furthermore, we believe that this measure meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it is endorsed by the NQF. The proposed adoption of this measure in the ASC Quality Reporting Program also is consistent with our goal to align measures across settings because we have proposed this measure for the Hospital OQR Program for CY 2014 payment determination and have previously adopted it for Hospital IQR Program for the FY 2014 payment determination. Therefore, we proposed to adopt the Surgical Site Infection Rate measure that is collected by the CDC via the NHSN for the ASC Quality Reporting Program for the CY 2014 payment determination.

Data submission for this measure for the CY 2014 payment determination would begin with infection events occurring on or after January 1, 2013 through June 30, 2013. The proposed reporting mechanism for this proposed HAI measure via the NHSN is discussed in greater detail in sections XIV.C.2.a. of the proposed rule and this final rule with comment period. In the proposed rule, we invited public comment on this proposed measure and the reporting mechanism.

Comment: Some commenters requested clarification on how infections will be identified by ASCs in cases where patients go home on the same day or go to another hospital for the infection. Commenters believed that it would be challenging to survey outpatients, including ASC patients, to determine whether an infection has developed and if it meets the NHSN definition for surgical site infection.

Some commenters believed that the NHSN module was not relevant for ASCs. A commenter cited the measure specification that ''SSI [surgical site infections] are to be identified on original admission or upon readmission to the facility of the original operative procedures'' and concluded this measure is inappropriate for ASCs due to patients' short length of stay and their likely admission to a hospital when an infection occurs. Because the commenter believed that the 10 NHSN-defined operative procedure categories have little relevance to the predominant procedures performed in ASCs, the commenter recommended that CDC re-specify the measure to include common ASC-specific procedures to identify related infections in the numerator.

One commenter urged CMS to consider facility exemptions in implementing this measure. The commenter stated that ASCs seldom perform operative procedures as defined by the CDC: ''an operative procedures as the one in which a surgeon makes at least one incision through the skin or mucous membrane, including laparoscopic approach, and closes the incision before the patient leaves the operating room.''

Another commenter stated that ASCs normally do not have an ongoing relationship with patients and recommended that CMS require ASCs to conduct follow-up phone calls with patients, caregivers or physicians within 30 days of procedures to identify patients who have developed surgical site infections. Commenters also recommended that CMS require that ASCs include this information in medical records as part of the data submission to NHSN, preferably via electronic submission.

Several commenters supported the surgical site infection measure but the disparate codes used by hospital outpatient departments and ASCs and the ICD codes used in the NHSN module would create potential inaccurate data submission. The commenters believed that the uncommon use of NHSN in ASCs would

[47] McKibben. L., Horan, T.: Guidance on public reporting of healthcare-associated infections: recommendations of the Healthcare Infection Control Practices Advisory Committee. AJIC 2005;33:217–26.

add challenges to follow-up surveillance.

Response: We thank the commenters for their views. As discussed below, we are not finalizing this proposed measure.

Comment: One commenter encouraged CMS to accelerate the timeframe for making the surgical site infection measure data for ASCs publicly available. The commenter believed that once this outcome measure is implemented, two ASC surgical infection control measures (ASC–5: Prophylactic IV antibiotic timing, and ASC–7: Prophylactic antibiotic selection for surgical patients) can be eliminated from the Hospital OQR Program. The commenter suggested harmonization of this measure across different HOPD surgical and ASC settings.

Response: We appreciate this supportive comment. At this time, we are not finalizing surgical site infection measures for the Hospital OQR Program or the ASC Quality Reporting Program. We will consider proposing a surgical site infection measure for the ASC Quality Reporting Program in the future. We agree with the commenters that a number of procedures frequently performed in outpatient surgical settings like ASCs are not addressed in the current surgical site infection measure adopted for the Hospital IQR Program, and that a follow-up and collection protocol that is better suited to outpatient surgical settings for such a measure should be developed. We also agree with the suggestion that we harmonize measures between the ASC Quality Reporting Program and the Hospital OQR Program, to the extent feasible. These comments will be taken into consideration in future surgical site infection measurement proposals for the ASC Quality Reporting Program.

Comment: A commenter believed that the measure should facilitate comparisons across ASCs and hospital outpatient surgery setting by making the data more patient-centered for easy comprehension.

Response: We appreciate the input from the commenter. Although we are not adopting this measure at this time, we will take this view into consideration as we consider proposing a surgical site infection measure in the future.

Comment: A commenter was very concerned about the burden to report to NHSN and cited that 40 ASCs that are currently participating in NHSN reported registration and data submission are very time-consuming. The commenter urged CDC to streamline these processes to make them more user-friendly.

Response: We appreciate the input from the commenter regarding potential burden and the need for user-friendly processes. As stated above, we are not finalizing this measure for the CY 2014 payment determination.

Comment: Some commenters requested that CMS delay implementation of the surgical site infection measure to the CY 2015 payment determination with data collection starting on January 1, 2014 through June 30, 2014 to allow ASC to gain experience with the NHSN module.

Response: As stated above, we are not finalizing the surgical site infection measure for the CY 2014 payment determination.

After consideration of the public comments we received, we are not finalizing the surgical site infection measure for ASCs for CY 2014 payment determination. We will consider proposing the measure once a suitable set of procedures and a protocol for ASCs and HOPDs has been developed.

In summary, we are finalizing five claims-based measures total using the QDC data collection mechanism for the CY 2014 payment determination. Based upon the public comment we received, we are finalizing the data submission for these five claims-based measures to begin on October 1, 2012. This issue is discussed in more detail in the Form, Manner and Timing section for this program. The quality measures we are adopting for ASCs for the CY 2014 payment determination are listed below with the ASC prefix:

ASC Program Measurement Set for the CY 2014 Payment Determination (Data submission to begin on October 1, 2012)
ASC-1: Patient Burn
ASC-2: Patient Fall
ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
ASC-4: Hospital Transfer/Admission
ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing

4. ASC Quality Measures for CY 2015 Payment Determination

a. Retention of Measures Adopted for the CY 2014 Payment Determination in the CY 2015 Payment Determination

In general, unless we otherwise specify in the retirement section of a rule, we proposed to retain measures from one CY payment determination to another. In the CY 2012 OPPS/ASC proposed rule (76 FR 42343), we proposed to retain the measures we proposed to adopt for the CY 2014 payment determination, if they are finalized in the CY 2012 OPPS/ASC final rule with comment period, for the CY 2015 payment determination. In the proposed rule, we invited public comments on this proposal.

Comment: One commenter supported the proposed retention of the measures we finalized for the CY 2014 payment determination for the CY 2015 payment determination.

Response: We thank the commenter for supporting the retention of these measures.

After consideration of the public comment we received, we are finalizing our proposal to retain measures from one CY payment determination to the next. For the CY 2014 payment determination, as discussed above, we are finalizing five claims-based measures. Therefore, we will retain these five measures for the CY 2015 payment determination.

b. Structural Measures for the CY 2015 Payment Determination

In the CY 2012 OPPS/ASC proposed rule (76 FR 42343 through 42346), for the CY 2015 payment determination, we proposed to adopt two structural measures: Safe Surgery Checklist Use, and ASC Facility Volume Data on

Selected ASC Surgical Procedures. We discuss these proposals below.

(1) Safe Surgery Checklist Use

A sound surgery safety checklist could minimize the most common and avoidable risks endangering the lives and well-being of surgical patients. The purpose of this proposed structural measure is to assess whether ASCs are using a safe surgery checklist that covers effective communication and helps ensure that safe practices are being performed at three critical perioperative periods: prior to administration of anesthesia, prior to incision, and prior to the patient leaving the operating room. The use of such checklists has been credited with dramatic decreases in preventable harm, complications and post-surgical mortality.[48] In November 2010, the New England Journal of Medicine published a study concluding that surgical complications were reduced by one-third, and mortality by nearly half, when a safe surgery checklist was used.[49]

We believe that effective communication and the use of safe surgical practices during surgical procedures will significantly reduce preventable surgical deaths and complications. Some examples of safe surgery practices that can be performed during each of these three perioperative periods are shown in the table below:

First critical point (prior to administering anesthesia)	Second critical point (prior to skin incision)	Third critical point (prior to patient leaving the operating room)
• Verbal confirmation of patient identity • Mark surgical site • Check anesthesia machine/medication • Assessment of allergies, airway and aspiration risk	• Confirm surgical team members and roles • Confirm patient identity, procedure, and surgical incision site • Administration of antibiotic prophylaxis within 60 minutes before incision • Communication among surgical team members of anticipated critical events • Display of essential imaging as appropriate	• Confirm the procedure • Complete count of surgical instruments and accessories • Identify key patient concerns for recovery and management of the patient

For example, mistakes in surgery can be prevented by ensuring that the correct surgery is performed on the correct patient and at the correct place on the patient's body.[50] A safe surgery checklist would reduce the potential for human error, which would increase the safety of the surgical environment. Another example of a checklist that employs safe surgery practices at each of these three perioperative periods is the World Health Organization Surgical Safety Checklist, which was adopted by The World Federation of Societies of Anesthesiologists as an international standard of practice. This checklist can be found at: *http://www.who.int/patientsafety/safesurgery/ss_checklist/en/index.html*.

The adoption of a structural measure that assesses Safe Surgery Checklist Use would align our patient safety initiatives with those of several surgical specialty societies including: the American College of Surgeons' Nora Institute for Patient Safety, the American Society of Anesthesiologists, TJC, the National Association for Healthcare Quality and the AORN. The measure would assess whether the ASC uses a safe surgery checklist in general, and would not require an ASC to report whether it uses a checklist in connection with any individual procedures.

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. This measure is appropriate for the measurement of quality of care furnished by ASCs because it pertains to best practices for surgeries, and ASCs perform ambulatory surgeries. It also reflects consensus among affected parties. As stated in sections XIV.C.2.c.1 of the proposed rule and this final rule with comment period, we believe that consensus among affected parties can be reflected through means other than NQF endorsement, including consensus achieved during the measure development process; consensus shown through broad acceptance and use of measures; and consensus through public comment.

The proposed safe surgery checklist measure assesses the adoption of a best practice for surgical care that is broadly accepted and in widespread use among affected parties. In addition to being adopted by The World Federation of Societies of Anesthesiologists, the use of a safe surgery checklist is one of the safe surgery principles endorsed by the Council on Surgical and Perioperative Safety,[51] which is comprised of the American Association of Nurse Anesthetists, the American College of Surgeons, the American Association of Surgical Physician Assistants, the

[48] Haynes, A.B.; Weiser, T.G.; Berry, W.G. *et al.* (2009). ''A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population''. New England Journal of Medicine. 360:491–499.

[49] de Vries EN, Prins HA, Crolla RMPH, *et al.* Effect of a comprehensive surgical safety system on patient outcomes. N Engl J Med 2010;363: 1928–37

[50] Hospital National Patient Safety Goals. The Joint Commission Accreditation Hospital Manual, 2011. *http://www.jointcommission.org/standards_information/npsgs.aspx.*

[51] *http://www.cspsteam.org/safesurgerychecklist/safesurgerychecklist.html.*

American Society of Anesthesiologists, the American Society of PeriAnesthesia Nurses, AORN, and the Association of Surgical Technologists. Two State agencies (Oregon, South Carolina), the Veterans Health Administration,[52] numerous hospital systems, State hospital associations (such as California and South Carolina), national accrediting organizations and large private insurers have endorsed the use of a safe surgery checklist as a best practice for reducing morbidity, mortality, and medical errors.[53] [54] Because the use of a safe surgery checklist is a widely accepted best practice for surgical care, we believe that the proposed structural measure of Safe Surgery Checklist Use reflects consensus among affected parties. We also note that TJC has included safe surgery checklist practices among those to be used to achieve NPSGs adopted for 2011 for surgeries performed in ambulatory settings and hospitals.[55]

The Safe Surgery Checklist Use structural measure is not NQF-endorsed, and there is no NQF-endorsed measure of safe surgery checklist use despite the broad acceptance and widespread endorsement of this practice. Therefore, it is not feasible or practicable to adopt an NQF-endorsed measure of safe surgery checklist use because there is no such NQF-endorsed measure. We note that section 1833(t)(17) of the Act does not require that each measure we adopt for the ASC Quality Reporting Program be endorsed by a national consensus building entity, or by the NQF specifically. Further, section 1833(i)(7)(B) of the Act states that section 1833(t)(17) of the Act, which contains this requirement, applies to the ASC Quality Reporting Program, except as the Secretary may otherwise provide. Under this provision, the Secretary has further authority to adopt non-endorsed measures. We note that the proposed adoption of this measure in the ASC Quality Reporting Program is consistent with our goal to align measures across settings because we also proposed the same measure for the Hospital OQR Program for CY 2014 payment determination.

For the CY 2015 payment determination, we proposed that data collection for this structural measure for ASCs would begin on July 1, 2013 and end on August 15, 2013 for the entire time period from January 1, 2012 through December 31, 2012. In other words, an ASC would report whether their facility employed a safe surgery checklist that covered each of the three critical perioperative periods for the entire calendar year of 2012 during the 45-day window from July 1 through August 15, 2013. The information for this structural measure would be collected via an online Web-based tool that will be made available to ASCs via the QualityNet Web site. This collection mechanism is also used to collect structural measures and other information for other programs, specifically for the Hospital IQR and Hospital OQR Programs.

In the proposed rule, we invited public comments on our proposal to add this new structural measure to the ASC quality measurement set and the submission process for the CY 2015 payment determination.

Comment: Several commenters fully supported the Safe Surgery Checklist measure and believed the measure helps to ensure safe surgical practices prior to administration of anesthesia, incision, and the patient's departure from the operating room. A commenter did not believe this measure would impose substantial burden on ASCs because the data is collected via a Web-based tool. Some commenters appreciated the flexibility given to ASCs in the design and use of a specific checklist to meet their needs. Commenters urged CMS to revise the measure name to include, ''safe surgery/procedure checklist'' and modify its purpose statement to indicate the intent of the measure as ''an assessment whether ASCs use a safe surgery/procedure checklist that addresses effective communication and helps ensure that safe practices are being performed at three critical perioperative or periprocedural periods: (1) Prior to the administrative of anesthesia or sedation; (2) prior to incision or the beginning of the procedure; and (3) prior to the patient leaving the operating or procedure room.'' Commenters urged harmonization with the same measure proposed in the Hospital OQR Program.

Response: We agree with the commenter that this measure would impose minimal burden because the data are submitted using a Web-based data submission tool. The ASC safe surgery checklist measure is aligned with the safe surgery checklist measure that we are adopting for HOPDs.

Comment: A few commenters recommended a 60-day time period for data submission rather than the 45-day window and suggested that CMS change this measure into a claims-based measure rather than using an online tool. Commenters recommended changing the proposed collection time period from January 1, 2012 through December 31, 2012 to January 1, 2013 through December 31, 2013 and delay the data submission period until early 2014. The commenters did not provide a rationale for this suggestion.

Response: The goal of this measure is to assess whether a particular ASC is using a safe surgery checklist from January 1, 2012 until December 31, 2012, requiring one yes/no response for this measure, not to assess whether a safe surgery checklist is used for each Medicare Part B patient. Therefore, a claims-based measure would not be appropriate to measure whether an ASC is using a safe surgery checklist because we are not measuring its use on an individual claims-based level.

We note that the Web based reporting tool is a minimally burdensome method of collecting this facility level information, and is currently in use for similar types of measures for both the Hospital IQR and Hospital OQR Programs. We seek to align the reporting periods for the reporting programs and currently, a 45-day window is being used for data collection for some structural measures in the Hospital IQR and Hospital OQR Programs. At this time, we are not changing the time periods for the structural measures because there is minimal burden and advance preparation to collect and report this information to CMS.

Comment: A few commenters did not support this measure for different reasons. Some commenters believed that the use of a checklist cannot be validated by CMS, and therefore, it should not be considered as a measure. Some commenters noted that it is not NQF-endorsed. Some commenters objected to the collection of patient- or procedure-detailed level data. Commenters were also concerned about the implementation of this measure simultaneously with ICD–10 conversion would further tax facilities' resources. A commenter stated this measure is duplicative because all accredited ASCs are already required to use a safe surgery checklist. Another commenter noted that the safe surgery checklist as required in the Conditions for Coverage could also meet the criteria for this measure. A few commenters stated this measure does not apply to ASCs performing GI surgical procedures and requested the adoption of a safe surgery

[52] Neily, J; Mills, PD, Young-Xu, Y. (2010). ''Association between implementation of a Medical Team Training Program and Surgical Mortality''. JAMA. 304 (15): 1693–1700.

[53] Haynes, AB; Weiser, TG; Berry, WR *et al* (2009) ''A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population''. NEJM. 360:491–499.

[54] Birkmeyer, JD (2010) ''Strategies for Improving Surgical Quality—Checklists and Beyond.'' NEJM. 363: 1963–1965.

[55] *http://www.jointcommission.org/standards_information/npsgs.aspx.*

checklist that is specific to GI procedures performed in ASCs.

Response: We acknowledge that this measure cannot be validated because it does not use charts or claims. Nonetheless, we believe the measure would heighten ASCs' awareness of patient safety during surgical procedures and safeguard against preventable human errors. As discussed above, we believe this measure meets the statutory requirements, even if it is not NQF-endorsed. There is no NQF-endorsed measure for safe surgery checklist use despite the broad acceptance and widespread endorsement of this practice. Therefore, it is not feasible or practicable to adopt an NQF-endorsed measure of safe surgery checklist use because there is no such NQF-endorsed measure. As stated in previous rulemaking, we believe that consensus among affected parties can be reflected through means other than NQF endorsement, including consensus achieved during measure development processes, consensus shown through broad acceptance and use of measure; and consensus through public comment. The use of a safe surgery checklist has been adopted by the World Federation of Societies of Anesthesiologists, and is one of the safe surgery principles endorsed by the Council on Surgical and Perioperative Safety which is comprised of multiple medical professional organizations.

We disagree with the commenters who suggested that a safe surgery checklist would not apply to GI procedures. Some GI procedures are performed under anesthesia, and wrong site surgery and wrong procedure is possible for GI procedures, all of which are general topics that would be covered under a safe surgery checklist. Therefore, we believe that a well-designed, comprehensive generic safe surgery checklist should cover GI-specific surgical procedure elements as well.

We do not believe that the reporting of this structural measure to CMS for this quality reporting program and subsequent public reporting is duplicative of accreditation requirements or conditions of coverage for ASCs, because these other requirements do not require the reporting this information to CMS annually by each eligible facility and the subsequent public reporting of this information on a CMS Web site. As stated previously, this measure is not collected on an individual patient or procedure level and does not involve the use of ICD–9 codes or ICD–10 codes.

After consideration of the public comments we received, we are finalizing this measure for CY 2015 payment determination. We are finalizing our proposal for the CY 2015 payment determination that ASCs would report their yes/no response regarding use of a safe surgery checklist between July 1, 2013 and August 15, 2013 for the time period from January 1, 2012 through December 31, 2012 using an online measure submission Web page available on *http://www.qualitynet.org*. Details regarding measure submission timelines and collection periods are discussed in the Form, Manner and Timing section for this program in this final rule with comment period.

(2) ASC Facility Volume Data on Selected ASC Surgical Procedures

There is substantial evidence in recent peer-reviewed clinical literature that volume of surgical procedures, particularly of high risk surgical procedures, is related to better patient outcomes, including decreased surgical errors and mortality.[56] [57] [58] This may be attributable to greater experience and/or surgical skill, greater comfort with and hence likelihood of application of standardized best practices, and increased experience in monitoring and management of surgical patients for the particular procedure. For this reason, the National Quality Forum has endorsed measures of total all-patient surgical volume for Isolated CABG and Valve Surgeries (NQF #0124), Percutaneous Coronary Intervention (PCI) (NQF #0165), Pediatric Heart Surgery (NQF #0340), Abdominal Aortic Aneurism Repair (NQF #357), Esophageal Resection (#0361), and Pancreatic Resection (NQF #0366). Additionally, many consumer-oriented Web sites reporting health care quality information sponsored by States (California, New York, Texas, Washington, Florida, Illinois, Michigan, Oregon) and private organizations (Leapfrog Group, U.S. News & World Report) are reporting procedure volume, in addition to provider performance on surgical process (SCIP measures) and outcome measures (surgical site infection, Patient Safety Indicators, and Mortality), because it provides beneficial performance information to consumers choosing a health care provider. The currently NQF-endorsed measures of procedure volume (noted above) relate to surgeries only performed in inpatient settings, and would not be applicable to the types of procedures approved to be performed in HOPDs and ASCs.

The recently issued Report to Congress entitled ''Medicare Ambulatory Surgical Center Value-Based Purchasing Implementation Plan'' included an analysis of CY 2009 ASC claims for Medicare beneficiaries. When stratified by specialty category, CMS identified six procedure categories that historically constitute 98.5 percent of the total volume of procedures performed in ASCs: Gastrointestinal, Eye, Nervous System, Musculoskeletal, Skin, and Genitourinary. In the CY 2012 OPPS/ASC proposed rule (76 FR 42345), we proposed that ASCs submit all patient volume data on these six broad categories of surgical procedures as a structural measure to be used for the ASC Quality Reporting Program CY 2015 payment determination. In section XIV.C.2.c.(2) of the proposed rule, we also proposed that HOPDs submit similar all patient volume data for eight broad procedure categories.

Structural measures assess whether a provider/facility possesses conditions for the care of patients that are associated with better quality. Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. Because surgical volume is associated with better quality, and surgical procedures are performed in ASCs, we believe that surgical volume is appropriate for measuring the quality of these six categories of surgical procedures performed in ASCs. We have previously established for other programs that we believe consensus among affected parties can be reflected through various means including widespread use among industry stakeholders. We believe that the ASC Facility Volume Data on Selected ASC Surgical Procedures structural measure reflects consensus among affected parties as being associated with quality of surgical care because of recent evidence published in well-respected and widely circulated peer-reviewed clinical literature, and because of its

[56] Livingston, E.H.; Cao, J. ''Procedure Volume as a Predictor of Surgical Outcomes''. JAMA. 2010;304(1):95–97.

[57] Flum, D.R.; Salem, L.; Elrod, J.B.; Dellinger, E.P.; Cheadle, A.; Chan, L. ''Early Mortality Among Medicare Beneficiaries Undergoing Bariatric Surgical Procedures''. JAMA. 2005;294(15):1903–1908.

[58] Schrag, D.; Cramer, L.D.; Bach, P.B.; Cohen, A.M.; Warren, J.L.; Begg, C.B.;'' Influence of Hospital Procedure Volume on Outcomes Following Surgery for Colon Cancer''. JAMA.2000; 284(23): 3028–3035.

widespread reporting among States and private stakeholders on Web sites featuring quality information. Because the current volume measures are endorsed for inpatient procedures, many of which are not performed in outpatient settings such as ASCs, it is not feasible or practicable to use NQF-endorsed measures of volume for ASCs. Further, section 1833(i)(7)(B) of the Act states that section 1833(t)(17) of the Act, which contains this requirement, applies to the ASC Quality Reporting Program, except as the Secretary may otherwise provide. Under this provision, the Secretary has further authority to adopt non-endorsed measures.

For the CY 2015 payment determination, we proposed that ASCs would report these data with respect to these six categories between the dates July 1, 2013 and August 15, 2013 with respect to the time period January 1, 2012 through December 31, 2012. In other words, under this proposal, an ASC would report its CY 2012 all-patient volume data for these six categories of procedures during the 45-day window of July 1 to August 15, 2013. In the CY 2012 OPPS/ASC proposed rule (76 FR 42346), we included a table which listed the HCPCS codes for which hospitals would be required to report all-patient volume data. Like the structural measures in the Hospital OQR Program, data on this proposed measure would be collected via an online Web-based tool that would be made available to ASCs via the QualityNet Web site. This collection mechanism is also used to collect structural measures and other information for other programs (Hospital IQR and Hospital OQR). In the proposed rule, we invited public comment on this proposal.

Comment: A commenter questioned why cardiovascular and respiratory codes are included for the same measure proposed in the Hospital OQR Program and not in the ASC Quality Reporting Program. The commenter recommended harmonizing the same categories for both programs for consistency.

Response: The procedures approved for HOPDs and for ASCs are not the same in type or frequency. For HOPDs, an analysis of prior years' data indicated that procedures performed in the eight broad categories that we proposed (eye, cardiovascular, gastrointestinal, genitourinary, musculoskeletal, nervous, respiratory, and skin systems) accounted for 99 percent of the procedures performed in HOPDs. When we assessed the frequency of procedures performed by ASCs using prior year's claims, we found that the six procedure categories of gastrointestinal, eye, nervous system, musculoskeletal, skin and genitourinary constitute 98.5 percent of the total volume of procedures performed in ASCs. Therefore, unlike HOPDs, cardiovascular and respiratory system procedures were not included in the list of most common procedures performed in ASCs. These two categories combined would account for 1.5 percent of procedures performed in ASCs. This is the reason why procedures performed in these two anatomic areas were not included in the ASC procedure volume list of procedure codes. We will continue to examine claims data on an ongoing basis, and should we become aware of commonly performed procedures in the Cardiovascular and Respiratory categories for which we should collect volume in the future, we will propose to collect ASC procedures for those categories in a future rule.

Comment: A few commenters fully supported the collection of all-patient volume data on surgical procedure measure and urged harmonization with the same measure adopted in the Hospital OQR Program. Another commenter noted that the provision of data on high volume procedures across hospital outpatient setting and ASC setting would facilitate comparisons and subsequent informed decisions. A commenter believed that this measure would create incentives for ASCs to increase their procedure volumes and improve their performance.

Response: We appreciate the commenters' support and their insights and recommendations. We will continue to work towards harmonizing measures, when possible, between different settings and facilities.

Comment: A few commenters believed that the measure is poorly specified, and should be refined to provide meaningful information to the consumer. Commenters recommended clarification on the most common ASC specialty-specific procedures performed, prior to creation of a clearly specified measure. Commenters also urged CMS to solicit input from the ASC community to determine how to make publication of volume data meaningful prior to implementation. A commenter stated this measure is unwarranted as volume data is already available on many State-supported or hospital-specific Web sites. Commenters believed that reporting volume without providing pertinent information on outcomes or patient-reported assessments of care may mislead patients about the quality of care delivered.

Response: Although this measure is not NQF-endorsed, we believed it reflects consensus among affected parties as evidenced by peer reviewed literature and widespread use on Web sites featuring quality information. We believe it is important to provide this information to consumers. We agree with commenters that information on outcomes should be provided to consumers as well, and we have adopted several surgical outcome measures in the ASC Quality Reporting Program so that this information can be provided to consumers. As discussed in the proposed rule, our goal for this measure is to provide consumers with useful information on surgical procedure volume in order to assist patients in making informed healthcare decisions. We are aware of Web sites reporting volume for some procedures performed in hospitals. However, we are not aware of Web sites that are reporting ASC volume by facility for commonly performed procedures. We want to create a standardized platform for consumers to be able to compare volume information based on procedure types commonly performed in ASCs within the 6 broad categories.

However, we agree with commenters that collecting and displaying information on the broad categories as currently specified may not be meaningful to consumers. Based on the public comments we received that the six broad categories will not be meaningful to consumers, we will further refine the specification for the categories by grouping the codes into procedure types commonly performed in ASCs within the 6 broad categories so that they are more meaningful to consumers. The codes in the 6 broad categories that ASCs would use to collect volume remain the same, but the information would be reported to CMS in the subcategories that will be defined in the Specifications Manual. We will include these refinements in the specifications for the measure that will be in an upcoming release of the ASC Specifications Manual. We agree with the commenter that obtaining stakeholder input as well as consumer testing prior to public reporting of the volume information will be beneficial, and will strive to do so, as we have done previously for information made available to the public from other quality reporting programs.

Comment: A commenter believed the proposed volume data submission via the QualityNet Web site is cumbersome and the implementation should be delayed to allow ASCs to gain experience with the online tool.

Response: The online tool is a low burden method of collecting facility level structural measures, and is currently in use for structural measures for both the Hospital IQR and Hospital OQR Programs. While the time period for the measure for CY 2015 would be calendar year 2012, the information would not be submitted by ASCs until mid-2013. Therefore, we do not believe further delay in the collection and submission of the measure is necessary.

After consideration of the public comments we received, we are finalizing the proposed ASC facility volume data on selected ASC surgical procedures measure for the CY 2015 payment determination, with a modification. Based upon public comment received, we will further group the codes for commonly performed procedure types within the 6 broad categories. This information will be provided in an upcoming Specifications Manual release. We are finalizing our proposal for the CY 2015 payment determination that ASCs would report data with respect to these six categories between July 1, 2013 and August 15, 2013 for the entire time period from January 1, 2012 through December 31, 2012 using an online measure submission Web page available on *http://www.qualitynet.org*. More information regarding the collection and submission requirements for this measure can be found in the Form, Manner and Timing section for this program in this final rule with comment period.

In summary, for the CY 2015 payment determination, we are retaining the five claims-QDC-based measures finalized for the CY 2014 payment determination, and adding two structural measures, safe surgery checklist use and ASC facility volume data on selected ASC surgical procedures, for a total of 7 measures.

The measures for ASCs for the CY 2015 payment determination are listed below:

ASC Program Measurement Set for the CY 2015 Payment Determination	
ASC-1: Patient Burn	
ASC-2: Patient Fall	
ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant	
ASC-4: Hospital Transfer/Admission	
ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing	
ASC-6: Safe Surgery Checklist Use*	
ASC-7: ASC Facility Volume Data on Selected ASC Surgical Procedures*	
Procedure Category	Corresponding HCPCS Codes
Gastrointestinal	40000 through 49999, G0104, G0105,G0121,C9716, C9724, C9725, 0170T
Eye	65000 through 68999, 0186, 0124T, 0099T, 0017T, 0016T, 0123T, 0100T, 0176T, 0177T, 0186T, 0190T, 0191T, 0192T, 76510, 0099T
Nervous System	61000 through 64999, G0260, 0027T, 0213T, 0214T, 0215T, 0216T, 0217T, 0218T, 0062T
Musculoskeletal	20000 through 29999, 0101T, 0102T, 0062T, 0200T, 0201T
Skin	10000 through 19999, G0247, 0046T, 0268T, G0127, C9726, C9727
Genitourinary	50000 through 58999, 0193T, 58805

*New measures for CY 2015 payment determination.

5. ASC Quality Measures for the CY 2016 Payment Determination

a. Retention of Measures Adopted for the CY 2015 Payment Determination in the CY 2016 Payment Determination

In general, unless otherwise specified in the retirement section of a rule, we proposed to retain measures from one CY payment determination to the next. In the CY 2012 OPPS/ASC proposed rule (76 FR 42346), we proposed to retain the measures we proposed to adopt for the CY 2015 payment determination, if they are finalized in an OPPS/ASC final rule with comment period, for the CY 2016 payment determination. In the proposed rule, we invited public comment on this proposal.

As discussed previously, we finalized our proposal to retain measures from one CY payment determination to another. We did not receive any comments objecting to the retention of the measures finalized for the CY 2015 payment determination for the CY 2016 payment determination. Thus, we are finalizing the retention of the seven measures finalized in the CY 2015 payment determination for the CY 2016 payment determination.

b. HAI Measure: Influenza Vaccination Coverage Among Healthcare Personnel (HCP) (NQF #0431)

The Influenza Vaccination among Healthcare Personnel measure assesses the percentage of healthcare personnel who have been immunized for influenza during the flu season. The specifications for this measure are available at *http://www.cdc.gov/nhsn/PDFs/HSPmanual/HPS_Manual.pdf.*

In the CY 2012 OPPS/ASC proposed rule (76 FR 42346), for the ASC CY 2016 payment determination, we proposed to adopt this NQF-endorsed HAI measure. We also proposed to adopt this measure for the Hospital OQR Program for the CY 2015 payment determination. We refer readers to the discussion in sections XIV.C.3.b. of the proposed rule and this final rule with comment period for detailed descriptions of this measure.

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. We believe this measure is appropriate for measuring quality of care in ASCs due to the significant impact of HCP influenza vaccination on the spread of influenza among patients. Furthermore, we believe that this measure meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it is endorsed by the NQF.

We proposed that ASCs use the NHSN infrastructure and protocol to report the measure for ASC Quality Reporting Program purposes. Collection of data via the NHSN for this measure would begin with immunizations from October 1, 2013 to March 31, 2014 for the CY 2016 payment determination. In the proposed rule, we invited public comment on our proposal to adopt this HAI measure into the ASC Quality Reporting Program for the CY 2016 payment determination.

Comment: A few commenters supported the measure, but were concerned that ASCs will require many resources to initiate this reporting process since they are not accustomed to reporting to NHSN. A commenter recommended that the measure be re-specified for the ASC setting to include only those employees for which ASCs can reasonably report vaccination status. The commenter recommended that CMS postpone data collection for immunizations from the proposed October 1, 2013 to March 31, 2014 to October 1, 2014 through March 31, 2015 for the CY 2016 payment determination.

Response: CMS and CDC recognize the potential challenges faced by ASCs in data collection for this measure. Recently, CDC submitted a revised measure proposal to NQF, based on results of field testing. The revised measure proposal reduces denominator data collection to employee healthcare personnel, defined as staff on facility payroll, and two categories of non-employee healthcare personnel: (1) Licensed independent practitioners, that is, physicians, advance practice nurses, and physician assistants; and (2) student trainees and adult volunteers.

Based on the public comments we received, we are changing the proposed initial reporting period for HCP influenza vaccination coverage so that a less burdensome, updated CDC protocol for the measures as well as infrastructure upgrades can be incorporated into the collection system and ASCs will have enough time to obtain training to collect and report the updated measure to NHSN. The reporting period will begin October 1, 2014 and continue through March 31, 2015 for ASCs as recommended by commenters. Further details on the submission requirements for this measure will be proposed in the Form Manner and Timing section for this program in a future rulemaking.

Comment: A commenter cautioned potential duplicative reporting efforts since some States already mandate vaccination of healthcare workers and public reporting of healthcare vaccination rates.

Response: We appreciate the commenter's cautionary note and recognize that requirements for measurement and reporting of HCP vaccination rates, as is the case for other measureable healthcare processes and outcomes, may exist at the State and federal levels. Standardizing reportable healthcare quality measurements is a priority because that reduces reporting burden while preserving the opportunities to use those data for different purposes at the State and federal levels.

Comment: A commenter stated that the measure should allow healthcare personnel to choose the vaccination type or brand most appropriate for them.

Response: The measure does not require healthcare personnel to receive a specific type or brand of influenza vaccine in order to be included in the measure.

After consideration of the public comments we received, we are finalizing the proposed Influenza Vaccination Coverage among Healthcare Personnel measure for the CY 2016 payment determination, with a modification. Because NQF's final review and an endorsement decision are pending with respect to the CDC's revised measure proposal and at the request of commenters, as discussed above, we are changing the data collection timeframe from what we proposed. Data collection via NHSN will begin on October 1, 2014 and continue through March 31, 2015. Details for submission of this measure will be proposed in a future rulemaking.

In summary, for the CY 2016 payment determination, we are retaining the seven measures that we adopted for the CY 2015 payment determination and are adding one NHSN HAI measure for a total of eight measures.

The measures for ASCs for the CY 2016 payment determination are listed below:

BILLING CODE 4120–01–P

ASC Program Measurement Set for the CY 2016 Payment Determination	
ASC-1: Patient Burn	
ASC-2: Patient Fall	
ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant	
ASC-4: Hospital Transfer/Admission	
ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing	
ASC-6: Safe Surgery Checklist Use	
ASC-7: ASC Facility Volume Data on Selected ASC Surgical Procedures	
Procedure Category	Corresponding HCPCS Codes
Gastrointestinal	40000 through 49999, G0104, G0105,G0121,C9716, C9724, C9725, 0170T
Eye	65000 through 68999, G0186, 0124T, 0099T, 0017T, 0016T, 0123T, 0100T, 0176T, 0177T, 0186T, 0190T, 0191T, 0192T, 76510, 0099T
Nervous System	61000 through 64999, G0260, 0027T, 0213T, 0214T, 0215T, 0216T, 0217T, 0218T, 0062T
Musculoskeletal	20000 through 29999, 0101T, 0102T, 0062T, 0200T, 0201T
Skin	10000 through 19999, G0247, 0046T, 0268T, G0127, C9726, C9727
Genitourinary	50000 through 58999, 0193T, 58805
ASC- 8: Influenza Vaccination Coverage among Healthcare Personnel *	

*New measure for CY 2016 payment determination.

6. ASC Measure Topics for Future Consideration

Below is a list of future measurement areas that we are considering for future ASC Quality Reporting Program payment determinations for which we sought comment in the CY 2012 OPPS/ASC proposed rule (76 FR 42347 through 42348).

In particular, we sought comment on the inclusion of Patient Experience of Care Measures in the ASC Quality Reporting Program measure set for a future payment determination, such as existing Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys for clinicians/groups and the CAHPS Surgical Care Survey, sponsored and submitted by the American College of Surgeons (ACS) and the Surgical Quality Alliance (SQA). We also, in particular, sought comment on the inclusion of procedure-specific measures for cataract surgery, colonoscopy and endoscopy, and for measures of Anesthesia Related Complications in the ASC Quality Reporting Program measure set.

Measures and Measurement Topics under Consideration for Future Payment Determinations
Patient Experience of Care:
Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys for clinicians/groups
CAHPS Surgical Care Survey
Procedure Specific Measures
Colonoscopy and other Endoscopy measures
Cataract Surgery measures
Anesthesia Related Complications:
Death
Cardiac Arrest
Perioperative Myocardial Infarction
Anaphylaxis
Hyperthermia
Transfusion Reaction
Stroke, Cerebral Vascular Accident, or Coma following anesthesia
Visual Loss
Medication Error
Unplanned ICU admission
Patient intraoperative awareness
Unrecognized difficult airway
Reintubation
Dental Trauma
Perioperative aspiration
Vascular access complication, including vascular injury or pneumothorax
Pneumothorax following attempted vascular access or regional anesthesia
Infection following epidural or spinal anesthesia
Epidural hematoma following spinal or epidural anesthesia
High Spinal
Postdural puncture headache
Major systemic local anesthetic toxicity
Peripheral neurologic deficit following regional anesthesia
Infection following peripheral nerve block

Measures and Measurement Topics under Consideration for Future Payment Determinations
Additional Future Measurement Topics:
NQF Serious Reportable Events in Healthcare
Medication administration variance
Medication reconciliation
Venous thromboembolism measures: outcome/assessment/prophylaxis.
Presence of Physician during Entire Recovery Period
Post-discharge follow up
Post-discharge ED visit within 72 hours

BILLING CODE 4120–01–C

In the proposed rule, we invited public comment on these quality measures and measurement topics so that we may consider proposing to adopt them for future ASC Quality Reporting Program payment determinations beginning with the CY 2015 payment determination. We also sought suggestions for additional measures and rationales for the ASC Quality Reporting Program that are not listed in the table above.

• Patient's Experience of Care Measure

Comment: One commenter noted that the CAHPS surgical care survey was not appropriate for ASCs since it may not address the short patient experience with staff performance at ASCs.

Response: We thank the commenter for the input and we will take it into consideration in future measure selection efforts for this program.

• Anesthesia Related Complications Measures

Comment: A commenter supported the anesthesia related complications measures listed, including, Use of Reversal Agents, Type of Anesthesia and Credentials of the Professional Administering Anesthesia When a Complication is Reported, Presence of Physician During Entire Recovery Period, and Post Discharge ED Visit within 72 Hours.

Response: We thank the commenter for the input on anesthesia related complications. We will take this input into consideration in future measure selection efforts for this program.

• Additional Future Measurement Topics

Comment: A commenter recommended CMS taking a cautious approach for the venous thromboembolism measures: outcome/assessment/prophylaxis measure because the incidence of deep vein thrombosis (DVT) and pulmonary embolism (PE) following total knee and hip replacement can be reduced but not eliminated. The commenter noted the trade off for lower DVT/PE rates is more wound complications, including surgical site infections.

Response: We thank the commenter for the input and recommendation. We will take them into consideration in future measure selection efforts for this program.

• Other Measure Topics

Comment: A commenter recommended the future inclusion of ASC specialty-specific measures, especially ASC-specific GI measures, plan for reprocessing endoscope, more measures related to safe injection practices, accreditation status, participation in a registry, sedation safety, and nursing sensitive structural measures.

Response: We thank the commenter for the input and recommendations for future measurement topics. We will take them into consideration in future measure selection efforts for this program.

7. Technical Specification Updates and Data Publication

a. Maintenance of Technical Specifications for Quality Measures

In the CY 2012 OPPS/ASC proposed rule (76 FR 42348), we proposed to provide technical specifications, and in some cases, links to technical specifications hosted on external third party Web sites, for the ASC Quality Reporting Program measure in a Specifications Manual, to be posted after publication of the CY 2012 OPPS/ASC final rule with comment period, on the CMS QualityNet Web site at *http://www.QualityNet.org*. Currently, the specifications for the proposed ASC measures for the CY 2014, CY 2015 and CY 2016 payment determinations, with the exception of the two structural measures, can be found at: *http://www.ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pdf; http://www.cms.gov/pqrs/downloads/2011_PhysQualRptg_MeasuresGroups_SpecificationsManual_033111.pdf?agree=yes&next=Accept; http://www.cdc.gov/vnhsn/psc.html;* and *http://www.cdc.gov/nhsn/PDFs/HSPmanual/HPS_Manual.pdf*. The specifications for the two structural measures are included in the discussion.

We proposed to maintain the technical specifications for the measures adopted for the ASC Quality Reporting Program by updating this Specifications Manual, including updating the detailed instructions and the calculation of algorithms as appropriate. In some cases where the specifications are available elsewhere, we may include links to Web sites hosting technical specifications. We currently use this same process for Hospital OQR Program measures, as discussed in sections XIV.A.3.a. of the proposed rule and this final rule with comment period. We proposed to follow the same technical specification maintenance process for the ASC Quality Reporting Program measures as for the Hospital OQR Program measures and we invited public comments on this proposal.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766 through 68767), we established a subregulatory process for updates to the technical specifications that we use to calculate Hospital OQR Program measures. This process is used when changes to the measure specifications are necessary due to changes in scientific evidence or other substantive changes, thereby giving CMS the option

to seek re-endorsement of that measure. The legal standard for adopting Hospital OQR measures is the measure must be appropriate to measure quality of care in the setting, there must be consensus among affected parties, and to the extent feasible and practicable, measures must be set forth by a consensus building entity. We note that NQF endorsement of an OQR measure is not required under sections 1833(i)(2)(D)(iv), (i)(7) or (t)(17) of the Act. The legal standard for adopting ASC measures is this same standard, except as the Secretary may otherwise provide. Changes of this nature to measures adopted for the ASC Quality Reporting Program may not coincide with the timing of our regulatory actions, but nevertheless require inclusion in the measure specifications so that measures are calculated based on the most up-to-date scientific standards and, in some instances, consensus standards.

For the Hospital OQR Program, we indicated that notification of changes to the measure specifications is available on the QualityNet Web site, *http://www.QualityNet.org,* and in the Hospital OQR Specifications Manual and would occur no less than 3 months before any changes become effective for purposes of reporting under the Hospital OQR Program. The Hospital OQR Specifications Manual is released every 6 months and addenda are released as necessary providing at least 3 months of advance notice for substantial changes, such as changes to ICD–9, CPT, NUBC, and HCPCS codes, and at least 6 months notice for substantive changes to data elements that would require significant systems changes. We proposed to follow the same subregulatory process for the ASC Quality Reporting Program for updates to the technical specifications. In the proposed rule, we invited public comments on this proposal.

Comment: A few commenters expressed appreciation of the technical specifications maintenance timeline, which proposes that at least 6 months of advance notice will be provided to participants for substantive changes to data elements that would require significant system changes and at least three months for substantial changes. A commenter noted that the implementation of a new reporting program requires even more advance notice and no less than a minimum of 6 months.

Response: We appreciate the commenters' support for our proposed technical specifications maintenance timeline. We will strive to provide as much advance notice as possible when substantive changes to technical specifications are made. We are providing more start up time for the program by delaying the start of required data submission for the program to October 1, 2012.

After consideration of the public comment we received, we are finalizing the policy of providing technical specifications and links to technical specifications in a Specifications Manual to be posted after publication of this final rule with comment period. However, we are finalizing a policy of posting it not only the CMS QualityNet Web site as we proposed, but also on a CMS Web site such as *http://www.cms.gov* because we wish to utilize multiple Web sites to increase ASC awareness of our technical and measure specifications in our outreach and education. We believe that posting the information on the QualityNet Web site would increase ASC awareness of our program's specifications. However, we also believe that many ASC's will review the CMS Web site, since CMS posts claims processing manuals and other documentation that are used by providers and practitioners to submit claims to CMS.

We also are finalizing our proposal to follow the same maintenance process used for the Hospital OQR Program, including maintenance of the technical specifications for the measures adopted by updating the Specifications Manual, and updating the detailed instructions and the calculation of algorithms as appropriate. We also are finalizing our policy to follow the same subregulatory process for the ASC Quality Reporting Program as used for the Hospital OQR Program for updates to the technical specifications, including issuing regular manual releases at six month intervals, to provide addenda as necessary, and providing at least 3 months of advance notice for substantial changes such as changes to ICD–9, CPT, NUBC, and HCPCS codes, and at least 6 months notice for substantive changes to data elements that would require significant systems changes.

b. Publication of ASC Quality Reporting Program Data

Section 1833(t)(17)(E) of the Act requires that the Secretary establish procedures to make data collected under the Hospital OQR Program available to the public. It also states that such procedures must ensure that a hospital has the opportunity to review the data that are to be made public with respect to the hospital prior to such data being made public. These requirements under section 1833(t)(17)(E) of the Act also apply to the ASC Quality Reporting Program except as the Secretary may otherwise provide. In the CY 2012 OPPS/ASC proposed rule (76 FR 42348), we proposed to make data that an ASC has submitted for the ASC Quality Reporting Program available on a CMS Web site after providing an ASC an opportunity to preview the data to be made public. We proposed that these data would be displayed at the CMS Certification Number (CCN) level. Publishing this information encourages beneficiaries to work with their doctors and ASCs to discuss the quality of care ASCs provide to patients, thereby providing an additional incentive to ASCs to improve the quality of care that they furnish. We intend to propose more detail on the publication of data in a later rulemaking. In the proposed rule, we solicited public comment on these proposed processes of making ASC quality data available to the public.

Comment: Commenters overwhelmingly supported transparency in ASC quality reporting and cost information and some recommended CMS publish the ASC quality data at the earliest opportunity.

Commenters believed the ASC quality information should be displayed in a manner that allows easy comparisons for quality and cost between HOPDs and ASCs. Commenters expressed concerns regarding potential inappropriate data displayed on *Hospital Compare.* These commenters suggested that, in publicly displaying ASC data, CMS should: (1) Provide contact information for program content area experts; (2) provide a provider-specific narrative section that would allow providers to advise consumers on any concerns the provider has regarding the reliability or accuracy of data posted; (3) provide each ASC's accreditation status; (4) display Medicare rates and patients' out-of-pocket costs for services provided in both HOPD and ASC settings; (5) distinguish ASCs where only GI procedures are done, those where they are also done, and those where they are not done; and (6) stratify performance data when it is publicly posted based on risk profiles.

Response: We thank the commenters for their support and suggestions. We will take the suggestions into consideration for future public reporting of the data.

Comment: Some commenters believed that ASCs should have one year of confidential feedback on measure participation, data completeness, QDC submission errors, and performance details at CCN level, prior to publication of the data. Some commenters recommended that an appeals process should be put in place for dispute of data accuracy.

Response: We will consider these suggestions. We are required to make the data submitted under this program available to the public. Prior to making the data available to the public, we also are required to provide facilities with the opportunity to review their data. We intend to propose a reconsideration and appeals process in future rulemaking.

Comment: A few commenters urged CMS to strive for user friendly data on the CMS Web site for the ASC Quality Reporting Program.

Response: We thank the commenters for their suggestion; we intend to make the display as consumer friendly as possible.

After consideration of the public comments we received, we are finalizing our proposed policy to make data that an ASC has submitted for the ASC Quality Reporting Program available on a CMS Web site after providing an ASC an opportunity to preview the data to be made public. As we proposed, these data will be displayed at the CCN level.

8. Requirements for Reporting of ASC Quality Data for the CY 2014 Payment Determination

In the CY 2012 OPPS/ASC proposed rule (76 FR 42348 through 42349), to participate in the ASC Quality Reporting Program for the CY 2014 payment determination, we proposed that ASCs must meet data collection and data submission requirements. We stated that we intend to propose administrative requirements, data validation and data completeness requirements, reconsideration and appeals processes, and CY 2015 payment determination reporting requirements in the CY 2013 OPPS/ASC proposed rule.

Comment: Several commenters stated their concern that administrative requirements, data validation and data completeness requirements, and reconsideration and appeal processes were not proposed or provided in detail. Several commenters suggested that rules for data validation and completeness as well as the proposed process for reconsideration and appeals be specified in an interim rule in the first quarter of 2012. One commenter stated their belief that since the use of claims-based quality data codes is a new approach to quality data reporting, data validation procedures must be included in a final ASC Quality Reporting Program. One commenter wished to consider the more detailed proposals intended for publication in later rulemaking and encouraged CMS to issue these proposals at the earliest opportunity. One commenter believed that the uncertainty associated with not knowing what is necessary to be a successful participant in the program is an unwanted deterrent to full participation.

Response: We thank these commenters for expressing their concerns regarding the deferring of proposals for administrative requirements, data validation and data completeness requirements, and reconsideration and appeals processes requirements until the CY 2013 OPPS/ASC proposed rule. We fully intend to put forth these proposals as soon as possible using the public comments we received on the CY 2012 OPPS/ASC proposed rule.

We agree that it is preferable to issue these proposals as soon as possible and based upon the comments received intend to do so in the FY 2013 IPPS/LTCH PPS proposed rule rather than the CY 2013 OPPS/ASC proposed rule. We intend to take this approach because the FY 2013 IPPS/LTCH PPS proposed rule is scheduled to finalize earlier and prior to data collection beginning with October 2012 services. We disagree with the comment that the use of claims-based quality codes is a new approach to quality data reporting; this mechanism is used to collect such information under the PQRS. However, regarding the necessity to include data validation procedures in a final ASC Quality Reporting Program, we will consider these comments for future rulemaking. We note that claims-based and structural measures historically have not been validated through independent medical record review in our hospital and physician quality reporting programs due to the lack of relevant information in medical record documentation for specific data elements, such as use of a safe surgery checklist.

Comment: One commenter stated that QualityNet accounts are automatically deactivated after a 120-day period of inactivity and yet as proposed, ASCs would only use the QualityNet for data submission infrequently. This commenter urged CMS to establish a process to avert account deactivation.

Response: We thank the commenter for raising this issue. While we did not make any proposals specifically addressing the need for a QualityNet account, we made proposals regarding the entering of structural measure data which may necessitate the need for a QualityNet account. In finalizing our proposals regarding structural measure data entry, we note that we have deferred the data entry for structural measure data until 2013; note that a QualityNet account is not necessary to access information that is posted to the Web site, such as specifications manuals and educational materials. We intend to address any QualityNet account requirements for the ASC Quality Reporting Program for program requirements in later rulemaking.

a. Data Collection and Submission Requirements for the Claims-Based Measures

In the CY 2012 OPPS/ASC proposed rule (76 FR 42348 through 42349), we proposed that, to be eligible for the full CY 2014 ASC annual payment update, ASCs would be required to submit complete data on individual quality measures through a claims-based reporting mechanism by submitting the appropriate QDCs on the ASC's Medicare claims. For the CY 2014 payment determination, we proposed to use Medicare fee-for-service ASC claims for services furnished between January 1, 2012 and December 31, 2012.

We proposed to consider an ASC as participating in the ASC Quality Reporting Program for CY 2014 payment determination if the ASC includes QDCs specified for the program on their CY 2012 claims relating to the proposed measures if finalized. As no determinations will be made affecting payment until the CY 2014 annual payment update, we proposed this approach in order to reduce ASC burden. We stated that we intend to provide additional details regarding participation notification and other administrative requirements in CY 2013 rulemaking.

We proposed that data completeness for claims-based measures would be determined by comparing the number of claims meeting measure specifications that contain the appropriate QDCs with the number of claims that would meet measure specifications, but did not have the appropriate QDCs on the submitted claim. We stated that we intend to propose how we will assess data completeness for claims-based measures in the CY 2013 OPPS/ASC proposed rule. In the CY 2012 OPPS/ASC proposed rule, we requested public comment on these proposals and were specifically interested in receiving public comment on what constitutes complete data in regard to our proposed ASC claims-based measures utilizing QDCs and methods to assess completeness.

Comment: Some commenters supported the proposal to consider an ASC as participating in the ASC Quality Reporting Program if the ASC includes the QDCs established for finalized claims-based measures on its submitted claim forms during the reporting period

for the CY 2014 payment determination as this approach was seen as reasonable and reduced burden.

Response: We thank these commenters for their support. We agree that this method is reasonable and will reduce burden.

Comment: Many commenters expressed their belief that the time line for beginning the reporting of quality data was too aggressive, citing issues of time to adapt billing systems and personnel training. Many commenters suggested that data collection be delayed, beginning with October 1, 2012 services, rather than January 1, 2012 services as proposed.

Response: We thank the commenters for their views. Based upon the many comments received regarding the data collection time period for the CY 2014 payment determination, we are delaying the beginning of the data collection until October 1, 2012. Thus, we will be using the claims-based QDC data collection mechanism for ASC services furnished for Medicare patients from October 1, 2012 through December 31, 2012 for the CY 2014 payment determination measures, as discussed in section XIV.K.3.a. of this final rule with comment period.

Comment: One commenter believed that a low threshold for data completeness should be established for data collection during CY 2012 because ASCs will not know the rules by which they are being judged until late in 2012 and that reporting thresholds of less than 100 percent for initial reporting periods are consistent with other CMS reporting programs. Some commenters suggested, that due to ASCs not being familiar with reporting, successful reporting on a limited number of claims, for example, 50 percent should be permitted, a level similar to that in the PQRS.

Response: We thank these commenters for responding to our request on what constitutes complete data for our proposed ASC claims-based measures. We agree that for the initial year of the program, a low threshold should be used and that a level such as the 50 percent used in the PQRS would be reasonable. As previously stated, we intend to propose how we will assess data completeness for claims-based measures in the FY 2013 IPPS/LTCH PPS proposed rule and will consider the comments when developing our proposals.

Comment: Some commenters believed that, given the variability in ASC case mix, it can reasonably be anticipated that some measures will not apply to all ASCs, and, therefore, that CMS should consider the need for exemptions based on case-mix. One commenter believed that some smaller facilities may not have any cases for the proposed ASC quality measures and that to maintain a process that limits burden, waiving data submission requirements when a facility has 5 or fewer cases for a measure as is done under the Hospital IQR and Hospital OQR Programs could be implemented.

Response: We thank the commenters for their views regarding criteria for reporting exemptions under the ASC Quality Reporting Program. We will consider these comments as we develop our proposals in future rulemaking. As stated above, based upon the comments received, we intend to make further proposals on data completeness in the FY 2013 IPPS/LTCH PPS proposed rule rather than the CY 2013 OPPS/ASC proposed rule as the former rule is scheduled to finalize earlier. We agree that waiving data submission requirements for low case loads is reasonable and we will consider this comment with all others when developing our proposals.

Comment: One commenter believed that, since the full complement of measures are not applicable to all ASCs, G-codes that ASCs can submit once during a performance period that indicates the measure is not applicable to the ASC should be developed, thereby exempting the ASC from data submission for the measure. One commenter believed that it is unclear how a facility should report with respect to a measure that may not be applicable to the services furnished by that type of ASC. One commenter sought clarification that ASCs would not need to report on all measures, but only those measures that applied.

Response: We thank the commenters for their views regarding methods to report when an ASC does not have cases for a quality measure. We understand that a measure may not be applicable to the services furnished by a type of ASC. For the reporting of quality data using QDCs, as stated in Section XIV.K.1.a.5, ASCs would add the appropriate QDCs for measure numerators and denominators on Medicare Part B claim forms to submit quality data. We intend to provide education and outreach on data submission for the reporting program, and we will publish details about the QDCs and whether they will need to be submitted for numerators and denominators in the ASC Quality Reporting Program Specifications Manual. We anticipate releasing this manual in second quarter 2012.

Comment: Some commenters believed that what CMS proposed as constituting ''successful'' reporting, that is complete submission, was vague.

Response: We are finalizing our proposals to assess the completeness of reporting by comparing the number of claims meeting measure specifications that contain the appropriate QDCs with the number of claims that would meet measure specifications, but did not have the appropriate QDCs on the submitted claims. We will be using public comments we received that addressed this issue in the development of our future proposals. As stated above, we intend to propose a specific definition of reporting completeness in the FY 2013 IPPS/LTCH PPS proposed rule in order to provide opportunity for notice and comment prior to October 2012 services.

After consideration of the public comments received, we are finalizing our proposals with some modification. As proposed, we are finalizing our proposal that, to be eligible for the full CY 2014 ASC annual payment update, an ASC must submit complete data on individual quality measures through a claims-based reporting mechanism by submitting the appropriate QDCs on the ASC's Medicare claims. Further, as proposed, we are finalizing our proposal that data completeness for claims-based measures be determined by comparing the number of claims meeting measure specifications that contain the appropriate QDCs with the number of claims that would meet measure specifications, but did not have the appropriate QDCs on the submitted claim. Finally, we are deferring the data collection time period for the CY 2014 payment determination to a later date, beginning data collection with services beginning October 1, 2012, rather than January 1, 2012, while maintaining the end date of December 31, 2012.

We also are finalizing our proposal to consider an ASC as participating in the ASC Quality Reporting Program for CY 2014 payment determination if the ASC includes QDCs specified for the program on their CY 2012 claims relating to finalized measures.

b. Data Submission Deadlines for the Surgical Site Infection Rate Measure

As discussed above, we proposed to adopt a HAI measure, Surgical Site Infection Rate, for the CY 2014 payment determination. We proposed to use the data submission and reporting standard procedures that have been set forth by the CDC for NHSN participation in general and for submission of this measure to the NHSN. We referred readers to the CDC's NHSN Web site (*http://www.cdc.gov/nhsn*) for detailed data submission and reporting

procedures. Our proposal seeks to reduce ASC burden by aligning CMS data submission and reporting procedures with NHSN procedures currently used by healthcare providers and suppliers. The submission timeframes for the CY 2014 payment determination that we proposed to use for the proposed Surgical Site Infection Rate measure were shown in the CY 2012 OPPS/ASC proposed rule (76 FR 42349). We stated that ASCs must submit their quarterly data to the NHSN for ASC Quality Data Reporting purposes within the date intervals shown in the table set out in the proposed rule (76 FR 43249) (any updates to this schedule would be posted on the QualityNet and CMS Web sites).

In the proposed rule, we requested public comments on these proposals. We did not receive any comments specifically on the proposed timeframes. However, as discussed above, we are not finalizing this measure at this time; therefore, we are not finalizing this time table for data collection.

XV. Changes to Whole Hospital and Rural Provider Exceptions to the Physician Self-Referral Prohibition: Exception for Expansion of Facility Capacity; and Changes to Provider Agreement Regulations Relating to Patient Notification Requirements

A. Background

Section 1877 of the Act, also known as the physician self-referral law: (1) Prohibits a physician from making referrals for certain ''designated health services'' (DHS) payable by Medicare to an entity with which the physician (or an immediate family member) has a financial relationship (ownership or compensation), unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those DHS furnished as a result of a prohibited referral. The Act establishes a number of specific exceptions and grants the Secretary the authority to create regulatory exceptions that pose no risk of program or patient abuse.

Section 1877(d) of the Act sets forth additional exceptions related to ownership or investment interests held by a physician (or an immediate family member of a physician) in an entity that furnishes DHS. Section 1877(d)(2) of the Act provides an exception for ownership or investment interests in rural providers. In order for an entity to qualify for the exception, the DHS must be furnished in a rural area (as defined in section 1886(d)(2) of the Act) and substantially all of the DHS furnished by the entity must be furnished to individuals residing in a rural area. Section 1877(d)(3) of the Act provides an exception, known as the ''whole hospital'' exception, for ownership or investment interests in a hospital located outside of Puerto Rico, provided that the referring physician is authorized to perform services at the hospital and the ownership or investment interest is in the hospital itself (and not merely in a subdivision of the hospital).

B. Changes Made by the Affordable Care Act

1. Provisions Relating to Exceptions to Ownership and Investment Prohibition (Section 6001(a) of the Affordable Care Act)

Section 6001(a) of the Affordable Care Act amended the whole hospital and rural provider exceptions to impose additional restrictions on physician ownership or investment in hospitals. The statute defines a ''physician owner or investor'' in a hospital as a physician or immediate family member of a physician who has a direct or indirect ownership or investment interest in a hospital. We will refer to hospitals with such ''physician owners or investors'' as ''physician-owned hospitals.''

We addressed section 6001(a) of the Affordable Care Act in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71800). In 42 CFR 411.362, we implemented most of the requirements of section 6001(a) of the Affordable Care Act, including patient safety requirements. In sections XV.B.2. and C. of the CY 2012 OPPS/ASC proposed rule (76 FR 42350) and this final rule with comment period, we address the process for a hospital to request an exception to the prohibition on expansion of facility capacity under section 6001(a)(3) of the Affordable Care Act. In section XV.D. of the proposed rule and this final rule with comment period, we address related patient notification requirements in the provider agreement regulations.

2. Provisions of Section 6001(a)(3) of the Affordable Care Act

The amended whole hospital and rural provider exceptions provide that a hospital may not increase the number of operating rooms, procedure rooms, and beds beyond that for which the hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of this date, but did have a provider agreement in effect on December 31, 2010, the date of effect of such agreement). Section 6001(a)(3) of the Affordable Care Act added new section 1877(i)(3)(A)(i) of the Act to set forth that the Secretary shall establish and implement an exception process to the prohibition on expansion of facility capacity. Referrals are prohibited if made by physician owners or investors after facility expansion and prior to the Secretary granting an exception. Exceptions for expanding facility capacity will protect only those referrals made after the exception is granted. In the CY 2012 OPPS/ASC proposed rule (76 FR 42350), we set forth proposed regulations for this process at § 411.362(c) and related definitions at § 411.362(a).

The proposed regulations at new § 411.362(c) set forth the process for a hospital to request an exception. Proposed new § 411.362(c)(2) outlined the requirements for an applicable hospital request and § 411.362(c)(3) outlined the requirements for a high Medicaid facility request. These terms are defined at sections 1877(i)(3)(E) and 1877(i)(3)(F) of the Act. The statute is clear that an applicable hospital may apply for an exception up to once every 2 years. Using our rulemaking authority under sections 1871 and 1877(i)(3)(A)(i) of the Act, we proposed to interpret the statute to impose the same 2-year frequency limit on high Medicaid facilities (as discussed in section XV.C.2. of this final rule with comment period).

We proposed to set forth the elements required for a complete request for an exception under proposed new § 411.362(c)(4). The opportunity for community input (required by section 1877(i)(3)(A)(ii) of the Act) and timing of a complete request were described in proposed new § 411.362(c)(5). Under proposed new § 411.362(c)(5), we proposed to provide an opportunity for individuals and entities in the community in which the hospital is located to provide input with respect to the hospital's request for an exception. For purposes of the proposed rule and this final rule with comment period, when the statute refers to an ''application,'' we use the term ''request.''

Because section 1877(i)(3)(D) of the Act provides that any increase in the number of operating rooms, procedure rooms, and beds for which a hospital is licensed pursuant to being granted an exception may occur only in facilities on the hospital's main campus, we proposed a definition of the ''main campus of the hospital'' at § 411.362(a), as discussed below. In addition, we proposed a definition of the ''baseline number of operating rooms, procedure

rooms, and beds'' for purposes of section 1877(i)(3)(C)(ii) of the Act.

Section 1877(i)(3)(H) of the Act provides that the Secretary shall publish the final decision with respect to an application in the **Federal Register** no later than 60 days after receiving a complete application. Under section XV.C.4. of the proposed rule and this final rule with comment period, we discuss our proposal for publishing decisions in the **Federal Register**, as well as on the CMS Web site.

Under section 1877(i)(3)(A) of the Act, the Secretary must promulgate regulations by January 1, 2012, concerning the process for a hospital to apply for an exception, and implement this process on February 1, 2012. In the proposed rule, we proposed an effective date of January 1, 2012. Below, we set out our proposals and our final policies related to the exception process in greater detail.

C. Process for Requesting an Exception to the Prohibition on Expansion of Facility Capacity

In order to conform our regulations to the amendments made to the rural provider and whole hospital exceptions by section 6001(a)(3) of the Affordable Care Act, in the CY 2012 OPPS/ASC proposed rule (76 FR 42350), we proposed to add two definitions in § 411.362(a) and a new § 411.362(c) to establish the process by which an applicable hospital or high Medicaid facility may request an exception to the prohibition on expansion of facility capacity. We proposed to define the terms ''baseline number of operating rooms, procedure rooms, and beds'' and ''main campus of the hospital.'' The process we proposed set forth the relevant data sources and the required elements of a complete request for an exception. Below we address comments we received on this proposal.

1. General Comments

Comment: Commenters were generally supportive of CMS' overall approach to the exception process. One commenter contended that the proposed rule honors the purpose and intent of the Affordable Care Act's elimination of the whole hospital exception while permitting reasonable grandfathering policies to protect self-referrals for existing physician-owned hospitals.

Response: We appreciate the commenters' support.

Comment: In the proposed rule (76 FR 42350 and 42351), CMS proposed that data from the CMS Healthcare Cost Report Information System (HCRIS) be used to determine whether a hospital satisfies the inpatient Medicaid admissions, bed capacity, and bed occupancy criteria for applicable hospitals or the inpatient Medicaid admissions criterion for high Medicaid facilities. CMS currently considers HCRIS to contain a sufficient amount of data for a particular fiscal year if HCRIS contains data from at least 6,100 hospitals for that fiscal year. Therefore, CMS proposed that HCRIS must contain data from at least 6,100 hospitals for a particular year in order for that year's data to be used under the exception process. CMS proposed that if HCRIS does not contain sufficient data for that year, data from the most recent year(s) that satisfy the threshold should be used.

Some commenters supported the CMS proposal to require hospitals to use data maintained within HCRIS to demonstrate that they satisfy the relevant eligibility criteria. These commenters asserted that use of standardized data sets will minimize inconsistent application of the eligibility criteria.

Response: We appreciate the commenters' support.

Comment: One commenter recommended that CMS consider using the Dartmouth Atlas ''Hospital Service Areas'' and the 24-kilometer radius around a hospital in determining whether a hospital has a legitimate need to increase its number of operating rooms, procedure rooms, and beds under the exception process for both applicable hospitals and high Medicaid facilities.

Response: The commenter did not provide details regarding how the suggested geographic areas should be considered in the exception process. If the commenter is recommending that we use these areas in lieu of the county, State, or national data referred to in sections 1877(i)(3)(E) and 1877(i)(3)(F) of the Act, the recommendation is contrary to these statutory directives, and, therefore, we decline to adopt it.

2. Applicable Hospital

Below we separately discuss each of the statutory criteria that a hospital must satisfy to qualify as an ''applicable hospital.'' In the CY 2012 OPPS/ASC proposed rule (76 FR 42350), we proposed the processes by which a hospital can determine whether it satisfies each criterion. The proposed data requirements for each criterion are further discussed in each section below.

We stated in the proposed rule that we will post the average percent of total inpatient Medicaid admissions per county, the average bed capacity per State, the national average bed capacity, and the average bed occupancy per State on the CMS Web site at: *http://www.cms.gov/physicianselfreferral/85_physician_owned_hospitals.asp.* We stated that hospitals could access these data to assess whether they satisfy the respective criteria to qualify as an applicable hospital. We also stated that we would make a reasonable effort to ensure that the data contained in HCRIS are correct and complete at the time of disclosure. We invited public comment on proposing and justifying alternative data sources other than HCRIS that could result in more accurate determinations as to whether a hospital satisfies the relevant criteria. We received the following comment regarding the requirement that hospitals must use data maintained within HCRIS to demonstrate satisfaction of the eligibility criteria.

Comment: One commenter recommended that CMS permit applicable hospitals to use State agency-maintained data to demonstrate that they meet the eligibility criteria concerning inpatient Medicaid admissions, bed capacity, and bed occupancy. The commenter asserted that State agency-maintained data are as accurate as data maintained within HCRIS and are often available more quickly.

Response: We are not persuaded to adopt the commenter's recommendation. We will require hospitals to use data maintained within HCRIS. We believe this will result in the use of uniform and consistent data, which will minimize inconsistent application of the eligibility criteria.

a. Percentage Increase in Population

Section 1877(i)(3)(E)(i) of the Act provides that an applicable hospital must be located in a county in which the percentage increase in the population during the most recent 5-year period (as of the application date) is at least 150 percent of the percentage increase in the population growth of the State in which the hospital is located during that period, as estimated by the Bureau of the Census.

To determine the percentage increase in population in the county and State in which the hospital is located, we proposed at new § 411.362(c)(2)(i) that the hospital use population estimates provided by the Bureau of the Census. If the hospital is located in an area referred to by the Bureau of the Census as a county equivalent area, such as an independent city, borough, or census area, we proposed that the hospital should use the Bureau of the Census estimates for the county equivalent area in which it is located. For the remainder of this subsection, ''county'' refers to

both a county and a county equivalent area.

We acknowledged that the Bureau of the Census may not provide county and State population size estimates that are current as of the date that a hospital submits its request for an exception. We proposed that a hospital should use only the most recent estimates available to perform the necessary calculations. For example, if a hospital submits a request for an exception in 2012, but the most recent year for which the Bureau of the Census has estimates is 2010, the hospital should perform the necessary calculations using estimates for the most recent 5-year period, which in this example, would include years 2006–2010.

We also proposed that a hospital use county and State population estimates for the same years. For example, if a hospital submits a request for an exception in 2012 and the most recent year for which the Bureau of the Census has State and county population estimates is 2011 and 2010, respectively, the hospital should perform the necessary calculations using estimates for the most recent 5-year period for which the Bureau of the Census has both State and county population estimates, which in this example, would include years 2006–2010. We proposed to review a request based on the population estimates available as of the date that a hospital submits its request even if the Bureau of the Census updates its estimates after the hospital submits its request and prior to our decision. We received the following comment regarding the population growth criterion for applicable hospitals.

Comment: Two commenters supported the proposal to require hospitals to use estimates from the Bureau of the Census for the population growth criterion. The commenters asserted that use of common data sets will minimize inconsistent application of the eligibility criteria.

Response: We appreciate the commenters' support for our proposal.

After consideration of the public comment we received, we are adopting as final our proposed new § 411.362(c)(2)(i), without modification.

b. Inpatient Admissions

Section 1877(i)(3)(E)(ii) of the Act provides that an applicable hospital means a hospital that has an annual percent of total inpatient admissions under Medicaid that is equal to or greater than the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located. We proposed at new § 411.362(c)(2)(ii) to require hospitals to calculate inpatient admissions using filed hospital cost report discharge data. We proposed that, in calculating the hospital's annual percent of total Medicaid inpatient admissions, the hospital should divide the number of discharges for the year that are paid for under Medicaid by the total number of discharges for the year paid for by any governmental or private payor. We invited public comment on other data sources that could be used to provide an accurate estimate of the annual percent of total inpatient Medicaid admissions for the applicable hospital and for all hospitals in the same county.

We did not receive any public comments on our proposal. Therefore, we are finalizing our proposal, without modification, to require hospitals to use hospital cost report discharge data to estimate the annual percentages of total inpatient Medicaid admissions.

The statute does not specify the number of years for which the hospital's annual percent of total inpatient admissions under Medicaid must be equal to or greater than the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located. We proposed at new § 411.362(c)(2)(ii) that a hospital must satisfy this criterion for each of the 3 most recent fiscal years for which data are available as of the date the hospital submits a request. We invited public comment on whether 3 years of data are sufficient to indicate a legitimate need by the hospital to increase its number of operating rooms, procedure rooms, and beds and, if not, how many years of data we should consider in evaluating a request for an exception.

We proposed at new § 411.362(c)(2)(ii) that the hospital would estimate its annual percentage of total inpatient admissions under Medicaid. The hospital would reference its own filed cost reports for the 3 most recent fiscal years for which data are available. We proposed that we would review a request based on the data available as of the date the hospital submits its request. We stated that we plan to issue guidance to further address the process for a hospital to estimate its annual percentage of total inpatient admissions under Medicaid. The guidance will also explain how we will determine and provide the average percentages of inpatient admissions under Medicaid for each county.

Comment: One commenter contended that CMS exceeded its statutory authority in proposing that applicable hospitals must satisfy the eligibility criteria concerning inpatient Medicaid admissions, bed capacity, and bed occupancy for each of the 3 most recent fiscal years. The commenter asserted that the proposal was not supported by the statutory text, which imposes such a requirement for high Medicaid facilities, but not for applicable hospitals. The commenter noted that the Congress could have required applicable hospitals to satisfy these criteria for each of the 3 most recent years, but did not.

Response: We disagree with the commenter that we exceeded our statutory authority in proposing the 3-year timeframe. The fact that Congress did not specify a timeframe for meeting this criterion does not preclude us from imposing a timeframe using our rulemaking authority under sections 1871 and 1877(i)(3)(A)(i) of the Act. We believe a general timeframe helps identify the need for an exception and ensure consistent application of the prohibition.

Comment: One commenter asserted that it was unreasonable to require 3 years of data to demonstrate a legitimate need by a hospital to expand its capacity. The commenter contended that such a requirement would make it virtually impossible for a hospital to qualify as an applicable hospital and would unreasonably delay a hospital's ability to qualify as an ''applicable hospital.'' The commenter recommended that CMS allow applicable hospitals to satisfy the inpatient admission, bed capacity, and bed occupancy criteria using data from any 1 of the last 3 most recent fiscal years prior to a facility capacity expansion request, which would allow hospitals to apply for an exception to the capacity restriction much sooner.

Another commenter expressed concern that 3 years of data on hospital admissions, bed capacity, and bed occupancy is too long to identify trends in the demand for health services, especially in high-growth markets with rapidly changing populations, and, therefore, would be incapable of identifying legitimate expansion needs in some areas of the country. The commenter suggested that data be weighted to identify health care demand trends in States and counties with rapidly changing populations.

Response: We are not persuaded to adopt the first commenter's proposal. We believe that allowing hospitals to use data from any 1 of the last 3 most recent years may result in inconsistent application of the eligibility criteria and the approval of an expansion request based on anomalous data. However, we have reconsidered our proposal to

require hospitals to satisfy eligibility criteria for each of the 3 most recent fiscal years for which data are available. We are adopting a modification of this proposal in this final rule with comment period. Under this modification, a hospital's eligibility for an exception to the prohibition against facility expansion can be established using the most recent year of data available regarding each of the criteria related to inpatient admission data, bed capacity, and bed occupancy rates. We believe that requiring 1 year of data on each of these criteria, together with the requirement to satisfy a 5-year population growth criterion, is sufficient to identify those hospitals with a legitimate need to expand capacity without risking the approval of exception requests based on aberrant data. In addition, we believe that requiring applicable hospitals to perform calculations and submit documentation for 1 year of data, as opposed to 3 years of data, will decrease the administrative burden on applicable hospitals.

With respect to the comment regarding weighted data, the commenter did not set forth a specific recommendation demonstrating how the data can be weighted. Without further detail, we are unable to adopt the commenter's suggestion. Moreover, we believe that our revised policy may address some of the commenter's concerns.

We are modifying proposed new § 411.362(c)(2)(ii), (iv), and (v) to provide that hospitals establish compliance with the inpatient Medicaid admission, average bed capacity, and average bed occupancy criteria for applicable hospitals using the most recent available fiscal year data. A hospital may access these data on the CMS Web site at: *http://www.cms.gov/physicianselfreferral/85_physician_owned_hospitals.asp.* If the hospital filed its own cost report for the respective year and satisfies the criteria to qualify as an applicable hospital, the hospital may submit a request starting on February 1, 2012.

Comment: In the proposed rule (76 FR 42351 and 42352), CMS proposed that estimates of inpatient Medicaid admissions would be based on filed hospital cost report discharge data. In completing the hospital cost report, hospitals report the number of discharges for whom Medicaid is the primary payer. One commenter recommended that, to estimate the annual percent of total inpatient Medicaid admissions, Medicaid should be considered as a whole and not broken down by primary and secondary payers.

Response: We do not agree with the commenter. The statute does not require Medicaid data to be considered as a whole. In addition, hospitals do not submit discharge data in the manner recommended by the commenter, and therefore such data are not readily available for use in the exception process.

After consideration of the public comments we received, we are finalizing at § 411.362(c)(2)(ii) the Medicaid inpatient admission criterion for applicable hospitals. As noted above, the final regulatory language has been modified to permit hospitals to satisfy this criterion using data for the most recent fiscal year for which data are available.

c. Nondiscrimination

Section 1877(i)(3)(E)(iii) of the Act provides that an applicable hospital does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries. We proposed to incorporate this requirement at new § 411.362(c)(2)(iii) of the regulations.

We did not receive any public comments regarding the nondiscrimination criterion. Therefore, we are adopting, as final, the incorporation of the requirement at new § 411.362(c)(2)(iii) without modification.

d. Bed Capacity

Section 1877(i)(3)(E)(iv) of the Act provides that an applicable hospital means a hospital that is located in a State in which the average bed capacity in the State is less than the national average bed capacity. The statute does not specify a time period over which a State's average bed capacity must be less than the national average bed capacity. We proposed at new § 411.362(c)(2)(iv) that the State average bed capacity must be less than the national average bed capacity for each of the 3 most recent fiscal years for which data are available as of the date that a hospital submits its request. We invited public comment on whether 3 years of data are sufficient to indicate a legitimate need by the hospital to increase its number of operating rooms, procedure rooms, and beds and, if not, how many years of data we should consider in evaluating any request for an exception. We note that, for the reasons stated in section XV.C.1.b. of this final rule with comment period, we are modifying the proposed regulatory language to require applicable hospitals to satisfy the bed capacity criterion during only the most recent fiscal year for which data are available.

Under our proposed process, we would use filed hospital cost reporting data to determine State and national average bed capacities. We stated that we plan to issue guidance explaining how we will determine and provide the average bed capacities. We proposed that we would review a request based on the data available as of the date a hospital submits its request. We discuss below the significant points raised by commenters to our proposal.

Comment: One commenter recommended that existing physician-owned hospitals should be permitted to expand in counties in which the hospital bed capacity per 1,000 population is below the national average.

Response: Section 1877(i)(3)(E)(iv) of the Act provides that an applicable hospital must be located in a State that has an average bed capacity that is less than the national average bed capacity. We are obligated to follow the statutory directive. Therefore, we are not adopting the commenter's recommendation to consider bed capacity at the county level.

Comment: One commenter asserted that the proposed criteria appear sufficiently flexible to allow hospitals located in areas with a low bed capacity and high bed occupancy to be granted an exception from the expansion requirements.

Response: We appreciate the commenter's support for the proposed eligibility criteria for applicable hospitals. We believe that our modified exception process closely mirrors the statute and will provide sufficient flexibility to allow hospitals in areas with a low bed capacity and high bed occupancy to be granted an exception.

After consideration of the public comments we received, we are adopting as final our proposed new § 411.362(c)(2)(iv) with the modification that the State average bed capacity must be less than the national average capacity for the most recent fiscal year for which data are available as of the date that a hospital submits its request, as discussed above in previous responses to comments.

e. Bed Occupancy

Section 1877(i)(3)(E)(v) of the Act provides that an applicable hospital means a hospital that has an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located. The statute does not specify the time period

over which the hospital's average bed occupancy rate must be greater than the State average bed occupancy rate. We proposed at new § 411.362(c)(2)(v) that the hospital's bed occupancy rate must be greater than the State average bed occupancy rate for each of the 3 most recent fiscal years for which data are available as of the date that a hospital submits its request. We invited public comment on whether 3 years of data are sufficient to indicate a legitimate need by the hospital to increase the number of its operating rooms, procedure rooms, and beds and, if not, how many years of data we should consider in evaluating any request for an exception. We note that, for the reasons stated in section XV.C.1.b. this final rule with comment period, we have modified this proposal and are requiring applicable hospitals to satisfy the bed occupancy criterion during only the most recent fiscal year for which data are available.

We proposed at new § 411.362(c)(2)(v) that the hospital use filed hospital cost reporting data to calculate its own average bed occupancy rate. We stated that we plan to issue guidance explaining how the hospital can calculate its bed occupancy rate. The guidance would also explain how we will determine and provide the State bed occupancy rates. We proposed that we would review a request based on the data available as of the date that the hospital submits its request.

Except for the comments regarding the need to use 3 years of data to establish that the bed occupancy criterion is satisfied, we did not receive any public comments specific to this criterion. Therefore, as discussed in section XV.C.1.b. of this final rule with comment period, we are finalizing at § 411.362(c)(2)(v) the requirement that an applicable hospital must have an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located for the most recent fiscal year for which data are available as of the date that a hospital submits its request.

3. High Medicaid Facility

Below we separately discuss each of the statutory criteria that a hospital must satisfy to qualify as a ''high Medicaid facility.'' In the CY 2012 OPPS/ASC proposed rule (76 FR 42351), we proposed the processes by which a hospital can determine whether it satisfies each criterion. The proposed data requirements for each criterion are further discussed in the sections below.

a. Number of Hospitals in County

Section 1877(i)(3)(F)(i) of the Act provides that a high Medicaid facility must be a hospital that is not the sole hospital in a county. We proposed to incorporate this requirement into the regulations at new § 411.362(c)(3)(i). We received the following comment regarding our proposal.

Comment: One commenter stated that the proposed rule will not allow expansion or construction of a physician-owned hospital that is the sole hospital in a county or where no other hospitals exist and expressed concern that this will reduce access to quality care.

Response: Section 1877(i)(3)(F)(i) of the Act provides that a high Medicaid facility cannot be the sole hospital in a county. We are obligated to follow this statutory directive. Also, we do not believe that the requirement reduces access to quality care. Therefore, we are not making any changes in response to the commenter's concern.

After consideration of the public comment we received, we are adopting as final our proposed policy under new § 411.362(c)(3)(i) without modification.

b. Inpatient Admissions

Section 1877(i)(3)(F)(ii) of the Act provides that a high Medicaid facility must be a hospital that, with respect to each of the 3 most recent years for which data are available, has an annual percent of total inpatient admissions under Medicaid that is estimated to be greater than such percent with respect to such admissions for any other hospital located in the county in which the hospital is located. We proposed to incorporate this requirement at new § 411.362(c)(3)(ii) of the regulations.

We proposed at new § 411.362(c)(3)(ii) that the hospital estimate its annual percentages of total inpatient admissions under Medicaid for each of the 3 most recent fiscal years for which data are available. We also proposed that the hospital estimate the annual percentage of such admissions for all other hospitals located in the county in which the hospital is located for each of the 3 most recent fiscal years for which data are available. We proposed that we would review a request based on the data available as of the date that the hospital submits its request.

We proposed to require the applicant hospital to use filed hospital cost reporting discharge data as a proxy for inpatient admissions under Medicaid. We stated that we would post the data necessary for a hospital to calculate the annual percentage of total inpatient admissions under Medicaid for all other hospitals located in the county in which the hospital is located on the CMS Web site at: *http://www.cms.gov/physicianselfreferral/85_physician_owned_hospitals.asp.* We also stated that we plan to issue guidance that further describes the process for hospitals to estimate inpatient admissions under Medicaid. We address below the specific comments received in response to our proposal.

Comment: In the proposed rule (76 FR 42351 and 42352), CMS proposed that estimates of inpatient Medicaid admissions would be based on filed hospital cost report discharge data. In completing the hospital cost report, hospitals report the number of discharges for whom Medicaid is the primary payer. One commenter recommended that, to estimate the annual percent of total inpatient Medicaid admissions, Medicaid should be considered as a whole and not broken down by primary and secondary payers.

Response: We do not agree with the commenter. The statute does not require Medicaid data to be considered as a whole. In addition, hospitals do not submit discharge data in the manner recommended by the commenter, and therefore such data is not readily available for use in the exception process.

Comment: One commenter stated that the proposed rule did not specify whether the average is weighted by total admissions.

Response: We believe the commenter's statement refers to the inpatient Medicaid admissions criteria for high Medicaid facilities. We are unsure of the exact position taken by the commenter as the commenter did not explain how the average could be weighted by total admissions. In the proposed rule (76 FR 42351), we stated that we would issue guidance that further describes the process for hospitals to estimate inpatient admissions under Medicaid.

After consideration of the public comment we received, we are finalizing our proposed policy at new § 411.362(c)(3)(ii) without modification.

c. Nondiscrimination

Section 1877(i)(3)(F)(iii) of the Act provides that a high Medicaid facility does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries. We proposed to incorporate this requirement at new § 411.362(c)(3)(iii) of the regulations.

We did not receive any public comments regarding the nondiscrimination criterion. Therefore,

we are finalizing our proposal at new § 411.362(c)(3)(iii) without modification.

4. Procedure for Submitting a Request

In the proposed rule, we stated that we are not creating an application form that a hospital must complete to apply for an exception to the prohibition on expansion of facility capacity. Rather, we proposed that a hospital submit to CMS a request that includes the information and documentation set forth in proposed new § 411.362(c)(4)(ii).

We proposed that each request must include: (i) The name and address, National Provider Identification number(s) (NPI), Tax Identification Number(s) (TIN), and CMS Certification Number(s) (CCN) of the hospital; (ii) the county in which the hospital is located; and (iii) the name, title, address, and daytime telephone number of a contact person who will be available to discuss the request with CMS on behalf of the hospital. Each request must include a clear statement as to whether the hospital is requesting an exception as an applicable hospital or a high Medicaid facility. We proposed that each request submitted by a hospital must include a clear explanation of how it satisfies the criteria using the information discussed in sections XV.C.1. or 2. of the proposed rule. This includes performing, recording, and submitting all calculations necessary to submit a complete request. The hospital's request must state that it does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries. Finally, we encouraged hospitals to clearly label all documentation submitted with a request and indicate the criteria for which the documentation provides supporting information.

We proposed at new § 411.362(c)(4)(ii)(E) that each request must include documentation supporting the hospital's calculation of the hospital's baseline number of operating rooms, procedure rooms, and beds as defined at section 1877(i)(3)(C)(iii) of the Act; the hospital's number of operating rooms, procedure rooms, and beds for which the hospital is licensed as of the date that the hospital submits its request; and the additional number of operating rooms, procedure rooms, and beds by which the hospital requests to expand.

We proposed at new § 411.362(c)(4)(iii) that each request must include a certification signed by an authorized representative of the hospital attesting that all of the information provided is true and correct to the best of his or her knowledge and belief.

We proposed at new § 411.362(c)(4)(i) that a hospital must either mail an original and one copy of its request to CMS or submit its request electronically. If a hospital submits its request electronically, the hospital must also submit an original, hard copy of the required certification.

We received the following comment regarding the process for submitting a request.

Comment: One commenter urged CMS to work with hospitals that would benefit from expanded capacity and to modify the application process, as necessary, in response to difficulties in meeting its requirements. The commenter asserted the proposed exception process requires complex calculations and substantial documentation. Another commenter had no objections to the proposed exception process, while a third commenter would not support the elimination of any of the steps in the process.

Response: The required documentation, set forth in proposed new § 411.362(c)(4), includes a statement of whether the hospital is seeking an exception as an applicable hospital or high Medicaid facility, an explanation of how the hospital satisfies the criteria, the submission of the calculations used to support the application, and a certification statement that the hospital does not discriminate against beneficiaries of Federal health programs. We believe each of these requirements is necessary to verify compliance with the statutory criteria for an exception to the capacity restrictions. We also note that performing these calculations is necessary to demonstrate compliance with the statutory criteria. In addition, we carefully considered the burden associated with the calculations and documentation. As stated above, we have reduced the burden on hospitals applying for an exception by requiring certain data from only the most recent fiscal year for which data are available. We do not believe any other changes to the application process are needed at this time, although we may consider changes after we have more experience with the process.

After consideration of the public comments we received, we are finalizing the proposed procedure for submitting a request under new § 411.362(c)(4) without modification.

5. Community Input

Section 1877(i)(3)(A)(ii) of the Act provides that individuals and entities in the community in which the applicable hospital is located shall have an opportunity to provide input on the applicable hospital's request for an exception to the prohibition against facility expansion. In the proposed rule (76 FR 42352), we proposed to incorporate this provision in proposed new § 411.362(c)(5) of the regulations. We proposed that the community input must take the form of written comments. In addition, using our rulemaking authority under sections 1871 and 1877(i)(3)(A)(i) of the Act, we proposed that individuals and entities in the community in which a high Medicaid facility is located have the same opportunity to submit written comments.

We proposed at new § 411.362(c)(5) that a hospital must disclose on any public Web site for the hospital that it is requesting an exception. The notice should be accessible to the public and should remain posted from the time a request is submitted to CMS until a decision is finalized by CMS. Once CMS has received the statements, certifications, and documentation required for a hospital's request, we stated that CMS will report that the hospital is requesting an exception on the CMS *Hospital Listserv* and will post the hospital's request for an exception on the CMS Web site. For specific information on how to subscribe to the CMS *Hospital Listserv*, we refer readers to the CMS Web site at *http://www.cms.gov/MLNProducts/downloads/MailingLists_FactSheet.pdf*. In addition, we proposed that we will publish a notice of the hospital's request in the **Federal Register**. We proposed at new § 411.362(c)(5) to allow individuals and entities in the community 30 days from the date of the notice's publication in the **Federal Register** to submit written comments.

We gave examples of community input, such as documentation demonstrating that the hospital does not satisfy one or more of the data criteria or that the hospital discriminates against beneficiaries of Federal health programs. These are examples only; we indicated that we were not restricting the type of community input that may be submitted. We proposed at new § 411.362(c)(5) that written comments must be submitted by mail or electronically to CMS.

We proposed at new § 411.362(c)(5)(i) that we will consider a request complete if we do not receive any written comments during the 30-day period

after notice of the hospital's request is published in the **Federal Register**.

In the proposed rule, we stated that if we receive written comments, we will notify the hospital in writing. We proposed at new § 411.362(c)(5)(ii) to allow the hospital 30 days after CMS notifies the hospital of the written comments to submit information and documentation that rebut the written comments. We stated that we would consider the request complete at the end of the 30-day period provided for the hospital's rebuttal, regardless of whether the hospital submits additional information or documentation. We also stated that we reserve the right to perform our own calculations based on a review of the material submitted and of information generally available to CMS.

We address below the comments received in response to our proposal.

Comment: Two commenters asserted that the proposed exception process closely follows the statute and balances efficient processing with the statute's requirements, especially those regarding public and community input on CMS decisions to grant exceptions. One commenter suggested that CMS publish a notice of an exception request in the **Federal Register** within 60 days of receiving it. The commenter asserted that such a deadline would reduce delays in obtaining a decision, which would allow hospitals to increase capacity sooner, ultimately benefiting Medicaid recipients in high growth areas.

Response: We are not adopting the commenter's suggested deadline. There are many factors external to CMS that affect publication dates in the **Federal Register**. However, we will make every effort to expedite our process for sending a notice of an exception request to the Office of the Federal Register for publication.

Comment: One commenter expressed concern that entities wishing to offer comments or contest an expansion must do so within 30 days of a notice being published in the **Federal Register**. Other commenters asserted that under the proposed rule, too much time will elapse between the date on which a hospital submits a request and the date when a final decision is received.

Response: In proposing a 30-day comment period, we carefully considered the entire exception process from both the viewpoint of the requesting hospitals and the individuals and entities in the hospital's community. We believe that the 30-day comment period balances a requesting hospital's interest in receiving a timely decision with that of the individuals and entities in the hospital's community in having a reasonable amount of time to provide input.

Comment: One commenter expressed concern that the proposed methods for notifying other area hospitals and the public of an exception request are not adequate. The commenter stated that hospitals, employers, payors, and members of the community should not have to sign up for the CMS *Hospital Listserv* or search the **Federal Register** or CMS Web site to find out if an application for an exception has been made. In addition to the proposed methods of notifications set forth in new § 411.362(c)(5), the commenter suggested that CMS require the hospital requesting an exception to supply written notification to every other hospital in the Metropolitan Statistical Area (MSA) or within 50 miles of the hospital, if the hospital is located in a rural area.

Response: We disagree with the commenter's statement that our proposed methods of notification are not adequate. Section 1877(i)(3)(A)(ii) of the Act requires that individuals and entities in the community of an applicable hospital or high Medicaid facility be allowed an opportunity to provide input on the hospital's request for an exception to the prohibition against facility expansion. In the proposed rule, we proposed to add new § 411.362(c)(5) to specify that a hospital is required to disclose on any public Web site for the hospital that it is requesting an exception. We will report that the hospital is requesting an exception on the CMS *Hospital Listserv*. Also, we will post the hospital's request for an exception on the CMS Web site and will have a notice of the hospital's request published in the **Federal Register**. We believe the proposed methods of notification allow sufficient opportunity for individuals and entities in the community to provide input. Moreover, we are not persuaded that the additional notice advocated by the commenter would be beneficial. We believe that written notice would be overly burdensome for hospitals requesting an exception and may not effectively provide notice to all interested individuals and entities in the hospital's community. For example, if a nonrural hospital is located near the perimeter of its MSA, there may be other interested hospitals in close proximity to the hospital but still located outside that MSA that would not receive individualized notice pursuant to this proposal. Additionally, we are not convinced that a 50-mile radius in some rural areas would include any interested hospitals. In summary, we do not believe that the commenter's suggested methods of providing written notice to hospitals will inform all individuals and entities in the community in a consistent, beneficial manner.

Comment: One commenter suggested that CMS require the hospital requesting an exception to place a notice of its request in the newspaper with the largest circulation in the MSA, or, if rural, the county in which the hospital is located. The commenter proposed that the notice should provide (1) the location where copies of the expansion request are available, (2) the timeframe for submitting comments, and (3) the name of the designated representative who is appointed to receive the comments.

Response: As stated in the preceding response, we do not believe additional notice is necessary. We also are concerned that the commenter's proposal would be costly and burdensome for the hospital requesting an exception.

After consideration of the public comments we received, we are finalizing the proposals concerning community input and notification at new § 411.362(c)(5) without modification.

6. Permitted Increase

Section 1877(i)(3)(C)(i) of the Act provides that a hospital granted an exception from the Secretary may increase the number of operating rooms, procedure rooms, and beds for which the hospital is licensed above its baseline number of operating rooms, procedure rooms, and beds. Section 1877(i)(3)(C)(iii) of the Act defines the ''baseline number of operating rooms, procedure rooms, and beds'' as the number of operating rooms, procedure rooms, and beds for which the applicable hospital is licensed as of [March 23, 2010] (or, in the case of a hospital that did not have a provider agreement in effect as of such date but does have such an agreement in effect on December 31, 2010, the effective date of such provider agreement). We proposed to incorporate this definition, with the clarification that it also applies to high Medicaid facilities, at new § 411.362(a) of the regulations.

Section 1877(i)(3)(C)(i) of the Act provides that if a hospital previously has been granted an exception by the Secretary, the hospital may increase the number of its operating rooms, procedure rooms, and licensed beds above the number of such rooms and beds for which the hospital is licensed after application of the most recent increase under such an exception.

a. Amount of Permitted Increase

Section 1877(i)(3)(C)(ii) of the Act provides that the Secretary shall not permit an increase in the number of operating rooms, procedure rooms, and beds for which an applicable hospital is licensed to the extent such increase would result in the number of operating rooms, procedure rooms, and beds for which the applicable hospital is licensed exceeding 200 percent of the baseline number of operating rooms, procedure rooms, and beds of the applicable hospital. In the proposed rule (76 FR 42353), we proposed to incorporate this provision at new § 411.362(c)(6)(i) of the regulations.

Using our rulemaking authority under sections 1871 and 1877(i)(3)(A)(i) of the Act, we proposed to adopt a parallel limit the increase in the number of operating rooms, procedure rooms, and beds for which a high Medicaid facility may request an exception. We invited public comment on whether the proposed limit would be sufficient to balance the intent of the general prohibition on expansion with the purpose of the exception process, which is to provide the opportunity to expand in areas where a sufficient need for access to high Medicaid facilities is demonstrated. We note that, although the statute provides that an applicable hospital may request an exception up to once every 2 years, we proposed to apply the same provision to high Medicaid facilities. We believe that providing a high Medicaid facility the opportunity to request an exception once every 2 years, while also limiting its total growth, as discussed above, balances the Congress' intent to prohibit expansion of physician-owned hospitals with the purpose of the exception process.

Comment: Commenters supported the proposal regarding the amount of permitted increase.

Response: We appreciate the commenters' support. Upon further review, however, we have concluded that the language of our proposed § 411.362(c)(6)(i) is inconsistent with the limitation set forth in section 1877(i)(3)(C)(ii) of the Act. Proposed § 411.362(c)(6)(i) provides that ''[a] permitted increase under this section may not exceed 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds.'' We have concluded that proposed § 411.362(c)(6)(i) does not clearly express that the 200 percent limitation applies to the *total* number of operating rooms, procedure rooms, and beds for which the hospital is licensed after a permitted increase, as opposed to the number of operating rooms, procedure rooms, and beds by which the hospital requests to expand. Therefore, in this final rule with comment period, we are modifying our proposed new § 411.362(c)(6)(i) to more closely track the statute. The modification clarifies that a permitted increase may not result in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed exceeding 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds.

Comment: One commenter supported the proposal to apply the same limit on total growth to both applicable hospitals and high Medicaid facilities. The commenter asserted that applying parallel requirements to both applicable hospitals and high Medicaid facilities would result in an efficient and consistent process.

Response: We agree with the commenter regarding our application of parallel requirements.

After consideration of the public comments we received, we are finalizing the proposed new § 411.362(c)(6)(i), with the modification discussed above.

b. Location of Permitted Increase

Section 1877(i)(3)(D) of the Act provides that any increase in the number of operating rooms, procedure rooms, and beds for which an applicable hospital is licensed may occur only in facilities on the main campus of the applicable hospital. In the proposed rule (76 FR 42353), we proposed to incorporate this provision at new § 411.362(c)(6)(ii) of the regulations. We proposed to define the term ''main campus'' as the term ''campus'' is defined at § 413.65(a)(2). Using our rulemaking authority under sections 1871 and 1877(i)(3)(A)(i) of the Act, we proposed that, with respect to high Medicaid facilities, the limitation on expansion of hospital capacity, as set forth at section 1877(i)(1)(B) of the Act, similarly applies to the number of operating rooms, procedure rooms, and licensed beds on the ''campus'' of the high Medicaid facility. We believe that applying the same limitation to applicable hospitals and high Medicaid facilities will result in an efficient and consistent process.

We did not receive any public comments regarding the location of the permitted increase. Therefore, we are finalizing the proposed new § 411.362(c)(6)(ii) without modification.

7. Decisions

Section 1877(i)(3)(H) of the Act states that the Secretary shall publish in the **Federal Register** the final decision with respect to an application for an exception to the prohibition against facility expansion not later than 60 days after receiving a complete application. In the proposed rule (76 FR 42353), we proposed to codify this provision at new § 411.362(c)(7). To facilitate access to decisions, we proposed to post our decisions on the CMS Web site as well. We proposed that the posted information will include the hospital's name, address, county, and our final decision. We also proposed that if an exception is granted under this section, we would post the number of operating rooms, procedure rooms, and beds by which the hospital may expand under the granted exception. We stated that we believe that posting decisions on the CMS Web site will enable us to inform the public and the affected community of our decisions in a timely manner and in a centralized location.

Comment: One commenter recommended that a request for an exception as an applicable hospital should be considered approved if the agency fails to publish a final decision in the **Federal Register** within 60 days of when the request is considered complete.

Response: We cannot adopt the commenter's proposal. Although section 1877(i)(3)(H) of the Act provides that the Secretary shall publish in the **Federal Register** the final decision with respect to such application not later than 60 days after receiving a complete application, section 1877(i)(3)(E) of the Act establishes criteria that must be met in order for a hospital to be granted an exception as an applicable hospital. We are obligated to grant exceptions only to those hospitals that meet the statutory criteria.

After consideration of the public comment we received, we are finalizing the proposed new § 411.362(c)(7), without modification.

8. Limitation on Review

Section 1877(i)(3)(I) of the Act provides that there shall be no administrative or judicial review of the process, either under section *1869* or section *1878* of the Act, or otherwise. We proposed to incorporate this limitation on review at proposed new § 411.362(c)(8) of the regulations. We proposed to interpret this limitation on review to mean that CMS' decision with respect to whether a hospital qualifies for an exception is not reviewable.

We did not receive any public comments regarding the limitation of review. Therefore, we are finalizing the proposed § 411.362(c)(8) without modification.

9. Frequency of Request

Section 1877(i)(3)(B) of the Act provides that the exception process shall permit an applicable hospital to apply for an exception up to once every 2 years. In the proposed rule (76 FR 42353), we proposed to incorporate this provision at new § 411.362(c)(1). Using our authority under sections 1871 and 1877 of the Act, we similarly proposed to permit a high Medicaid facility to submit a request for an exception up to once every 2 years from the date of a CMS decision on the hospital's most recent request. We proposed to consider the date of a CMS decision to be the date of the decision letter sent to the requesting party.

We did not receive any public comments regarding the frequency of request. Therefore, we are finalizing our proposed new § 411.362(c)(1) without modification.

D. Changes Related to Provider Agreement Regulations on Patient Notification Requirements

Section 1866 of the Act states that a provider of services shall be qualified to participate in the Medicare program and shall be eligible for Medicare payments if it files a Medicare provider agreement and abides by the requirements applicable to Medicare provider agreements. These requirements are incorporated in our existing regulations at 42 CFR Part 489, Subparts A and B (Provider Agreements and Supplier Approval). Section 5006 of the Deficit Reduction Act of 2005 required the Secretary to develop a strategic and implementing plan to address certain issues with respect to physician ownership of specialty hospitals. As part of that plan, we used our authority under sections 1866, 1820(e)(3), and 1861(e)(9) of the Act (as well as our general rulemaking authority under sections 1102 and 1871 of the Act) to impose certain additional requirements on physician-owned hospitals as part of their provider agreements. These new requirements were established in the FY 2008 IPPS final rule with comment period (72 FR 47385 through 47391) and the FY 2009 IPPS final rule (73 FR 48686 through 48688).

Specifically, we added a new provision to require that all hospitals and CAHs: (1) Furnish all patients written notice at the beginning of their inpatient hospital stay or outpatient service if a doctor of medicine or osteopathy is not present in the hospital 24 hours a day, 7 days a week; and (2) describe how the hospital or CAH will meet the medical needs of any patient who develops an emergency medical condition at a time when no doctor of medicine or osteopathy is present in the hospital or CAH. These requirements are codified at § 489.20(w). The requirements of §§ 489.20(u) and (w) were made applicable to both inpatient hospital stays and outpatient services because, as we stated in the FY 2008 IPPS final rule with comment period, these provisions are in the interest of the health and safety of all individuals who receive services in these institutions. The notice requirements are intended to permit individuals to make more informed decisions regarding their treatment.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72251), we stated that we saw no reason to treat the safety of hospital inpatients differently than hospital outpatients, and, thus, applied these patient safety requirements to hospital inpatients and outpatients. We continue to believe that both hospital inpatients and outpatients should receive these disclosures prior to admission. However, after hospitals in general informed us that it would be unduly burdensome to provide disclosures to all outpatients, and hospitals with emergency departments reported the individual notice requirement makes the registration process more cumbersome and time-consuming than is desirable in the emergency department setting, we revisited this issue.

In the CY 2012 OPPS/ASC proposed rule (76 FR 42354), we stated that we have reconsidered the patient safety requirements related to patient notification of physician presence, and in the proposed rule, we proposed that hospital outpatients would need to receive such disclosures only where the risk of an emergency or the length of the outpatient visit make their situations more like that of hospital inpatients. Under this proposal, we proposed to require disclosures only for those outpatients receiving observation services, surgery, or any other procedure requiring anesthesia. We proposed that signage would be required for hospital outpatients in the emergency department, as we recognize the merit of finding a less cumbersome manner to provide the required notice in this setting. Other hospital outpatient encounters are relatively short and, in many cases, scheduled in advance. The risk of emergency is relatively low in most of these scheduled encounters. As a result, we believe the safety of these particular hospital outpatients would not be compromised in any way if hospitals were not required to provide disclosures in these circumstances.

In the proposed rule, we proposed to revise paragraph (w)(1) of § 489.20 to reduce the categories of outpatients who must be notified if a hospital does not have a doctor of medicine or osteopathy on site 24 hours a day, 7 days a week. We proposed that only those outpatients who receive observation services, surgery, or services involving anesthesia, must receive such written notice. We stated that we believe this change would reduce burden, but ensure that notice goes to those categories of patients who are more likely to find themselves in a situation where a doctor of medicine or osteopathy is not present when an emergency develops. (We noted that we were not proposing to make any changes to similar patient safety requirements for physician-owned hospitals at § 411.362(b)(5)(i).) We proposed to add a provision that notice would be required at the beginning of a planned or unplanned inpatient stay or outpatient visit, and we provided explanation of when a planned or unplanned stay or visit begins. We proposed to add a provision to state that an unplanned stay or visit begins at the earliest point at which the patient presents to the hospital. The current regulation describes when a stay or visit begins by referring to the time when a package of information is provided regarding scheduled preadmission testing and registration for a planned hospital admission or outpatient service. However, many admissions to the hospital are unplanned admissions of patients who present on an unscheduled visit to the emergency department. Therefore, it was necessary to clarify when we considered such unplanned stays or visits to begin.

We proposed to add a new paragraph (w)(2) to § 489.20 (existing paragraph (w)(2) would be redesignated as discussed below) that would require a hospital that is a main provider that has one or more remote locations of the hospital or satellites, to make the determination of whether notice is required separately at each location providing inpatient services. We proposed to use the terms ''main provider,'' ''remote location of a hospital,'' and ''satellite'' as these terms are defined at § 413.65(a)(2), § 412.22(h), or § 412.25(e), as applicable. We proposed that notice would be required for all applicable patients, that is, all inpatients and applicable outpatients, at each location at which inpatient services are furnished and at which a doctor of medicine or osteopathy is not present 24 hours a day, 7 days a week. We proposed to move language that is

currently in paragraph (w)(1) to a new paragraph (w)(3), governing the content of the written notice. We proposed to redesignate existing paragraph (w)(2), which requires the hospital to receive a signed acknowledgment from the patient who has received a notice that the patient understands that a doctor of medicine or osteopathy may not be present during all hours in which services are furnished to the patient, as paragraph (w)(4) and to revise the redesignated paragraph. We proposed to add a provision to state that, before providing an outpatient service to an outpatient for whom a notice is required, the hospital must receive the signed acknowledgment. This revision would make this requirement consistent with our proposed revisions to paragraph (w)(1) limiting the notice requirement to certain categories of outpatients.

We proposed to add a new paragraph (w)(5) which would require every hospital that has a dedicated emergency department in which a doctor of medicine or osteopathy is not present 24 hours a day, 7 days a week, to post a notice conspicuously in a place or places likely to be noticed by all individuals entering the dedicated emergency department. We proposed that ''dedicated emergency department'' would have the meaning found in existing § 489.24(b) of the regulations. We proposed to require the notice to state that the hospital does not have a doctor of medicine or osteopathy present in the hospital 24 hours a day, 7 days a week, and to indicate how the hospital will meet the needs of any patient with an emergency medical condition, as that term is defined in § 489.24(b), at a time when no doctor of medicine or osteopathy is present within the hospital. In the event that there is a decision to admit a patient from the emergency department as an inpatient, we proposed that the individualized written disclosure and acknowledgment would have to be made at the time the patient is admitted.

Comment: A majority of commenters supported the proposal to limit the types of outpatient situations in which notice of physician availability is required. Several of these commenters added that, from the beginning, they had considered the requirement to provide notice to all outpatients as overly burdensome and unnecessary except in the limited circumstances reflected in the proposed revision.

Response: We appreciate the commenters' support.

Comment: Two commenters objected to any notice to patients concerning the onsite availability of a doctor of medicine or osteopathy. One commenter indicated the requirement would impose costs and potentially alarm patients without any evidence that it will make patients safer or improve quality of care. The other commenter believed that the information might not be accurate about physician availability because a physician who is not on site in a rural setting might be more readily available than a physician who is on site at a larger facility.

Response: We believe our proposal will reduce costs to hospitals and critical access hospitals because it would require significantly fewer notices than are required under the current regulation, which requires notice to all outpatients in affected hospitals and CAHs. In the years since the current regulation first took effect, we have not received any feedback of patients being unduly alarmed as a result of receiving notice. While there may be some individual circumstances in which a doctor of medicine or osteopathy who is off site might be able to reach a patient experiencing an emergency more quickly than one who is on site, we believe that this scenario is likely the exception rather than the rule. The complete elimination of the notice requirement implicit in the commenters' statements would not be appropriate. As we stated when this provision was first adopted, we believe consumers have certain expectations concerning availability of care by doctors of medicine or osteopathy in hospitals and CAHs, and that, as patients, they have a right to make informed decisions concerning their care. Consumers may have an expectation that a hospital or CAH, as a health care facility that provides services 24 hours a day, 7 days a week, always has a doctor of medicine or osteopathy on site. Therefore, it is important to ensure that patients receive notice when a doctor of medicine or osteopathy is not always on site, and how the hospital or CAH handles patient emergencies when a doctor of medicine or osteopathy is not present.

Comment: One commenter described the proposal as requiring all physician-owned hospitals and CAHs to furnish outpatients receiving observation services, surgery or any other procedure requiring anesthesia a written notice that a doctor of medicine or osteopathy is not on site 24 hours a day, 7 days a week.

Response: The patient notification provision at proposed § 489.20(w)(1) would apply to all hospitals, not just physician-owned hospitals, and CAHs that do not have a doctor of medicine or osteopathy on site 24 hours a day, 7 days a week, and would apply to all inpatients and certain categories of outpatients.

Comment: Two commenters noted and objected to differences in requirements for physician-owned hospitals compared to other hospitals and CAHs. One commenter stated that the proposed rule at § 489.20(w) would not apply to physician-owned hospitals and challenged the differential treatment. The commenter noted that CMS stated in the proposal that the safety of ''these particular outpatients'' [that is, those who would not receive notice under the proposed rule] would not be compromised if hospitals were not required to provide disclosures, and questioned why CMS would not apply that rationale to make the change applicable to all hospitals.

Response: It is not correct that § 489.20(w) does not apply to physician-owned hospitals. It applies to all hospitals and CAHs, including those that are physician-owned. However, we believe the commenter is referring to the fact that there is an additional regulation at § 411.362(b)(5)(i) that applies only to physician-owned hospitals. We did not propose a similar revision to this regulation, which requires physician-owned hospitals that do not have a doctor of medicine or osteopathy on site 24 hours a day, 7 days a week, to provide notice to all inpatients and all outpatients. Section 411.362(b)(5)(i) was adopted in order to implement provisions of section 6001(a) of the Affordable Care Act. That provision pertains specifically to physician-owned hospitals and governs the notice to be provided to patients when the physician-owned hospital does not have a doctor of medicine or osteopathy on site at all times.

Comment: One commenter requested guidance to ensure that the presence of a doctor of medicine or osteopathy includes the presence of residents.

Response: Residents who are doctors of medicine or osteopathy would be included when determining whether a hospital or CAH has a doctor of medicine or osteopathy on site.

Comment: One commenter requested further clarification of the timing for the disclosure to, and acknowledgement by, an outpatient who is not receiving observation services, surgery, or other procedure requiring anesthesia, and who experiences a change in medical condition which requires immediate surgery or inpatient admission. The commenter stated that it might not always be feasible to make the disclosure and receive the acknowledgement under these circumstances.

Response: When an outpatient encounter that does not require a notice involves a medical emergency that requires immediate surgery or inpatient admission, the situation is similar to that of a patient who presents to a hospital or CAH emergency department and requires immediate admission for surgery or other treatment. In our proposal with respect to such emergency department patients, we stated that, in the event that there is a decision to admit a patient from the emergency department as an inpatient, the individualized written disclosure and acknowledgment would have to be made at the time the patient is admitted. At the same time, we acknowledge that in some circumstances the emergent nature of the patient's condition and need to initiate treatment immediately may result in some necessary delay in completion of the disclosure and acknowledgment requirements.

After consideration of the public comments we received, we are finalizing the proposed revisions to § 489.20(w), without modification, relating to patient notification when a doctor of medicine or osteopathy is not on site 24 hours a day, 7 days a week. Revised paragraph (w)(1) specifies that only those outpatients who receive observation services, surgery, or services involving anesthesia must receive written notice if the hospital does not have a doctor of medicine or osteopathy on site 24 hours a day, 7 days a week. New paragraph (w)(2) requires a hospital that is a main provider, that has one or more remote locations of the hospital or satellites, to make the determination of whether notice is required separately at each location providing inpatient services. New paragraph (w)(3) includes provisions (moved from existing paragraph (w)(1)) governing the content of the written notice. Paragraph (w)(4) requires the hospital to receive a signed acknowledgement from the patient who has received a notice that the patient understands that a doctor of medicine or osteopathy may not be present during all hours in which services are furnished to the patient (previously language in existing paragraph (w)(2); and states that, before providing an outpatient service to an outpatient for whom a notice is required, the hospital must receive the signed acknowledgement. New paragraph (w)(5) requires that every hospital that has a dedicated emergency department in which a doctor of medicine or osteopathy is not present 24 hours a day, 7 days a week, to post a notice conspicuously in a place or places likely to be noticed by all individuals entering the dedicated emergency room and sets forth the required statements for the notice.

XVI. Additional Hospital Value-Based Purchasing (Hospital VBP) Program Policies

A. Hospital VBP Program

1. Legislative Background

Section 3001(a) of the Affordable Care Act added section 1886(o) to the Act. This section requires the Secretary to establish a hospital inpatient value-based purchasing program under which value-based incentive payments are made in a fiscal year to hospitals meeting performance standards established for a performance period for such fiscal year. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary.

Section 1886(o)(1)(B) of the Act directs the Secretary to begin making value-based incentive payments under the Hospital Inpatient Value-Based Purchasing Program (Hospital VBP Program) to hospitals for discharges occurring on or after October 1, 2012. These incentive payments will be funded for FY 2013 through a reduction of 1.0 percent to the FY 2013 base operating DRG payment amount for each discharge, as required by section 1886(o)(7)(B)(i) of the Act, and this amount will rise to 1.25 percent in FY 2014.

Section 1886(o)(1)(C) of the Act provides that the Hospital VBP Program applies to subsection (d) hospitals (as defined in section 1886(d)(1)(B) of the Act), but excludes from the definition of the term ''hospital,'' with respect to a fiscal year: (1) A hospital that is subject to the payment reduction under section 1886(b)(3)(B)(viii)(I) of the Act (the Hospital IQR Program) for such fiscal year; (2) a hospital for which, during the performance period for the fiscal year, the Secretary cited deficiencies that pose ''immediate jeopardy'' to the health or safety of patients; and (3) a hospital for which there are not a minimum number (as determined by the Secretary) of measures for the performance period for the fiscal year involved, or for which there are not a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for such fiscal year.

2. Overview of the Hospital Inpatient VBP Program Final Rule

We previously issued the Hospital Inpatient VBP Program Final Rule, which implemented the Hospital VBP Program under section 1886(o) of the Act (76 FR 26490 through 26547). The Hospital Inpatient VBP Program Final Rule was developed based on extensive research we conducted on hospital value-based purchasing, including research that formed the basis of a 2007 report we submitted to Congress, entitled ''Report to Congress: Plan to Implement a Medicare Hospital Value-Based Purchasing Program.'' This report is available on our Web site (*https://www.cms.gov/AcuteInpatientPPS/downloads/HospitalVBPPlanRTCFINALSUBMITTED2007.pdf*) and takes into account input from stakeholders and other interested parties.

As described more fully in the Hospital Inpatient VBP Program Final Rule, we adopted for the FY 2013 Hospital VBP Program 13 measures that we have already adopted for the Hospital IQR Program, categorized into two domains (76 FR 26495 through 26511). We grouped 12 clinical process of care measures into a clinical process of care domain, and placed the HCAHPS survey measure into a patient experience of care domain. We adopted a 3-quarter performance period from July 1, 2011 through March 31, 2012 for these measures (76 FR 26494 through 26495). To determine whether a hospital meets the performance standards for these measures, we will compare each hospital's performance during this performance period to its performance during a 3-quarter baseline period from July 1, 2009 through March 31, 2010 (76 FR 26493 through 26495).

We also finalized a methodology for assessing the total performance of each hospital based on performance standards under which we will score each hospital based on achievement and improvement ranges for each applicable measure. We will calculate a Total Performance Score for each hospital by combining the greater of the hospital's achievement or improvement points for each measure to determine a score for each domain, weighting each domain score (for the FY 2013 Hospital VBP Program, the weights will be clinical process of care = 70 percent, patient experience of care = 30 percent), and adding together the weighted domain scores. We will convert each hospital's Total Performance Score into a value-based incentive payment using a linear exchange function. We refer readers to the Hospital Inpatient VBP Program Final Rule for further explanation of the details of the FY 2013 Hospital VBP Program (76 FR 26490 through 26547).

For FY 2014, we adopted 13 outcome measures comprised of 3 mortality measures, 2 AHRQ composite measures, and 8 hospital-acquired condition

(HAC) measures (76 FR 26511). These measures are discussed more fully in the Hospital Inpatient VBP Program Final Rule (76 FR 26510 through 26511). In the FY 2012 IPPS/LTCH Final Rule, we also adopted a new Medicare Spending Per Beneficiary Measure for the FY 2014 Hospital Inpatient VBP Program and incorporated the measure into a new Efficiency Domain (76 FR 51654).

We received a number of general comments in response to the proposals we made with respect to the FY 2014 Hospital VBP Program in the proposed rule. Our responses to these comments appear below.

Comment: Some commenters argued that the proposed performance periods for the HAC and AHRQ composite measures are not statutorily compliant because data on the measures will not have been included on *Hospital Compare* for one year prior to the March 3, 2012 performance period start date. The commenters also stated that the Medicare spending per beneficiary measure is not statutorily compliant because it has not been properly specified and data on the measure has not been included on the *Hospital Compare* Web site for a minimum of one year prior to the start of the measure's performance period.

Commenters argued that in order for a measure to be included in the Hospital VBP Program, the statute requires that the measure be specified under the Hospital IQR Program, which includes publicly releasing a document that outlines the numerator, denominator, exclusions, and any applicable risk adjustment, as well as following the process that the measure undergoes in the Hospital IQR Program. In addition, these commenters stated that the measure data must be displayed on the *Hospital Compare* Web site for a year prior to its inclusion in the Hospital VBP Program. Citing their interpretation of the requirements in section 1886(o) of the Act, their view of Congress' intent under the Affordable Care Act, and the need for hospitals to understand measures that will be used in the Hospital VBP Program, commenters urged CMS to choose different performance periods for the HAC, AHRQ, and Medicare spending per beneficiary measures for FY 2014, which could necessitate delaying their introduction into the program until after FY 2014. Commenters also argued that the proposed performance periods for the HAC and AHRQ measures are too short to fairly distinguish performance among hospitals.

Response: One of our most pressing concerns is to improve patient safety and efficiency as quickly as the law allows and, therefore, we interpreted the requirements under section 1886(o) of the Act in a way that enabled us to move swiftly. We also took into account comments submitted in response to the Hospital Inpatient VBP Program Proposed Rule that encouraged us to move with urgency in adopting measures for the Hospital VBP Program. We posted a brief description of each HAC and AHRQ measure on *Hospital Compare* more than 1 year prior to March 3, 2012, the beginning of the seven month performance period that we proposed to adopt for these measures. Likewise, we posted on *Hospital Compare* a brief description of the Medicare spending per beneficiary Measure on April 21, 2011, which is more than 1 year prior to the May 15, 2012 performance period start date.

However, we acknowledge the suggestion from commenters that hospitals would benefit from seeing publicly posted performance data on measures before we include those measures in the Hospital VBP Program and make them part of the basis for value-based incentive payments, and note that we posted HAC and AHRQ measure data on *Hospital Compare* on October 13, 2011.

We recognize that some commenters seek additional information related to the specifications for the Medicare spending per beneficiary measure that we previously articulated. In light of these comments, we intend to publicly release further details related to the specifications for this measure and, in doing so, we will ensure that interested parties have an opportunity to comment on them. We also note that in light of comments received, we are working expeditiously to appropriately post Medicare spending per beneficiary measure data on *Hospital Compare*.

In addition, we appreciate the commenters' concern that the proposed 7-month performance period for the HAC and AHRQ measures may be too short to fairly assess hospital performance on these measures. Although we do not believe that a low incidence of HAC events necessarily results in unstable HAC rates, or that a seven month performance period compromises the reliability of the AHRQ composite measures, we recognize that a longer performance period would provide more data on which to compare hospital performance.

Taking all of these factors into account, we have concluded that we will publicly post hospital performance on all Hospital VBP Program candidate measures on *Hospital Compare* for at least one year prior to the time when the performance period for those measures would start under the Hospital VBP Program. Hospitals will, thus, have an opportunity to become familiar with their performance on a measure before the measure is included in the Hospital VBP Program.

In order to give full effect to the process of posting hospital data for one year, and after consideration of the public comments we received, we have also decided to suspend the effective dates of the HAC, AHRQ, and Medicare spending per beneficiary measures in the Hospital VBP Program because data on these measures will not have been made publicly available on *Hospital Compare* for at least one year prior to these dates. Because there will not be enough time to both publicly post the measure data for a year, as well as collect a requisite amount of performance period data to calculate reliable measure scores for FY 2014, the result of this effective date suspension is that the HAC, AHRQ and Medicare spending per beneficiary measures will not be included in the FY 2014 Hospital VBP Program. We note that our decision to suspend the effective dates of the HAC, AHRQ and Medicare spending per beneficary measures in the FY 2014 Hospital VBP Program has no effect on the status of these measures under the Hospital IQR Program.

We believe that the decision to suspend the effective dates of the HAC, AHRQ and Medicare spending per beneficiary measures is a logical outgrowth of the comments we received in response to the CY 2012 OPPS/ASC proposed rule, a reasoned response to the concerns raised by the public in those comments, and, alternatively, is supported by good cause.

The policies we proposed to adopt in the proposed rule with respect to the HAC, AHRQ, and Medicare spending per beneficiary measures rest squarely on the foundation that these measures were properly included in the Hospital VBP Program in the first place. To the extent that this foundation has been called into question by commenters, and to the extent that we wish to implement a Hospital VBP Program that both responds to this concern and enjoys wide public support, we have concluded that it is, at this time, premature to adopt requirements that would, in conjunction with the requirements we have previously adopted, incorporate these questioned measures into the FY 2014 program. And, because we do not interpret section 1886(o) of the Act to authorize the Secretary to include ''placeholder'' measures in the Hospital VBP Program by adopting them but giving them no

effect, we believe that in order to both implement this posting of data process and comply with the statutory requirements, we must suspend the effective dates of these measures.

Therefore, we conclude that we have good cause to waive notice and an opportunity to comment under the Administrative Procedure Act with respect to our decision to suspend the effective dates of the HAC, AHRQ and Medicare spending per beneficiary measures. We seek public comment on this issue.

Finally, for all of the reasons explained above, we are not finalizing any proposals in the CY 2012 OPPS/ASC proposed rule relating to the HAC, AHRQ and Medicare spending per beneficiary measures at this time. We intend to adopt these measures for future years of the Hospital VBP Program and will take the comments into account as we develop our future policies.

Comment: Some commenters requested that CMS align Hospital VBP rulemaking processes in the future, noting that CMS published details on the Hospital VBP Program in three separate regulations.

Response: We have used more than one regulation to implement the Hospital VBP Program in order to meet the aggressive deadlines set forth in section 1886(o) of the Act. This approach also enabled us to give the public additional time to comment on our proposals. We will make every effort to, where possible, reduce the number of the rulemaking vehicles for future Hospital VBP Program proposals.

Comment: Some commenters objected to the Hospital VBP Program's structure, arguing that hospitals should be rewarded for meeting objective performance criteria instead of competing with other hospitals.

Response: The basic framework of the Hospital VBP Program is set forth in section 1886(o) of the Act, which we believe represents the culmination of substantial research and stakeholder outreach on the topic of value-based purchasing. As detailed in the Hospital Inpatient VBP Program Final Rule (76 FR 26493), we developed the 2007 Report to Congress as a plan to develop a hospital value-based purchasing program after implementing quality reporting in the hospital setting. This report is well-known to the public and formed the basis of the Hospital VBP Program as structured by the Affordable Care Act. We believe the finalized scoring methodology for the Hospital VBP Program provides strong incentives to hospitals to provide high quality care and to improve their performance over time.

Comment: Some commenters suggested technical changes to the HF–1 (Discharge Instructions) quality measure to improve providers' compliance. Commenters argued that the measure should capture discharge ''orders,'' and not the discharge ''summary,'' to avoid unintentionally penalizing hospitals when doctors change medication orders after the summary is created. Commenters urged CMS to not adopt the HF–1 measure for the Hospital VBP Program until such technical changes are made.

Response: While we are aware of the difficulties hospitals face in developing streamlined, effective discharge processes, we believe hospitals should be able to align discharge orders and summaries without further modifications to this measure.

Comment: Some commenters reiterated their opposition to the use of HAC measures in the Hospital VBP Program, arguing that hospitals are already not paid for those conditions and will be subjected to payment reductions based on HAC incidents beginning in 2015.

Response: As noted above, we are suspending the effective date of these measures for the Hospital VBP Program. We will take these comments into consideration as we develop our future policies.

Comment: Some commenters called on CMS to thoroughly test and monitor measures for continued validity. Commenters also suggested that claims-based measures need adequate risk adjustment to be valid for public reporting. Some commenters urged CMS to reconsider the policy on ''topped-out'' measures, arguing that we should continue monitoring topped-out measures to ensure that hospitals continue to perform at high levels. Commenters also argued that topped-out status should not, by itself, be enough to disqualify measures from the Hospital VBP Program.

Response: We agree that measures should be tested and monitored for continued validity. We believe that our analysis of ''topped-out'' measures described in the Hospital Inpatient VBP Program Final Rule (76 FR 26496 through 26497) is one component of that monitoring strategy, by continuing to measure whether a measure is still ''topped-out'' for each year of the program. Although we agree that some claims-based measures can and should be risk-adjusted, we do not believe that it is appropriate to risk adjust all claims-based measures. For example, many of the HAC measures are ''never'' events that we believe should be counted in every instance. We also note that the three mortality measures we have adopted for the FY 2014 Hospital VBP Program are currently undergoing maintenance by the NQF. Should the NQF recommend that changes be made to any of these measures, we will take that recommendation under advisement as we develop future measure proposals for the Hospital VBP Program.

With regard to ''topped-out'' measures, we have previously stated that, as a general matter, we would not adopt topped-out measures for the Hospital VBP Program because they present a number of scoring challenges and because their use would mask true performance differences among hospitals (76 FR 26497). We proposed to adopt an exception to this general approach for the eight HAC measures for which we are suspending the effective date because we believe the HAC measures capture critical patient safety data that are strong indicators of the quality of hospital care. We do not believe we should create exceptions for other measures at this time. We also note that we are not finalizing our proposed HAC scoring methodology at this time for the reasons discussed above.

Comment: Some commenters argued that the Hospital VBP Program inappropriately captures mortality data twice in the outcome domain, through both the 30-day mortality measures and the AHRQ composite measures. Commenters argued that such double-counting will harm tertiary care hospitals that often receive dying patients.

Response: As detailed in the Hospital Inpatient VBP Program Final Rule (76 FR 26495 through 26511), we believe the AHRQ composite measures and the 30-day mortality measures capture important patient safety and quality data in the outcome domain. We note that the two sets of mortality measures do not measure the same concepts. The AHRQ mortality measures assess in-hospital deaths only and do not use a predefined index period. On the other hand, the 30-day mortality measures assess deaths that occur 30 days after admission, which, depending on the length of stay, may occur post-discharge. The 30-day mortality measures also do not count patients receiving comfort care only or enrolled in hospice care.

As noted above, we are suspending the effective date of the AHRQ measures for the Hospital VBP Program. Therefore, we will take these comments into consideration as we develop our future policies.

Comment: Some commenters expressed support for the use of the Medicare spending per beneficiary measure, arguing that CMS has met the statutory requirements for public display and suggesting that hospitals have experience tracking spending through the Medicare low-cost county payments created by the Affordable Care Act. These commenters also noted that attempts to move toward a value-based payment system must include measures for enhancing the efficiency of health care delivery, and suggest that CMS' proposed 20 percent weight for the efficiency domain underestimated its importance as a method to improve outcomes and patient care for Medicare.

One commenter expressed the belief that CMS' plan to include the Medicare spending per beneficiary measure in the FY 2014 Hospital VBP Program is consistent with Congress' intent, because Medicare spending per beneficiary is the only measure that Congress specifically included in the Affordable Care Act, mandating its inclusion in the Hospital VBP Program.

Response: We agree that measurement of efficiency is an important goal for the Medicare program, and we thank the commenters for their support. However, for the reasons explained above, we are suspending the effective date of the Medicare spending per beneficiary measure in the Hospital VBP Program. We will take these comments into consideration as we develop future proposals regarding this measure.

Comment: Several commenters expressed their views regarding the Medicare spending per beneficiary measure, including the Medicare payments to be included, adjustments to be made, length of the episode, period of performance, and measure endorsement. Some commenters also argued that the Medicare spending per beneficiary measure's performance standards do not sufficiently consider the significant variation in health care costs per beneficiary throughout the country. Other commenters suggested that CMS develop condition-specific spending per beneficiary measures in order to appropriately capture each hospital's service mix. Several commenters stated that the measure should be adjusted for socioeconomic status and hospital case mix.

Response: We appreciate these comments and refer commenters to the FY 2012 IPPS/LTCH PPS final rule where we finalized the Medicare spending per beneficiary measure for inclusion in the Hospital IQR Program (76 FR 51618 through 51628). However, as noted above, we are suspending the effective date of this measure in the Hospital VBP Program for FY 2014. Therefore, we will take these comments into consideration as we develop future proposals regarding this measure for the Hospital VBP Program.

3. Additional FY 2014 Hospital VBP Program Measures

In the CY 2012 OPPS/ASC proposed rule (76 FR 42355 through 42356), for the FY 2014 Hospital VBP Program, we proposed to retain all 13 of the measures that we adopted for the FY 2013 Hospital VBP Program, which include 12 clinical process of care measures and the patient experience of care survey. We also proposed to add one measure to the clinical process of care domain: SCIP–Inf-9: Postoperative Urinary Catheter Removal on Postoperative Day 1 or 2. This measure was specified for the Hospital IQR Program beginning with FY 2011 and subsequent payment determination years (74 FR 43869 through 43870), and information about the measure first appeared on *Hospital Compare* in December 2010. Thus, we believe that this measure meets the requirement in section 1886(o)(2)(C)(i) of the Act to be included in the Hospital VBP Program because it has been specified for the Hospital IQR Program and will have been displayed on *Hospital Compare* for at least one year before the applicable performance period begins. In addition, SCIP–Inf–9 is NQF-endorsed (#453).

The measure is relevant to the Hospital VBP Program because it assesses a practice that reduces Catheter Associated Urinary Tract Infection (CAUTI), and improves patient safety, which is highlighted as one of the Institute of Medicine's six quality aims along with effectiveness, patient-centeredness, timeliness, efficiency, and equity. SCIP–Inf–9 is one of the NQF-endorsed SCIP infection prevention measures; these measures are referenced as a whole among the metrics listed in the HHS Action Plan to Prevent HAIs. This Action Plan can be found at the following Web site: *http://www.hhs.gov/ash/initiatives/hai/actionplan/*. Furthermore, this measure meets other criteria considered for measure selection for the Hospital VBP Program, such as not being ''topped-out'' and displaying meaningful variability among hospitals. Therefore, we believe it would be a meaningful measure to include in the Hospital VBP Program.

In the CY 2012 OPPS/ASC proposed rule (76 FR 42356), we listed the clinical process of care and patient experience of care measures we proposed to adopt for the FY 2014 Hospital VBP Program. We note that these measures are currently NQF-endorsed or undergoing NQF review for maintenance. We will continue to monitor these measures to ensure that they reliably measure hospital quality, for example, ensuring that, among other things, these measures are not ''topped-out,'' and their measurement criteria remain endorsed by NQF and/or are otherwise appropriate. In the CY 2012 OPPS/ASC proposed rule (76 FR 42356), we noted that to the extent we determine that these measures are topped-out, we may choose not to finalize them.

We invited public comment on these proposals.

Comment: Many commenters expressed support for the proposal to add the SCIP–Inf–9 measure to the FY 2014 Hospital VBP Program.

Response: We thank commenters for their support.

Comment: Some commenters suggested alternative measures as replacements for the SCIP clinical process measures in the Hospital VBP Program, such as surgical outcomes measures. Commenters argued the alternative measures are risk-adjusted and better capture high quality surgeries than the current SCIP measures. Other commenters suggested that CMS consider adopting additional HAI process and outcome measures in future years.

Response: We thank commenters for their suggestions. We will consider these categories of additional measures for the Hospital VBP Program in the future.

After consideration of the public comments we received, we are finalizing for the FY 2014 Hospital VBP Program, the 13 clinical process of care measures, including SCIP–Inf–9, and the patient experience of care measure, composed of 8 dimensions of the HCAHPS survey. Set out in the table below are the finalized clinical process of care measure, the patient experience of care measure and the mortality measures that will be included in the FY 2014 Hospital VBP Program.

BILLING CODE 4120–01–P

Clinical Process of Care, Patient Experience of Care and Outcome Measures for the FY 2014 Hospital VBP Program	
Clinical Process of Care Measures	
Measure ID	**Measure Description**
Acute myocardial infarction	
AMI-7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival
AMI-8a	Primary PCI Received Within 90 Minutes of Hospital Arrival
Heart Failure	
HF-1	Discharge Instructions
Pneumonia	
PN-3b	Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital
PN-6	Initial Antibiotic Selection for CAP in Immunocompetent Patient
Healthcare-associated infections	
SCIP-Inf-1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision
SCIP-Inf-2	Prophylactic Antibiotic Selection for Surgical Patients
SCIP-Inf-3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time
SCIP-Inf-4	Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose
SCIP-Inf-9	Postoperative Urinary Catheter Removal on Post Operative Day 1 or 2
Surgeries	
SCIP-Card-2	Surgery Patients on a Beta Blocker Prior to Arrival That Received a Beta Blocker During the Perioperative Period
SCIP-VTE-1	Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered
SCIP-VTE-2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery
Patient Experience of Care Measures	
Measure ID	**Measure Description**
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey*
Outcome Measures	
Measure ID	**Measure Description**
MORT-30-AMI	Acute Myocardial Infarction (AMI) 30-Day Mortality Rate
MORT-30-HF	Heart Failure (HF) 30-Day Mortality Rate
MORT-30 PN	Pneumonia (PN) 30-Day Mortality Rate

*The finalized dimensions of the HCAHPS survey for use in the FY 2014 Hospital VBP Program are: Communication with Nurses, Communication with Doctors, Responsiveness of Hospital Staff, Pain Management, Communication about Medicines, Cleanliness and Quietness of Hospital Environment, Discharge Information and Overall Rating of Hospital.

BILLING CODE 4120–01–C

4. Minimum Numbers of Cases and Measures for the Outcome Domain for the FY 2014 Hospital VBP Program

a. Background

Section 1886(o)(1)(C)(ii)(III) of the Act requires the Secretary to exclude for the fiscal year hospitals that do not report a minimum number (as determined by the Secretary) of measures that apply to the hospital for the performance period for the fiscal year. Section 1886(o)(1)(C)(ii)(IV) of the Act requires the Secretary to exclude for the fiscal year hospitals that do not report a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for the fiscal year. In the Hospital Inpatient VBP Program Final Rule, we adopted 13 outcome measures for the FY 2014 Hospital VBP Program (76 FR 26511), but we did not adopt a minimum number of cases for such measures to apply to hospitals, nor did we adopt a minimum number of measures necessary for the outcome domain to be included in the Total Performance Score.

Under section 1886(o)(1)(C)(iii) of the Act, in determining the minimum number of reported measures and cases under sections 1886(o)(1)(C)(ii)(III) and (IV), the Secretary must conduct an independent analysis of what minimum numbers would be appropriate. As described in the Hospital Inpatient VBP Final Rule (76 FR 26528 through 26529), to fulfill this requirement, we commissioned Brandeis University to perform an independent analysis that examined technical issues concerning the minimum number of cases per measure and the minimum number of measures per hospital for clinical process of care measures needed to derive reliable domain scores. Based on that analysis, we finalized our policy to exclude any clinical process of care measures for which a hospital reported fewer than 10 cases, and to exclude from the Hospital VBP Program any hospital to which fewer than 4 of the clinical process of care measures applied. We also finalized our proposal to exclude any hospital reporting fewer than 100 HCAHPS surveys during the performance period (76 FR 26529 through 26531).

To determine the minimum numbers of measures and cases that should be required for the outcome domain, we again commissioned Brandeis University to perform an independent analysis. This analysis examined hospital performance on the 13 finalized outcome measures using data from the proposed baseline periods (discussed below) for the FY 2014 Hospital VBP Program. As we did to analyze the reliability of scores in the clinical process of care domain, different minimum numbers of cases and measures were tested to determine the combination of minimum numbers of cases and measures that would lead to reliable scores in the outcome domain while allowing the maximum number of hospitals to be scored for the Hospital VBP Program. Concurrent with the Brandeis analysis, we contracted with researchers at Mathematica Policy Research (Mathematica) to explore the minimum number of cases a hospital would need to report for each individual outcome measure.

b. Minimum Number of Cases for Mortality Measures, AHRQ Composite Measures, and HAC Measures

The analyses by Brandeis and Mathematica determined that in order to receive a score on a mortality measure, the hospital would need to report a minimum of 10 cases, and in order to receive a score on an AHRQ composite measure, a hospital would need to report a minimum of 3 cases. Consistent with these analyses, we proposed that these case minimums would apply for the FY 2014 Hospital VBP Program.

Mathematica also examined the minimum number of cases a hospital would need to report in order to receive a reliable score on each HAC measure. Along with reliability concerns, when conducting this analysis, Mathematica also took into consideration our view, more fully explained in section XVI.A.6.d. of the proposed rule, that the incidence of HACs raises significant safety and quality concerns for patients and for the Medicare program. Therefore, we believed that a hospital should be held accountable when HACs occur in all instances in order to protect and promote patient safety. Mathematica concluded that a minimum of one Medicare claim would be sufficient to compute an accurate score on each HAC measure, and in accordance with this conclusion, we proposed that hospitals be evaluated based on the presence or absence of HAC occurrences, regardless of the number of Medicare cases a hospital treats, as long as the hospital submits at least one Medicare claim during the performance period. As we discuss further below, we anticipated that all participating hospitals will submit at least one Medicare claim during the performance period, which would be sufficient for the hospitals to receive a score on seven of the eight HAC measures.

c. Minimum Numbers of Measures for Outcome Domain

Brandeis researchers also analyzed the reliability of the outcome domain scores for hospitals depending upon the total number of outcome measures on which they reported. The analysis showed that the data provide a meaningful and sufficiently reliable indication of outcomes for hospitals in the outcome domain as long as the hospitals submit the minimum number of cases (discussed above) on each of 11 outcome measures for FY 2014. Specifically, the analysis found that using at least 11 outcome measures per hospital provided sufficiently comparable reliability of hospitals' scores in the outcome domain (particularly in terms of rank ordering relative to other hospitals) as compared with what hospitals' scores would have been if they had reported on more outcome measures. Brandeis concluded that this 11 measure minimum could be comprised of the 8 HAC measures, together with 3 measures comprised of any combination of the 3 mortality measures and the 2 AHRQ composite measures.

We note that, in conducting its analysis, Brandeis evaluated how the outcome domain score would be affected if a hospital reported all eight finalized HAC measures. However, one of these HAC measures, Foreign Object Retained After Surgery, will not apply to a very small subset of hospitals that do not perform surgeries. Taking this into account, as well as our own further analysis which showed that the reliability of the outcome domain score would not be significantly different as a statistical matter, in the CY 2012 OPPS/ASC proposed rule (76 FR 42357), we proposed that the minimum number of measures a hospital would need to report in order to receive a score on the outcome domain is 10, comprised of 7 of the 8 HAC measures (all but the Foreign Object Retained After Surgery measure), along with 3 other measures comprised of any 3 of the other outcome measures (for example, 2 AHRQ composite measures and 1 mortality measure, or 3 mortality measures). We believed that this proposal was consistent with the conclusions reached by Brandeis. In addition, from an inclusiveness standpoint, we believed that a 10 measure minimum would maximize hospital participation in the FY 2014 Hospital VBP Program.

Furthermore, because we believed that every domain is an important component of an accurate Total Performance Score, we proposed that, in order for a hospital to receive a Total

Performance Score and be included in the FY 2014 Hospital VBP Program, the hospital must have enough cases and measures to report on all finalized domains. This proposed requirement should not impose any new barrier to hospitals or greatly reduce the number of hospitals in the FY 2014 Hospital VBP Program as compared to the FY 2013 Hospital VBP Program, when hospitals will only be scored on clinical process of care and patient experience of care measures. This is because, as stated above, an analysis of the existing data shows that virtually all hospitals participating in the FY 2014 Hospital VBP Program will report on a sufficient number of cases and measures to receive outcome domain scores in addition to the clinical process and patient experience domain scores for FY 2014.

We invited public comment on the proposed minimum numbers of cases and measures required for the outcome domain in the FY 2014 Hospital VBP Program. We also invited public comment on the proposed requirement that hospitals must report on all four domains (if finalized) to receive a Total Performance Score for the FY 2014 Hospital VBP Program.

Comment: Several commenters urged CMS to make public our independent analyses of the minimum cases and measures required for the various Hospital VBP Program domains, arguing that they could not provide informed comments in response to those proposals without the analyses.

Response: To the extent that these analyses are not subject to privilege, we will make available additional information, including the study results and methods, on the Hospital Value-Based Purchasing Web site at *http://www.cms.gov/hospital-value-based-purchasing/* within 30 to 45 days of this final rule with comment period.

Comment: Some commenters objected to the proposals for minimum numbers of cases and measures in the outcome domain, arguing that the minimum numbers of cases proposed for HAC and AHRQ measures are too low. Commenters argued that these proposals will result in inaccurate performance measurement, especially for low-volume hospitals. Some commenters suggested that CMS apply the AHRQ composite measures' minimum number of cases to each component indicator.

Response: We thank commenters for their input on appropriate minimum numbers of cases for HAC and AHRQ measures. We will consider these comments in future rulemaking.

Comment: Some commenters sought more clarity on the different minimum numbers of cases and measures required in various parts of the Hospital VBP Program. Commenters argued that CMS should choose a consistent standard for minimum cases and measures to avoid provider confusion.

Response: As noted in the Hospital Inpatient VBP Program Final Rule (76 FR 26528), we believe the most important factor in setting minimum case and measure thresholds for the Hospital VBP Program is to determine a combination of thresholds that allows the maximum number of hospitals to be scored reliably. While we agree that a single minimum cases standard across domains may reduce the potential for confusion, we have proposed different standards where we believe them to be necessary to accommodate different types of measures and to be as inclusive as possible. We believe that our proposals appropriately reflect the different types of measure data captured, the relative importance of the measures with regard to patient safety and our belief that as many hospitals as possible should be allowed to participate in the program.

Comment: Some commenters suggested that CMS use a 25-case minimum for the mortality measures, arguing that 25 cases is the standard for reporting on *Hospital Compare* and is recommended by the Institute of Medicine.

Response: We have used a 25-case minimum for public reporting. However, our analysis determined that a hospital only needed to report a minimum of 10 cases in order to receive a reliable score on the mortality measures. We note that this minimum number of cases is also consistent with the minimum number of cases required in the clinical process of care domain. We believe that this minimum number of cases provides us with accurate mortality measure data for use in the outcome domain and in the calculation of the Total Performance Score, while enabling hospital inclusion and providing consistency with the case minimums in the clinical process of care domain.

Comment: Some commenters noted that if CMS chose to include only the three mortality measures in the outcome domain in the FY 2014 program that it would need to re-evaluate the minimum number of measures required for a hospital to be eligible for the domain.

Response: We thank the commenters for this observation, and agree that because we have decided to suspend the effective date of the HAC and AHRQ measures, and use only the three mortality measures in the outcome domain, we need to re-evaluate the minimum number of measures necessary for the domain.

In conjunction with Brandeis, we reexamined the previous analyses regarding the sufficient number of measures needed to produce a reliable outcome domain score and have determined that hospitals must report on two of the three mortality measures in order to receive an outcome domain score. In the analysis, Brandeis noted that the vast majority of subsection (d) hospitals admit at least 10 congestive heart failure cases and at least 10 pneumonia cases each year. However, many fewer hospitals admit more than 10 acute myocardial infarction cases annually. The Brandeis study indicated that a large number of these hospitals (2,548) would receive an outcome domain score if the minimums of 10 mortality cases, 3 AHRQ cases, and 1 Medicare discharge for HAC measures are reported. A large number of the remaining hospitals (422) would receive an outcome domain score if the AMI mortality measure were excluded from this minimum measure threshold. This difference occurs because smaller hospitals typically do not treat a sufficient number of AMI cases to reach the minimum threshold of ten cases needed to generate useful AMI mortality values. If the AMI mortality measure were excluded from the minimum measure threshold, approximately 3,000 hospitals would receive outcome domain scores in the FY 2014 Hospital Inpatient VBP Program, which is approximately the same number of hospitals able to participate in the FY 2013 Hospital Inpatient VBP Program.

As we noted above, we are suspending the effective date of the AHRQ and HAC measures. Therefore, requiring two mortality measures to qualify for participation will allow many more hospitals to be included in the Hospital VBP Program, which is consistent with our views on the appropriate balance between reliability and inclusiveness that we described in the Hospital Inpatient VBP Program Final Rule (76 FR 26529). Most hospitals will report sufficient data on all three mortality measures, while almost all hospitals will report sufficient data on at least two of the mortality measures. This approach allows us to include as many hospitals as possible in the program while ensuring the reliability of the domain score. In either case, the outcome domain is sufficiently reliable to include as part of the Total Performance Score.

Comment: Some commenters supported the proposal to require hospitals to report on all four proposed

domains in order to receive a Total Performance Score.

Response: We thank commenters for their support.

As stated above, we are not finalizing our proposal regarding the minimum numbers of cases and measures in the outcome domain insofar as that proposal relates to the HAC and AHRQ measures. However, after considering the comments, we are finalizing our proposal that a hospital must report a minimum of 10 cases to receive a score on a mortality measure, and we note that this minimum is consistent with our previously finalized policy regarding the minimum number of cases that a hospital must report in order to receive a score on a clinical process of care measure. As we stated in the proposed rule, this policy is consistent with the analyses performed by Brandeis and Mathematica (76 FR 42357).

Accordingly, we are finalizing that the minimum number of measures that a hospital must report in order to receive a score on the outcome domain is two measures. As discussed further below, we will normalize outcome domain scores in order to make fair comparisons in that domain between hospitals with scores on two mortality measures and those hospitals reporting sufficient data on all three.

Concurrently, we are finalizing our proposal that hospitals must report the minimum number of cases and measures on all finalized domains in order to receive a Total Performance Score in FY 2014. Because we are suspending the effective date of the Medicare spending per beneficiary measure, the number of finalized domains will be three instead of four.

5. Performance Periods and Baseline Periods for FY 2014 Measures

Section 1886(o)(4) of the Act requires the Secretary to establish a performance period for the Hospital VBP Program for a fiscal year that begins and ends prior to the beginning of such fiscal year.

a. Clinical Process of Care Domain and Patient Experience of Care Domain Performance Period and Baseline Period

In the CY 2012 OPPS/ASC proposed rule (76 FR 42357 through 42358), for the FY 2014 Hospital VBP Program, we proposed a 9-month (3-quarter) performance period from April 1, 2012 to December 31, 2012 for the clinical process of care and patient experience of care domain measures. As described in the Hospital Inpatient VBP Program Final Rule (76 FR 26494 through 26495), due to various statutory deadlines and other challenges we faced in implementing the FY 2013 Hospital VBP Program in a timely fashion, we adopted a 3-quarter performance period for the clinical process of care and patient experience of care domains for the FY 2013 Hospital VBP Program. We have stated our intent to move to a 12-month performance period when feasible. We believe that this proposed 3-quarter performance period will allow us to notify hospitals of the amount of their value-based incentive payment at least 60 days before the start of FY 2014. It will also allow us to consider selecting CY 2013, a 12-month performance period, as the performance period for the FY 2015 Hospital VBP Program. In addition, this proposed performance period for FY 2014 would begin immediately after the end of the FY 2013 performance period, provide reliable performance information, and ensure that incentive payments can be made beginning with October 1, 2013 discharges.

As we explained in the Hospital Inpatient VBP Program Final Rule (76 FR 26485), we believe that baseline data should be used from a comparable 9-month (3-quarter) period. Therefore, we proposed April 1, 2010 to December 31, 2010 as the baseline period for these proposed measures for FY 2014. We invited public comment on these proposals.

Comment: Many commenters expressed support for the proposed clinical process and patient experience performance periods for FY 2014.

Response: We thank commenters for their support.

After consideration of the public comments we received, we are finalizing the performance period and baseline period for FY 2014 clinical process of care and patient experience of care measures as proposed.

b. Outcome Domain and Performance Periods and Baseline Periods

In the Hospital Inpatient VBP Program proposed rule, we proposed an 18-month performance period of July 1, 2011 to December 31, 2012 and an 18-month baseline period of July 1, 2008 to December 31, 2009 for the three mortality outcome measures currently specified under the Hospital IQR Program (MORT–30–AMI, MORT–30–HF, MORT–30–PN). In response to public comment and for reasons discussed in the Hospital Inpatient VBP Program Final Rule (76 FR 26494), we adopted a 12-month performance period of July 1, 2011 to June 30, 2012 and a 12-month baseline period of July 1, 2009 to June 30, 2010 for these measures.

In the Hospital Inpatient VBP Program Final Rule, we stated that we would begin the performance period for the proposed HAC and AHRQ measures 1 year after such measures were included on *Hospital Compare.* Because all the finalized HAC and AHRQ measures were included on *Hospital Compare* on March 3, 2011, we finalized March 3, 2012 as the start of the performance period for these measures in the Hospital Inpatient VBP Program Final Rule (76 FR 26494 through 26495). We stated in the Hospital Inpatient VBP Program Final Rule (76 FR 26495) that we would propose the performance period end date for these measures in the CY 2012 OPPS/ASC proposed rule.

We noted that in order for the HAC and AHRQ measures to be scored for the FY 2014 Hospital VBP Program, the performance period for these measures would need to end by the fourth quarter of FY 2012 to allow us sufficient time to collect and process the necessary claims data. We stated that this time period needs to be longer for HAC and AHRQ measures than for clinical process and patient experience measures, which are based on chart-abstracted data and surveys rather than claims. Claims data require at least three months following a given calendar quarter to process and necessitate two additional months to complete measure calculation, including risk adjustment, statistical modeling, quality assurance, programming, and generating reports on patient-level data, which is provided to hospitals.

Therefore, in the CY 2012 OPPS/ASC proposed rule (76 FR 42358), we proposed to adopt a nearly 7-month performance period for the HAC and AHRQ measures for FY 2014 by selecting September 30, 2012 as the end of the performance period. We stated that while we would prefer to use a 12-month performance period, analysis of existing data indicates that a 7-month performance period would provide sufficiently robust values on these critical measures.

We also stated that because we believe that a comparable period should be selected for the baseline data, we proposed to set March 3, 2010 to September 30, 2010 as the baseline period for the proposed HAC and AHRQ measures for the FY 2014 Hospital VBP Program. We invited public comment on these proposals.

Comment: Some commenters opposed the performance and baseline period proposals, arguing that the various performance period dates specified for the measures within each domain is confusing and impose hardships on hospitals' quality management staff. Commenters suggested that CMS instead

propose to adopt harmonized performance periods.

Response: We agree that a single performance period that applies to all of the Hospital VBP measures for a particular payment year would be desirable and we intend to move towards this goal in future program years. In the meantime, we proposed to adopt performance periods that take into account the time limitations associated with collecting performance data and scoring for different measures. We note that for the FY 2014 Hospital VBP Program, the clinical process and patient experience of care measures will have the same performance period. We believe that all providers will work to track achievement and improvement across all measures and we will continue to work towards harmonized periods in the future.

As noted above, we are suspending the effective dates of the AHRQ and HAC measures for the Hospital VBP Program, and the mortality measures will be the only measures in the outcome domain in FY 2014. The following tables include all finalized baseline and performance periods for the FY 2013 and FY 2014 program years.

FY 2013 Hospital VBP Program
Baseline and Performance Periods

Domain	Baseline Period	Performance Period
Clinical Proces of Cares	July 1, 2009 – March 31, 2010	July 1, 2011 – March 31, 2012
Patient Experience of Care	July 1, 2009 – March 31, 2010	July 1, 2011 – March 31, 2012

FY 2014 Hospital VBP Program
Baseline and Performance Periods

Domain	Baseline Period	Performance Period
*Clinical Process of Care**	April 1, 2010 - December 31, 2010	April 1, 2012 - December 31, 2012
Patient Experience of Care *	April 1, 2010 - December 31, 2010	April 1, 2012 - December 31, 2012
Outcome Mortality Mortality	July 1, 2009 – June 30, 2010	July 1, 2011 – June 30, 2012

*Finalized in this final rule with comment period

6. Performance Standards for the FY 2014 Hospital VBP Program

a. Background

Section 1886(o)(3)(A) of the Act requires the Secretary to establish performance standards for the measures selected under the Hospital VBP Program for a performance period for the applicable fiscal year. The performance standards must include levels of achievement and improvement, as required by section 1886(o)(3)(B) of the Act, and must be established and announced not later than 60 days before the beginning of the performance period for the fiscal year involved, as required by section 1886(o)(3)(C) of the Act. Achievement and improvement standards are discussed more fully in the Hospital Inpatient VBP Program Final Rule (76 FR 26511 through 26513). In addition, when establishing the performance standards, section 1886(o)(3)(D) of the Act requires the Secretary to consider appropriate factors, such as: (1) Practical experience with the measures, including whether a significant proportion of hospitals failed to meet the performance standard during previous performance periods; (2) historical performance standards; (3) improvement rates; and (4) the opportunity for continued improvement.

b. Mortality Measures

In the Hospital Inpatient VBP Program Final Rule, we finalized the achievement performance standard (achievement threshold) for each of the proposed FY 2014 Hospital VBP Program mortality measures at the median of hospital performance (50th percentile) during the applicable baseline period. We also finalized the improvement performance standard (improvement threshold) for each mortality measure at each specific hospital's performance on each measure during the baseline period of July 1, 2009 to June 30, 2010 (76 FR 26511 through 76 FR 26512). In addition, we finalized the precise achievement thresholds and benchmarks for these mortality measures (76 FR 26513), as shown below:

Achievement Thresholds for the FY 2014 Hospital VBP Program Mortality Outcome Measures (Displayed as Survival Rates)			
Mortality Outcome Measures			
Measure ID	**Measure Description**	**Performance Standard (Achievement Threshold)**	**Benchmark**
MORT-30-AMI	Acute Myocardial Infarction (AMI) 30-Day Mortality Rate	0.8477	0.8673
MORT-30-HF	Heart Failure (HF) 30-Day Mortality Rate	0.8861	0.9042
MORT-30 PN	Pneumonia (PN) 30-Day Mortality Rate	0.8818	0.9021

We received a few comments on the mortality measure performance standards.

Comment: Some commenters argued that the performance standards for the mortality measures are so compressed or ''topped-out'' as to render them ineffective measures of quality for performance scoring.

Response: We disagree with commenters' assertion. As described above, we finalized performance standards for the mortality measures selected for the FY 2014 Hospital VBP Program in the Hospital Inpatient VBP Final Rule and considered comments on this topic there (76 FR 26511 through 26513).

As we noted in the Hospital Inpatient VBP Program Final Rule (76 FR 26496 through 26497), our analysis of possibly topped-out measures was not limited to the breadth of the achievement range. We also analyzed the variation in measure scores achieved by hospitals, as a small coefficient of variation would indicate that the distribution of individual hospital scores is clustered tightly around the mean value, which would suggest that the measure is not useful to draw distinctions between individual hospital performance scores. We do not believe the mortality measures meet our criteria for topped-out measures.

c. Clinical Process of Care and Patient Experience of Care FY 2014 Performance Standards

As discussed in section XVI.A.5.a. of the CY 2012 OPPS/ASC proposed rule (76 FR 42359 through 42360), we proposed to adopt a 9-month (3-quarter) performance period of April 1, 2012 to December 31, 2012 for the clinical process of care and patient experience of care measures for the FY 2014 Hospital VBP Program. To set achievement and improvement performance standards for these proposed measures for the FY 2014 Hospital VBP Program, in the CY 2012 OPPS/ASC proposed rule (76 FR 42359), we proposed to use the same approach adopted in the Hospital Inpatient VBP Program Final Rule for the FY 2013 Hospital VBP Program. That approach, as well as our rationale for adopting it, is explained in detail at 76 FR 26511 through 76 FR 26513.

We proposed to set the achievement performance standard (achievement threshold) for each proposed measure at the median of hospital performance (50th percentile) during the proposed baseline period of April 1, 2010 through December 31, 2010. We also proposed to set the improvement performance standard (improvement threshold) for each of the proposed measures at each specific hospital's performance on the applicable measure during the proposed baseline period of April 1, 2010 through December 31, 2010. We proposed to set each benchmark for each measure as the mean of the top decile performance of applicable hospitals during the proposed baseline period. We invited public comment on these proposals.

Comment: Some commenters asked CMS to release the HCAHPS floors for the FY 2014 program year to allow hospitals to plan for quality improvement efforts.

Response: We published the floors (0th percentile) for the eight HCAHPS dimensions included in the FY 2013 Hospital VBP Program baseline period in the Hospital Inpatient VBP Program Final Rule (76 FR 26519). The FY 2014 Hospital VBP Program baseline period floor for each of the HCAHPS dimensions appears below.

Comment: Some commenters were concerned that the risk adjustment models for the HCAHPS survey are not adequate and do not control for the severity of a patient's condition, socioeconomic status, and geographic differences.

Response: HCAHPS dimensions are currently patient-mix adjusted. We adjust HCAHPS data for patient characteristics that are not under the control of the hospital that may affect patient reports of hospital experiences. The goal of adjusting for patient-mix is to estimate how different hospitals would be rated if they all provided care to comparable groups of patients. As part of the endorsement process for

HCAHPS, NQF endorsed the HCAHPS patient-mix adjustment currently in use.

The HCAHPS patient-mix adjustment (PMA) model incorporates important and statistically significant predictors of patients' HCAHPS ratings that also vary meaningfully across hospitals (O'Malley *et al.,* 2005). The PMA model includes seven variables, as follows: Self-reported health status, education, service line (medical, surgical, or maternity care), age, response order percentile (also known as ''relative lag time,'' which is based on the time between discharge and survey completion), service line by linear age interactions, and primary language other than English.

Initially the model also included admission through an emergency room, but because admission through an emergency room is no longer available on the UB–92 Form, this adjustor is no longer available for the patient-mix model. We are exploring other options to obtain that information in the future.

We have found that evaluations of care increase with self-rated health and age (at least through age 74), and decrease with educational attainment. Maternity service has generally more positive evaluations than medical and surgical services. Response order percentile (relative lag time) findings show that late responders tend to provide less positive evaluations than earlier responders. From research conducted during the development of HCAHPS, we found little evidence that DRG matters beyond the service line, which is included in the patient mix model.

To further address specific concerns about the adjustment model, it is important to note that self-reported health status is a widely accepted measure of a person's overall health status. In general, ''how would you rate your health'' is the most widely used single self-reported health item and is used in many national health surveys. Education also captures important aspects of socio-economic status. Income is generally not available to adjust survey data. Patient-mix adjustment is based on variation by patient-level factors within hospitals so that true differences between hospitals are not included in the adjustment. Controlling for geographic region (a hospital-level factor) as part of a patient-mix adjustment model could mask important differences in quality across the country.

Comment: A few commenters were concerned that the HCAHPS scores publicly reported on *Hospital Compare* differ by bed size, type of hospital and geography and thought the HCAHPS scores should be adjusted for these factors. These commenters thought HCAHPS needs to be vetted more to understand these differences to ensure that HCAHPS is a reliable measure.

Response: We recognize that HCAHPS results differ by bed size and other hospital characteristics. However, we do not interpret these differing results to mean that the survey should be risk-adjusted for these factors. HCAHPS results also differ among hospitals with the same characteristics, which we view as evidence that the results account for differences in the quality of care received by patients. In general, risk-adjustment models control for exogenous factors that are beyond the control of a hospital, not for hospital characteristics that are endogenous, or within their control.

We also believe that the HCAHPS survey has been thoroughly vetted, including through reviews in peer reviewed journals and through notice and comment rulemaking when we adopted it for the Hospital IQR Program. HCAHPS also has been endorsed by the NQF.

After consideration of the public comments we received, we are finalizing the FY 2014 clinical process of care and patient experience of care performance standards as proposed. We set out final achievement performance standards for the finalized FY 2014 clinical process of care and patient experience of care measures using the applicable baseline period data in the table below.

BILLING CODE 4120–01–P

FY 2014 Achievement Performance Standards for Clinical Process of Care Measures			
Measure ID	**Measure Description**	**Performance Standard (Achievement Threshold)**	**Benchmark**
Process of Care Measures			
AMI-7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival	0.8066	0.9630
AMI-8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	0.9344	1.0000
HF-1	Discharge Instructions	0.9266	1.0000
PN-3b	Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital	0.9730	1.0000
PN-6	Initial Antibiotic Selection for CAP in Immunocompetent Patient	0.9446	1.0000
SCIP-Inf-1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision	0.9807	1.0000
SCIP-Inf-2	Prophylactic Antibiotic Selection for Surgical Patients	0.9813	1.0000
SCIP-Inf-3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time	0.9663	0.9996

FY 2014 Achievement Performance Standards for Clinical Process of Care Measures			
Measure ID	**Measure Description**	**Performance Standard (Achievement Threshold)**	**Benchmark**
SCIP-Inf-4	Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose	0.9634	1.0000
SCIP-Inf-9	Postoperative Urinary Catheter Removal on Post Operative Day 1 or 2	0.9286	0.9989
SCIP-Card-2	Surgery Patients on a Beta Blocker Prior to Arrival That Received a Beta Blocker During the Perioperative Period	0.9565	1.0000
SCIP-VTE-1	Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered	0.9462	1.0000
SCIP-VTE-2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery	0.9492	0.9983

FY 2014 Achievement Performance Standards for Patient Experience of Care Measures				
Measure ID	**Measure Description**	**Performance Standard (Achievement Threshold)**	**Benchmark**	**Floor**
Patient Experience of Care Measure				
HCAHPS				
	Communication with Nurses	75.79%	84.99%	42.84%
	Communication with Doctors	79.57%	88.45%	55.49%
	Responsiveness of Hospital Staff	62.21%	78.08%	32.15%
	Pain Management	68.99%	77.92%	40.79%
	Communication about Medicines	59.85%	71.54%	36.01%
	Hospital Cleanliness & Quietness	63.54%	78.10%	38.52%
	Discharge Information	82.72%	89.24%	54.73%
	Overall Rating of Hospital	67.33%	82.55%	30.91%

BILLING CODE 4120–01–C

d. AHRQ Measures

For the reasons we have discussed in the Hospital Inpatient VBP Program Final rule (76 FR 26514), in the CY 2012 OPPS/ASC proposed rule (76 FR 42360), we proposed to set the achievement performance standard (achievement threshold) for each AHRQ composite measure at the median of hospital performance (50th percentile) during the proposed baseline period of March 3, 2010 to September 30, 2010. We proposed to set the benchmark for each AHRQ composite measure at the mean of the top decile of hospital performance during the proposed baseline period of March 3, 2010 to September 30, 2010. We also proposed to set the improvement performance standard (improvement threshold) for each of the proposed measures at each specific hospital's performance on the applicable measure during the proposed baseline period of March 3, 2010 to September 30, 2010.

We did not receive any comments on the proposed AHRQ measures performance standards. However, as described above, we will not finalize these performance standards.

e. HAC Measures

We adopted eight HAC measures in the Hospital Inpatient VBP Program Final Rule. For each of these eight HAC measures, at least one quarter of hospitals achieved a 100 percent rating based on administrative data for all IPPS hospitals participating in the Hospital IQR Program for Medicare discharges from October 1, 2008 through June 30, 2010 (that is, they did not have any reportable HAC occurrences). In addition, based on the administrative data from October 1, 2008 through June 30, 2010, at least one half of all hospitals achieved a measure rate of 100 percent on six of the eight HAC measures (Foreign Object Retained After Surgery; Air Embolism; Blood Incompatibility; Pressure Ulcer Stages III and IV; Catheter-Associated UTI; Manifestations of Poor Glycemic Control). Accordingly, the achievement threshold for these measures would be zero if we proposed to set performance standards for each individual measure using the same methodology that we finalized with respect to the mortality measures.

We believe that the HAC measures are extremely important in promoting patient safety, improving quality of care, and reducing costs. According to a 2010 HHS Office of the Inspector General report, entitled ''Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries'' (*http://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf*), an estimated 13.5 percent of hospitalized Medicare beneficiaries experienced adverse events during their hospital stays. We believe that all the finalized HAC measures assess the presence of conditions and outcomes that are reasonably preventable if high quality care is furnished to the Medicare beneficiary. We also believe that the incidence of HACs in general raises major patient safety issues for Medicare beneficiaries. Outcome measures,

including HAC outcome measures, are widely regarded by the provider community as strongly indicative of the quality of medical care and as integral to reporting and improving quality and patient safety. Therefore, we believe it is important to include HAC outcome measures in the Hospital VBP Program.

For these reasons, in the CY 2012 OPPS/ASC proposed rule (76 FR 42360 through 42361), we proposed that our topped-out policy would not apply to the HAC measures. We also proposed to treat the eight individual HAC measures as a single aggregate HAC score for purposes of performance scoring, and believe that this approach will enable us to calculate meaningful distinction among hospitals and variation in hospital performance on these measures. In addition, this aggregation of the scores for the HAC measures ensures that the HAC measures do not unduly outweigh the remainder of the measures in the outcome domain. Accordingly, in taking into account our HAC policy and reliability concerns, we proposed to set achievement performance standards, benchmarks, and improvement performance standards based on hospital combined performance on seven or eight HAC measures, as applicable, during the proposed performance or baseline period. Because certain hospitals will report on only seven of the eight HAC measures, we proposed separate performance standards depending on whether the hospitals report on seven or eight HAC measures.

We proposed to set the achievement performance standard (achievement threshold) for the HAC aggregate score for those hospitals that report on all eight of the HAC measures at the median of hospital performance (50th percentile) of those hospitals reporting on all eight of the HAC measures during the proposed baseline period of March 3, 2010 to September 30, 2010. We proposed to set the achievement performance standard (achievement threshold) for the HAC aggregate score for those hospitals that report on seven of the HAC measures at the median of hospital performance (50th percentile) on only those seven measures for those hospitals reporting on either seven or eight of the HAC measures during the proposed baseline period of March 3, 2010 to September 30, 2010.

We proposed to set the benchmark for the HAC aggregate score for those hospitals that report on all eight of the HAC measures at the mean of the top decile of hospital performance for those hospitals reporting on all eight HAC measures during the proposed baseline period of March 3, 2010 to September 30, 2010. We proposed to set the benchmark for the HAC aggregate score for those hospitals that report on seven of the HAC measures at the mean of the top decile of hospital performance on only those seven measures for hospitals reporting on either seven or eight of the HAC measures during the proposed baseline period of March 3, 2010 to September 30, 2010.

We also proposed to set the improvement performance standard (improvement threshold) for the HAC aggregate score at each specific hospital's performance during the proposed baseline period of March 3, 2010 to September 30, 2010, whether the hospitals report on seven or eight HAC measures. Please see below for further discussion of the proposed aggregate HAC scoring methodology.

We noted that the proposed performance standards for the HAC aggregate score were shown as a score composed of all eight individual HAC measures. We recognized that all hospitals report on seven of these individual measures, and nearly all (about 95 percent) of hospitals report all eight. However, a small number of hospitals do not report on the Foreign Object Removal after Surgery HAC measure. We believe that any numerical differences between the HAC performance standards for hospitals reporting on seven of eight HAC measures compared to the standards for hospitals reporting on all eight HAC measures will be statistically insignificant. However, in the CY 2012 OPPS/ASC proposed rule (76 FR 42361), we noted that we intended to provide updated performance standards in the CY 2012 OPPS/ASC final rule with comment period for those hospitals only reporting on seven of the eight HAC measures.

We invited public comment on the proposed methodology for setting performance standards for the aggregate HAC score for HAC measures finalized for the FY 2014 Hospital VBP Program.

Comment: Some commenters asked if CMS had considered how to transition performance data on claims-based measures from ICD–9 to ICD–10. Commenters asked if CMS would consider delaying claims-based measures given the burden on providers of implementing ICD–10.

Response: We are considering how to best conduct the transition from ICD–9 to ICD–10 for purposes of performance scoring and will provide more details in future rulemaking.

Comment: Some commenters expressed concerns about the proposals to use HAC measures capturing healthcare-associated infections (HAI) data, especially vascular catheter-associated bloodstream infections and catheter-associated urinary tract infections. Some commenters argued that unintended consequences for patient care, such as patient falls, may result from catheter removal too quickly. Other commenters argued that scoring HAC measures in the aggregate will complicate CMS' stated intent to retire claims-based HAI measures when more appropriate measures become available. Commenters also argued that aggregating the HAC measures may mislead consumers and suggested that CMS remove all HACs related to HAIs from the aggregated HAC score. Some commenters suggested that CMS use a different methodology to set performance standards for the HAC measures, arguing that they are very high standards to be attained as proposed. Other commenters argued that HACs represent such rare events that the proposed separate performance standards for hospitals depending on whether they report 7 or 8 HACs could exacerbate scoring reliability problems.

Response: As explained above, we are not finalizing any proposals related to the HAC measures at this time. We thank commenters for their input and will consider these comments in future rulemaking.

After consideration of the public comments we received, we are not finalizing the performance standards proposed for the HAC measures.

7. FY 2014 Hospital VBP Program Scoring Methodology

a. FY 2014 Domain Scoring Methodology

In the Hospital Inpatient VBP Program Final Rule, we adopted a methodology for scoring all clinical process of care, patient experience of care, and outcome measures. As noted in the Hospital Inpatient VBP Program Final Rule, this methodology outlines an approach that we believe is well-understood by patient advocates, hospitals and other stakeholders because it was developed during a lengthy process that involved extensive stakeholder input, and was presented by us in a report to Congress. Further, we have conducted extensive research on a number of other scoring models for the Hospital VBP Program to ensure a high level of confidence in the scoring methodology (76 FR 26514). In addition, we believe that, for simplicity and consistency of the Hospital VBP Program, it is important to score hospitals under the same general methodology for subsequent fiscal years, with appropriate modifications to accommodate new domains and

measures. We finalized a similar scoring methodology for the Medicare spending per beneficiary measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51654 through 51656).

Therefore, in the CY 2012 OPPS/ASC proposed rule (76 FR 42361), we proposed to use the same scoring methodology for these measures in the FY 2014 Hospital VBP Program, with the changes discussed below for HAC measures. We invited public comment on this proposal.

Comment: Some commenters sought clarification on the outcome domain calculation, specifically asking if CMS intends to weight measures equally within the domain.

Response: As described in the Hospital Inpatient VBP Program Final Rule (76 FR 26525), hospitals' measure scores are ''summed (weighted equally) to determine the total earned points for the domain.'' As we noted above, since some hospitals will not report the 30-day AMI mortality measure, we will convert the points earned for each of the remaining mortality measures to a percentage of total points. The points earned for each measure that applies to the hospital would be summed (weighted equally) to determine the total earned points for the domain.

Comment: Some commenters asked CMS to clarify the Hospital VBP scoring methodology, arguing that it is unclear how *Hospital Compare* data are translated into value-based purchasing scores.

Response: We interpret the commenter to erroneously believe that the measure rates currently posted on *Hospital Compare* are directly translated into Hospital VBP scores. That is not the case. Clinical process of care and patient experience of care measure rates currently displayed on *Hospital Compare* are calculated using four quarters of Hospital IQR Program data added on a rolling basis, while the HAC, AHRQ and mortality measure rates currently displayed on *Hospital Compare* are calculated using data from across multiple years. Under the Hospital VBP Program, we will use the measure data submitted with respect to the applicable performance period to calculate performance scores using the scoring methodology finalized for the program.

Comment: Some commenters argued that CMS should align *Hospital Compare* data with Hospital VBP performance periods to allow hospitals to more easily track their performance in the Hospital VBP Program.

Comment: Some commenters opposed the performance and baseline period proposals, arguing that the various dates specified are confusing and impose hardships on hospitals' quality management staff. Commenters suggested that CMS instead propose harmonized performance periods.

Response: We intend to work towards harmonized performance periods in the Hospital VBP Program in future program years, and we will take these comments into account as we determine how best to do so in the future. We intend to display Hospital VBP data on a section of the *Hospital Compare* Web site, as required by section 1886(o)(10) of the Act, and will provide details on those postings in future rulemaking.

After consideration of the public comments we received, we are finalizing our general scoring methodology for the clinical process and patient experience domains as outlined in the Hospital Inpatient VBP Program Final Rule. We are also finalizing our scoring methodology for the outcome domain, insofar as it applies to the mortality measures.

b. HAC Measures Scoring Methodology

In the CY 2012 OPPS/ASC proposed rule (76 FR 42361 through 42362), we proposed to score the HAC measures using an aggregated HAC rate based on the unweighted average of the rates of the individual HAC measures. However, as explained above, we are aware that hospitals may only report on seven of the eight finalized HAC measures. This is because some hospitals do not perform surgeries, and therefore would not submit eligible claims that would be the basis for the Foreign Object Retained After Surgery HAC measure. The remaining seven HAC measures would apply to all hospitals, however, because all hospitals that participate in the Hospital VBP Program will submit eligible claims for these measures. We also anticipate that most hospitals will report on all eight of the individual HAC measures because most hospitals that participate in the Hospital VBP Program perform surgeries and would submit eligible surgical claims that would be the basis for the Foreign Object Retained After Surgery HAC measure.

Accordingly, we proposed that the aggregate HAC score for each hospital be calculated as the equally-weighted average of the rates on all HAC measures for which the hospital reports Medicare claims, which will most often be an equally-weighted average of the rates on all eight measures, but may be rates on seven of the HAC measures. As stated above, the HAC aggregate score will be calculated if a hospital submits at least one Medicare claim during the performance period. For example, if a hospital submits one or more Medicare claims during the performance period, and those claims do not indicate any HAC occurrences, the hospital will receive a perfect score on all applicable HAC measures. The aggregate HAC rate would then be used to assign points in accordance with the proposed performance standards discussed above to calculate an individual hospital's aggregate HAC achievement and improvement scores. The single aggregate HAC score would be the greater of the hospital's achievement or improvement score. The hospital's aggregate HAC score would be combined with the hospital's score on other outcome measures to derive an outcome domain score, with the aggregate HAC score weighted equally with the other outcome measures in the domain. We note that in assigning points for this aggregate HAC score, lower aggregate HAC scores represent better performance. We believe our proposed aggregate scoring methodology for HAC measures allows us to meaningfully score hospitals on these critical patient safety measures.

We welcomed public comment on this proposal.

Comment: While many commenters generally objected to the proposals to use HAC measures, most commenters did not object to the proposed aggregated scoring methodology. Commenters argued that CMS must finalize a HAC scoring methodology that is statistically reliable in order to provide reliable comparisons between hospitals on these measures.

Response: We thank commenters for their support. However, for the reasons discussed above, we are not finalizing our proposed scoring methodology with respect to the HAC measures at this time. We will consider these comments in future rulemaking.

After consideration of the public comments we received, we are not finalizing our proposed methodology to score HAC measures as an aggregate.

8. Ensuring HAC Reporting Accuracy

As described in the FY 2012 IPPS/LTCH PPS proposed rule, for the FY 2013 Hospital VBP Program, the validation process we adopted for the Hospital IQR Program will ensure that the Hospital VBP data are accurate (76 FR 26537 through 26538). In addition, Medicare Administrative Contractors (MACs) review claims to ensure that accurate Medicare payments are made. This claims review ensures that HAC data included on the claims are accurately reported both for the Hospital IQR Program and the Hospital VBP Program. In addition, we are

considering proposing to adopt additional targeting to assess the accuracy of HAC data reported on claims. Specifically, we are considering targeting a subset of hospitals that report zero or an aberrantly low percentage of HACs on Medicare fee-for-service IPPS claims relative to the overall national average of HACs.

This consideration is supported by our analysis of HAC rates calculated using data from Medicare fee-for-service claims from October 1, 2008 through June 30, 2010. We publicly released these rates in March 2011, and they can be found on our Web site at: *http://www.cms.gov/HospitalQualityInits/06_HACPost.asp#TopOfPage.* This analysis revealed a range in hospital-reporting of the eight HACs from a low of 0.0001 percent (that is, 1 discharge out of every 100,000 applicable discharges) of hospital inpatient discharges (23 discharges) reporting a blood incompatibility, to a high of 0.0564 percent (that is, 56.4 discharges out of every 100,000 applicable discharges) reporting Falls and Trauma. According to this analysis, however, these HAC rates appear to be underreported occurrences when compared to similar HAI measures.

For example, the Catheter Associated Urinary Tract Infection (CAUTI) measure rate was 5.4 percent, or 54 out of every 1,000 eligible discharges, as reported in the AHRQ 2008 National Healthcare Quality Report. This rate is more than 125 times greater than the national HAC reported CAUTI rate of 0.317 out of every 1,000 eligible discharges. While we recognize that definitional differences in the measures might contribute to this rate difference, we also believe that underreporting of HAC claims data contributed to this difference. It is important to note that the 5.4 percent CAUTI rate was calculated using medical record documentation as a data source and a random sample of Medicare beneficiaries for acute care hospital stays, as discussed in a separate Federal report about healthcare quality (AHRQ 2008 National Healthcare Quality Report). We note that this analysis is exploratory in nature, and we cannot definitively conclude any systematic underreporting by any particular hospitals. Nonetheless, we believe that this analysis provides sufficient information for CMS to consider development of a HAC validation process to assess potential underreporting by hospitals and ensure accurate reporting among all hospitals reporting HACs on Medicare claims.

Our goal is to improve quality and patient safety through accurate reporting of hospital quality data and accurately linking quality to payment in the Hospital VBP Program. We strive to ensure accurate reporting, and we believe that validating a random subset of hospitals that report an aberrantly low number of HACs would strengthen our overall effort to link value to quality. We welcomed public comments regarding our consideration of a HAC validation process. We also noted that we intend to take appropriate action if we discover systematic underreporting of HAC and other adverse event information, including, where appropriate, reporting such instances to the HHS Office of the Inspector General for its review.

Comment: Some commenters supported the proposals to validate HAC data as long as it does not cause undue burden to hospitals. Other commenters suggested that CMS target hospitals with aberrantly high HAC rates instead of those with aberrantly low rates. Some commenters noted that HAC validation may prove to be difficult and suggested that CMS could better identify HACs through data sources other than claims.

Response: We thank commenters for their support. We intend to validate HAC data in such a way as to avoid any undue burden on hospitals. We will consider commenters' suggestion that we target hospitals with aberrantly high HAC rates in the future. We welcome commenters' suggestion that we could identify HACs through other data sources and would appreciate input on such sources and methodologies. At this time, however, we believe the claims-based HAC measures are the best available source for HAC data.

We thank the commenters for their views and will take them into account as we further develop our policies in this area.

9. Domain Weighting for the FY 2014 Hospital VBP Program

For the FY 2013 Hospital VBP Program, we adopted a weighting scheme that weights the clinical process of care domain at 70 percent of the Total Performance Score, and weights the patient experience of care domain at 30 percent. However, the addition of the outcome domain and the proposed addition of an efficiency domain necessitate the adoption of a different domain weighting scheme than we adopted for the FY 2013 Hospital VBP Program. We discuss below the factors we considered in determining the appropriate weight to propose for each domain in the FY 2014 Hospital VBP Program.

As we have previously stated, we believe that the patient's experience associated with receiving inpatient services in a hospital is important in determining the hospital's overall quality of care for purposes of the Hospital VBP Program. Thus, as we finalized for the FY 2013 Hospital VBP Program, in the CY 2012 OPPS/ASC proposed rule (76 FR 42362 through 42363), we proposed to weight the patient experience of care domain at 30 percent for the FY 2014 Hospital VBP Program. We believe that this weighting proposal appropriately encourages hospitals to provide patient-centered care across the full spectrum of their services.

As we stated in the Hospital Inpatient VBP Program Final Rule (76 FR 26491), we believe that domains need not be given equal weight, and that over time, scoring methodologies should be weighted more towards outcomes, patient experience of care and functional status measures (measures assessing physical and mental capacity, capability, well-being and improvement).

Consistent with this policy and our analysis showing that many of the clinical process of care measures are nearly topped-out, in the CY 2012 OPPS/ASC proposed rule (76 FR 42362 through 42363), we proposed to reduce the weighting for the clinical process of care domain in FY 2014 to 20 percent. We also proposed to weight the outcome domain at 30 percent of the Total Performance Score for the FY 2014 Hospital VBP Program. Because we believe that scoring hospitals on outcome measures will improve treatment outcomes and patient safety, we intend to propose increasing the weighting for the outcome domain in subsequent fiscal years as more outcome measures become available.

As we indicated in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25927 through 25928), we believe that efficiency is an important component of improving outcomes, the patient experience of care and the overall quality of care provided to Medicare beneficiaries in the inpatient hospital setting. Accordingly, in the CY 2012 OPPS/ASC proposed rule (76 FR 42363), we proposed to weight the efficiency domain at 20 percent of the Total Performance Score for the FY 2014 Hospital VBP Program in order to encourage the delivery of high quality, coordinated, and efficient care to Medicare beneficiaries.

Therefore, we proposed the following domain weights for the FY 2014 Total Performance Score: outcome domain = 30 percent; clinical process of care

domain = 20 percent; patient experience of care domain = 30 percent; and efficiency domain = 20 percent. Under this proposed weighting scheme, the clinical care-related domains (process of care and outcome domains) would, together, constitute 50 percent of the total performance score (20 percent for clinical process of care and 30 percent for outcome), the patient experience of care domain would constitute 30 percent, and the efficiency domain would constitute 20 percent. We believe that this proposed weighting scheme will hold hospitals accountable for all aspects of patient care, including clinical outcomes and efficiency.

We invited public comment on the proposed weighting of the four proposed domains to be used in the calculation of the Total Performance Score for the FY 2014 Hospital VBP Program.

Comment: Several commenters suggested alternative weighting schemes for the FY 2014 Hospital VBP Program, some arguing that the patient experience of care domain would be weighted too high at 30 percent. Some commenters suggested we reconsider the distribution of the clinical process of care domain weighting.

Response: We disagree with commenters' argument that the patient experience domain is weighted too high at 30 percent. While hospitals have less direct control over the patient experience domain than, for example, the clinical process domain, we do not believe that the Hospital VBP Program should diminish the importance of the patient's experience of care. We believe that hospitals must strive to improve the patient's experience concurrently with their efforts to improve their performance on other domains as part of a broad quality improvement effort. In determining the weighting for clinical process of care measures, we consider the available measures in each domain while balancing the importance of patient experience and our emphasis on outcomes, as discussed below.

Comment: Commenters disagreed with the proposed outcome domain weighting. Some commenters suggested that CMS weight it less than proposed, while others suggested that CMS give more weight to the outcome measures. Some commenters suggested that CMS redistribute the weight of the outcome domain and apply more weight to the clinical process of care domain.

Response: We agree that the outcome domain should be weighted to encourage hospitals to improve treatment outcomes. However, because we are suspending the effective date of the HAC and AHRQ measures in the Hospital VBP Program, the outcome domain will only have three measures for the FY 2014 program. Therefore, we believe that it is necessary to reduce the weight applied to this domain as a result of our decision to suspend the effective date of the HAC and AHRQ measures. However, we still believe that outcome measures are critical to patient safety. We believe that the three mortality measures serve as very good predictors of the quality of care patients receive and that they will serve as a good basis to encourage hospitals to improve outcomes. Taking this into account, and the fact that we are not finalizing an efficiency domain, we are finalizing a weighting methodology that increases the weight of the clinical process of care domain, as had been supported by some commenters who requested a reduction to the weight of the outcome domain. We are also reducing the weight of the outcome domain to account for the fact that the domain will only include three measures. We believe that this approach reflects our belief regarding the importance of these measures and maintains the same weight for the patient experience of care domain. For these reasons, for FY 2014, we are finalizing a weighting of 25 percent for the outcome domain, 45 percent for the clinical process of care domain, and 30 percent for the patient experience of care domain.

Comment: Some commenters expressed concern about the proposed weighting for the efficiency domain, arguing that 20 percent is too high for its first year in the program, especially because it is composed of a single, non-NQF endorsed measure. Some commenters suggested that CMS did not display this measure on *Hospital Compare* in a timely manner, did not fully specify the measure for the Hospital IQR Program, or did not provide hospitals with sufficient data on the measure, and that the efficiency domain should therefore be weighted at zero. Other commenters expressed general concern about weighting 50 percent of the program (patient experience and efficiency domains) on measures that are somewhat less under a hospital's control than clinical process and outcome measures.

Response: In light of our decision to suspend the effective date of the Medicare spending per beneficiary measure in the Hospital VBP Program, there is no efficiency domain to weight. We will take these comments into consideration as we develop policies in future rulemaking.

Comment: Some commenters argued that domain weighting changes should occur gradually to allow hospitals to adjust to program changes.

Response: We reiterate our belief that strong incentives for hospitals to redesign care processes for the delivery of coordinated, efficient health care services to Medicare beneficiaries are a priority. We intend to revisit the domain weighting in the future. We believe the addition of the outcome domain in FY 2014 necessitates rapid adoption and significant weighting, particularly because it captures important information for quality improvement.

Comment: Some commenters expressed support for the domain weighting proposal, arguing that the emphasis on outcomes and efficiency, as well as reduced emphasis on clinical processes, is consistent with the National Quality Strategy to promote higher quality health care. Other commenters expressed support for giving the proposed outcome domain a higher weight than the clinical process domain.

Response: We thank commenters for their support. After consideration of the public comments we received, we are not finalizing our FY 2014 domain weighting as proposed. Instead, we will finalize the FY 2014 domain weighting as follows: clinical process of care = 45 percent; patient experience of care = 30 percent; outcome = 25 percent.

B. Review and Correction Process Under the Hospital VBP Program

1. Background

Section 1886(o)(10)(A)(i) of the Act requires the Secretary to make information available to the public regarding individual hospital performance in the Hospital VBP Program, including: (1) Performance of the hospital on each measure that applies to the hospital; (2) the performance of the hospital with respect to each condition or procedure; and (3) the hospital's Total Performance Score. To meet this requirement, we stated our intent in the Hospital Inpatient VBP Program Final Rule to publish hospital scores with respect to each measure, each hospital's condition-specific score (that is, the performance score with respect to each condition or procedure, for example, AMI, HF, PN, and SCIP), each hospital's domain-specific score, and each hospital's Total Performance Score on *Hospital Compare* (76 FR 26534 through 26536). We intend to make proposals related to making this information publicly available in future rulemaking.

Section 1886(o)(10)(A)(ii) of the Act requires the Secretary to ensure that each hospital has the opportunity to

review, and submit corrections for, the information to be made public with respect to each hospital under section 1886(o)(10)(A)(i) of the Act prior to such information being made public.

For the FY 2013 Hospital VBP Program, the finalized measures consist of chart-abstracted clinical process of care measures and a survey-based patient experience of care measure. In the CY 2012 OPPS/ASC proposed rule (76 FR 42363 through 42365), we proposed that hospitals will have an opportunity to review and correct chart-abstracted data and patient experience data through the processes discussed below. We intend to make additional proposals regarding the review and correction of outcome measures, efficiency measures, and domain, condition, and Total Performance Scores in future rulemaking.

2. Review and Corrections of Data Submitted to the QIO Clinical Warehouse on Chart-Abstracted Process of Care Measures and Measure Rates

In the CY 2012 OPPS/ASC proposed rule (76 FR 42363 through 42364), we proposed that the process utilized to give hospitals an opportunity to review and correct data submitted on the Hospital IQR Program chart-abstracted measures also be used to allow hospitals to correct data and measure rates on chart-abstracted measures for the Hospital VBP Program. Under this proposed process, hospitals would continue to have the opportunity to review and correct data they submit on all Hospital IQR Program chart-abstracted measures, whether or not the measure is adopted as a measure for the Hospital VBP Program. We proposed to use the Hospital IQR Program's data submission, review, and correction processes, which will allow for review and correction of data on a continuous basis as it is being submitted for the Hospital IQR Program, which in turn would allow hospitals to correct data and measure rates used to calculate the Hospital VBP Program Total Performance Score for those hospitals that participate in both programs. We believe this process would satisfy the requirement in section 1886(o)(10)(A)(ii) of the Act to allow hospitals to review and submit corrections for one of the pieces of information that will be made public with respect to each hospital—the measure rates for chart-abstracted measures. For hospitals that do not participate in the Hospital IQR Program but do participate in the Hospital VBP Program, such as Maryland hospitals, we intend to make proposals regarding how those hospitals will be able to review and correct their Hospital VBP data in future rulemaking.

Under the Hospital IQR Program, hospitals currently have an opportunity to submit, review, and correct any of the chart-abstracted information submitted to the QIO Clinical Warehouse for the full 4½ months following the last discharge date in a calendar quarter. (We note that in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25915), we proposed to reduce the submission period from 4 ½ months to 104 days. However, we did not adopt this proposal in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51640 through 51641).) Hospitals can begin submitting data on the first discharge day of any reporting quarter. Hospitals are encouraged to submit data early in the submission schedule so that they can identify errors and resubmit data before the quarterly submission deadline. Users are able to view and make corrections to the data that they submit within 24 hours of submission. The data are populated into reports that are updated nightly with all data that have been submitted and successfully processed for the previous day. Hospitals are able to view a report each quarter which shows the numerator, denominator and percentage of total for each Clinical Measure Set and Strata. That report contains the hospital's performance on each measure set/strata submitted to the QIO Clinical Warehouse. The numerator is the number of cases that satisfies the conditions of the performance measure, and a denominator is the number of successfully accepted cases in the measure population evaluated by the performance measure. The percentage of total is calculated by using the numerator divided by the denominator multiplied by 100. The sum of the numerators and the denominators for each measure across the performance period is the same as the Hospital VBP measure rate for the quarter.

We believe that 4 ½ months is sufficient time for hospitals to be able to submit, review data, make corrections to the data, and view their percentage of total, or measure rate, on each Clinical Measure Set/Strata for use in both the Hospital IQR and Hospital VBP Programs. Additionally, because this process is familiar to most hospitals, use of this existing framework reduces the burden that could have been placed on hospitals that participate in the Hospital IQR Program if they had to learn a new process for submitting data for the Hospital VBP Program. Following the period in which hospitals can review and correct data and measure rates for chart-abstracted measures as specified above, we proposed that hospitals will have no further opportunity to correct such data or measure rates.

We proposed that once the hospital has an opportunity to review and correct quarterly data related to chart-abstracted measures submitted in the Hospital IQR Program, we will consider that the hospital has been given the opportunity to review and correct this data. We proposed to use this data to calculate the measure scores for purposes of the Hospital VBP Program, and these measure scores will be used to calculate domain, condition, and Total Performance Scores for the Hospital VBP Program without further review and correction. We invited public comment on this proposal.

Comment: Many commenters expressed support for the proposed review and corrections process for chart-abstracted measures, noting that the Hospital IQR Program's review process is working well.

Response: We thank commenters for their support.

Comment: Some commenters asked that CMS provide details on review and corrections for claims-based measures, particularly because the Affordable Care Act requires that hospitals have an opportunity to appeal the measure data submitted.

Response: We will provide more details on review and corrections for claims-based measures in future rulemaking. We also intend to propose an appeals process in future rulemaking.

After consideration of the public comments we received, we are finalizing the review and corrections process for chart-abstracted measures as proposed.

3. Review and Correction Process for Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Data

In the CY 2012 OPPS/ASC proposed rule (76 FR 42364 through 42365), we proposed a ''two-phase'' process for the review and correction of HCAHPS data. Under this proposed process, hospitals would have the opportunity to review and correct data they submitted on all HCAHPS Hospital IQR Program items in the first phase, whether or not such items or combination of items are adopted as HCAHPS dimensions for the Hospital VBP Program. In the second phase, hospitals would have the opportunity to review the patient-mix and mode adjusted HCAHPS scores (details on the HCAHPS adjustment process may be found at: *http://www.hcahpsonline.org/files/Final%20Draft%20Description%20of%20HCAHPS%20*

Mode%20and%20PMA%20with%20bottom%20box%20modedoc%20April%2030,%202008.pdf) on dimensions that we will use to score hospitals under the Hospital VBP Program to determine whether they believe CMS calculated their scores on these dimensions correctly.

We believe that this proposal for a two-phase review process will expedite hospital review and correction of data. We also believe that this proposal will improve quality of care because hospitals will be able to timely review their HCAHPS scores and respond efficiently in improving patient care to address areas of weakness reflected in their scores. We are not proposing to release any patient level data to the public. This proposed review process would only grant each hospital the authority to review and correct the hospital's patient-level data.

a. Phase One: Review and Correction of HCAHPS Data Submitted to the QIO Clinical Warehouse

For the first phase of the HCAHPS review and correction process, we proposed to reduce the HCAHPS submission deadline under the Hospital IQR Program by one week in order to create a 1-week period for hospitals to review and correct their HCAHPS data. We included this proposal to reduce the submission deadline in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25916). Currently, hospitals have approximately 14 weeks after the end of a calendar quarter to submit HCAHPS data for that quarter to the QIO Clinical Warehouse. Under this proposal, hospitals would have approximately 13 weeks after the end of a calendar quarter to submit HCAHPS data for that quarter to the QIO Clinical Warehouse and a 1-week period to review and correct that data. During the 13-week submission period, hospitals would be able to resubmit their data to make corrections to the patient-level records. The 1-week review and correction period would occur immediately after the 13-week data submission deadline.

The proposed 1-week review and correction period would allow hospitals to provide missing data or replace incorrect data in the data files they have submitted to the QIO Clinical Warehouse. The 1-week review and correction period would allow hospitals to identify any issues with the data they had submitted in the 13-week submission period. Hospitals will have the opportunity to review frequency distributions of all of their submitted data items, which include hospital summary information, patient administrative data, and patient survey responses, and resubmit their HCAHPS data files to correct identified issues during the 1-week review and correction period. We define the term ''review and correct'' to mean that hospitals can correct their existing data records, but not add new data records. Accordingly, hospitals would not be allowed to add new patient-level records or remove existing patient-level records during the review and correction period. Following the conclusion of the 1-week review and correction period, hospitals would not be allowed to review, correct, or submit additional HCAHPS data for the applicable calendar quarter. We finalized this proposal in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641 through 51642).

b. Phase Two: Review and Correction of HCAHPS Scores for the Hospital VBP Program

In the second phase of the proposed HCAHPS review and correction process, hospitals would be given the opportunity to review their scores on the HCAHPS items that will be used in the Hospital VBP Program. These HCAHPS scores are constructed after the data that hospitals had submitted have been analyzed to identify and remove incomplete surveys and after adjustments for the effects of patient-mix and survey mode have been applied. (Details on the HCAHPS adjustment process may be found at: *http://www.hcahpsonline.org/files/Final%20Draft%20Description%20of%20HCAHPS%20Mode%20and%20PMA%20with%20bottom%20box%20modedoc%20April%2030,%202008.pdf.*) Hospitals would have approximately 1 week to examine their HCAHPS dimension scores for the applicable Hospital VBP Program performance period. A participating hospital would have the opportunity to question CMS if the hospital believes its scores were miscalculated. We would respond to a hospital's inquiries by checking the calculation and, if necessary, recalculating the hospital's HCAHPS scores. In this proposed second phase of the HCAHPS review and correction process, hospitals would not be allowed to change or submit new HCAHPS data or delete existing data. Their right to correct information during this period would be limited to reviewing their HCAHPS dimension scores and notifying CMS of any errors in its calculation of those scores.

We intend to propose the procedural aspects of the second phase of the proposed HCAHPS review and correction process in future rulemaking.

In summary, for the chart-abstracted and patient experience of care measures, we proposed that existing procedures for submission, review, and correction related to chart-abstracted measures under the Hospital IQR Program, coupled with the proposed two phase review of HCAHPS scores discussed above, would constitute an opportunity for review and correction of measure data and measure rates under the Hospital VBP Program. Because these procedures give hospitals the opportunity to review and correct the data and/or measure rates, such data and measure rates may be used to calculate domain, condition, and Total Performance Scores for the Hospital VBP Program. We intend to make proposals related to making this information publicly available, and to make additional proposals regarding the review and correction of outcome measures, efficiency measures, and domain, condition, and Total Performance Scores in future rulemaking. We invited public comment on these proposals.

Comment: Some commenters expressed support for the proposed two-phase review and corrections process, agreeing that it provides an appropriate opportunity to review data to be made public.

Response: We thank commenters for their support.

Comment: Some commenters recommended that CMS provide clear guidance for missing and incorrect data correction in the first phase and suggested that CMS reconsider allowing new records to be submitted in the second phase.

Response: In order to create stability in the data submission process and ensure adequate time for data cleaning and processing, score calculation and report preparation, we have never allowed HCAHPS data to be submitted into the data warehouse after the data submission deadline. Permitting post-deadline data submissions could result in the strategic submission, alteration or withholding of HCAHPS surveys. Maintaining a firm data submission deadline is also consistent with CMS Data Warehouse policy that applies to all measures. Accordingly, we will not allow new records to be submitted or accepted in the data warehouse after the end of the data submission period for either Phase One or Two of the new Review and Correction process.

As noted in the FY 2012 IPPS/LTCH PPS final rule and CY 2012 OPPS/ASC proposed rule, the data submission deadline will occur one week earlier than previously in order to allow time for the Phase One Review and

Correction period. During the data submission period, which will last approximately 13 weeks, hospitals and survey vendors can submit surveys and will also have the opportunity to resubmit surveys to correct any issues regarding the patient records. During the new one-week Phase One Review and Correction period, hospitals and survey vendors will be permitted to correct and resubmit any previously submitted patient records. Phase Two of the Review and Correction process will occur months after the relevant data submission deadlines and long after the HCAHPS Hospital VBP scores have been calculated. Therefore, no HCAHPS records could be submitted or accepted at that time; otherwise, HCAHPS data could not be finalized in a timely manner.

We will provide detailed information on the HCAHPS Review and Correction process closer to the inaugural Phase One and Phase Two of the program.

Comment: Some commenters opposed the proposal to allow a one-week HCAHPS review period, arguing that hospitals need at least two weeks or longer to review their results.

Response: The one-week HCAHPS review and correction period allows a formal opportunity for hospitals (or their HCAHPS survey vendors) to resubmit data for patients in order to correct errors in the data submitted for those patients.

Given the amount of time necessary for participating hospitals or their survey vendors to fully administer the HCAHPS survey, receive survey responses, and create the necessary data files, we do not believe it is appropriate to further shorten the data submission period either by beginning the period sooner, or ending it sooner.

During the proposed one-week Review and Correction period for Phase One, hospitals or their survey vendors will have access to a summary report of their data that had been submitted during the data submission period. HCAHPS scores would not be available until the Phase Two period.

After consideration of the public comments we received, we are finalizing as proposed our two-phase review and corrections process for HCAHPS data.

XVII. Files Available to the Public via the Internet

In the past, a majority of the Addenda to which we referred throughout the preamble of the OPPS/ASC proposed and final rules with comment periods appeared in the printed version of the **Federal Register** as part of the annual rulemakings. However, beginning with the CY 2012 OPPS/ASC proposed rule (76 FR 42365 through 42366), the Addenda of the proposed rules and the final rules with comment period will be published and available only via the Internet on the CMS Web site. Our existing regulations at §§ 416.166(b), 416.171(b), and 416.173 provide for the publication of covered surgical procedures, covered ancillary services, the payment methodology, and the payment rates under the ASC payment system in the **Federal Register**. In the proposed rule (76 FR 42365 and 42391 through 42392), we proposed to revise these three regulations to make the Addenda for the ASC payment system available via the Internet on the CMS Web site.

We did not receive any public comments regarding publication of the Addenda only via the Internet on the CMS Web site. Therefore, we are finalizing, without modification, our proposal for CY 2012. We also are finalizing the revisions to §§ 416.166(b), 416.171(b), and 416.173 to provide for the publication of covered surgical procedures, covered ancillary services, payment methodologies, and payment rates under the ASC payment system via the Internet on the CMS Web site. In the CY 2012 OPPS/ASC proposed rule, we inadvertently omitted the last sentence of existing § 416.171(b), which we did not propose to change. In this final rule with comment period, we are finalizing § 416.171(b) with the inclusion of language to correct this technical error.

To view the Addenda of this final rule with comment period pertaining to the CY 2012 payments under the OPPS, go to the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS/HORD* and select ''1525–FC'' from the list of regulations. All Addenda for this final rule with comment period are contained in the zipped folder entitled ''2012 OPPS FC Addenda'' at the bottom of the page.

To view the Addenda of this final rule with comment period pertaining to the CY 2012 payments under the ASC payment system, go to the CMS Web site at: *http://www.cms.gov/ASCPayment/ASCRN/* and select ''1525–FC'' from the list of regulations. All Addenda for this final rule with comment period are contained in the zipped folder entitled ''Addenda AA, BB, DD1, and DD2'', and ''Addendum EE'' at the bottom of the page.

A. Information in Addenda Related to the CY 2012 Hospital OPPS

Addenda A and B provide various data pertaining to the CY 2012 payment for items and services under the OPPS. Specifically, Addendum A includes a list of all APCs that are payable under the OPPS, including the scaled relative weights, the national unadjusted payment rates, the national unadjusted copayments, and the minimum unadjusted copayments for each APC that we are adopting for CY 2012. Addendum B includes a list of all active HCPCS codes, including the APC assignments, the scaled relative weights, the national unadjusted payment rates, the national unadjusted copayments, the minimum unadjusted copayments, and the payment status indicators and comment indicators for the CY 2012 OPPS.

For the convenience of the public, we also are including on the CMS Web site a table that displays the HCPCS code data in Addendum B sorted by APC assignment, identified as Addendum C.

Addendum D1 defines the payment status indicators that we used in Addenda A and B. Addendum D2 defines the comment indicators that are used in Addendum B.

Addendum E lists the HCPCS codes that are only payable to hospitals as inpatient procedures and that are not payable under the OPPS for CY 2012.

Addendum L contains the out-migration wage adjustment for CY 2012.

Addendum M lists the HCPCS codes that are members of a composite APC and identifies the composite APC to which each is assigned. Addendum M also identifies the status indicator for each HCPCS code and a comment indicator if there is a change in the code's status with regard to its membership in the composite APC. Each of the HCPCS codes included in Addendum M has a single procedure payment APC, listed in Addendum B, to which it is assigned when the criteria for assignment to the composite APC are not met. When the criteria for payment of the code through the composite APC are met, one unit of the composite APC payment is paid, thereby providing packaged payment for all services that are assigned to the composite APC according to the specific I/OCE logic that applies to the APC. We refer readers to the discussion of composite APCs in section II.A.2.e. of this final rule with comment period for a complete description of the composite APCs.

Addendum N, ''Bypass Codes for Creating 'Pseudo' Single Procedure Claims for CY 2012 OPPS,'' contains a list of the HCPCS codes that we used to create ''pseudo'' single claims from multiple procedure claims so that the most claims data can be used to set median costs for the CY 2012 OPPS. We refer readers to section II.A.1.b. of this final rule with comment period for a full discussion of the use of this file in the

CY 2012 OPPS ratesetting process. Addendum N contains the following elements for the CY 2012 bypass codes: (1) HCPCS code; (2) short descriptor; (3) overall bypass indicator; and (4) an indicator if the code was not used as a bypass code in ratesetting activities prior to this final rule with comment period. The data in Addendum N were previously issued as a table (usually Table 1) in the preamble of the applicable proposed or final rule. We are issuing it as an addendum to this final rule with comment period because it is lengthy and users can better analyze the file if it is furnished in Excel format on the CMS Web site.

B. Information in Addenda Related to the CY 2012 ASC Payment System

Addenda AA and BB provide various data pertaining to the CY 2012 payment for the covered surgical procedures and covered ancillary services for which ASCs may receive separate payment. Addendum AA lists, for CY 2012, the ASC covered surgical procedures, whether the procedure is subject to multiple procedure discounting, the payment indicator for each procedure, the comment indicator if applicable, and the payment weight and rate for each procedure. Addendum BB displays, for CY 2012, the ASC covered ancillary services, the payment indicator for each service, the comment indicator if applicable, and the payment weight and rate for each service.

Addendum DD1 defines the payment indicators that are used in Addenda AA and BB. Addendum DD2 defines the comment indicators that are used in Addenda AA and BB.

Addendum EE lists the surgical procedures to be excluded from Medicare payment if furnished in ASCs. The excluded procedures listed in Addendum EE are surgical procedures that are assigned to the OPPS inpatient list, are not covered by Medicare, are reported using a CPT unlisted code, or have been determined to pose a significant safety risk to a Medicare beneficiary when performed in an ASC or for which standard medical practice dictates that the beneficiary typically requires active medical monitoring and care at midnight following the procedure.

The Medicare Physician Fee Schedule (MPFS) data files are located at the CMS Web site at: *http://www.cms.gov/PhysicianFeeSched/*.

The links to all of the FY 2012 IPPS wage index-related tables (that are used for the CY 2012 OPPS) are accessible on the CMS Web site at: *http://www.cms.gov/AcuteInpatientPPS/WIFN*.

XVIII. Collection of Information Requirements

A. Legislative Requirements for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and to solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In the CY 2012 OPPS/ASC proposed rule, we solicited public comments on each of the issues outlined above as discussed below that contained information collection requirements.

B. Requirements in Regulation Text

The CY 2012 OPPS/ASC proposed rule contained the following proposed information collection requirements specified in the regulatory text:

1. ICRs Regarding Basic Commitments of Providers (§ 489.20)

Section 489.20(w) contains a physician presence disclosure requirement that requires disclosure when a doctor of medicine or a doctor of osteopathy is not onsite 24 hours per day, 7 days per week. The burden associated with the physician presence disclosure requirement is the time and effort necessary for each hospital and CAH to develop a standard notice to furnish to its patient, obtain the required patients' signatures, and maintain a copy in the patient's medical record. Although this requirement is subject to the PRA, the associated burden is approved under OMB control number 0938–1034.

Our proposed amendment to § 489.20(w) would require that, for hospitals and CAHs that are not physician owned, the existing physician presence disclosure requirement regarding outpatient services would apply only to outpatients receiving observation services, surgery, and procedures requiring anesthesia. The burden associated with this requirement would be greatly reduced and includes revisions to the time and effort necessary for each hospital and CAH to revise and disseminate the existing standard notice to its patients. The requirements in § 489.20(w) apply to all hospitals as defined in § 489.24(b). We estimated that there are approximately 2,597 hospitals and CAHs that may not have a doctor or medicine or a doctor of osteopathy onsite at all times. We estimated that it will take each hospital or CAH 4 hours to develop or amend and review a disclosure form on a one-time basis, 30 seconds to make each disclosure, another 30 seconds to obtain the patient's signature, and an additional 30 seconds to include a copy of the notice in the patient's medical record. We estimated that on average each hospital or CAH that is subject to the disclosure requirement will make 1,966 disclosures per year. The estimated annual burden associated with developing an amended form, obtaining patient signatures, and copying and recording the form is 138,032 hours at a cost of approximately $2,557,733. We note that these numbers reflect correction of a minor arithmetic error reflected in our proposal, increasing the cost over our original estimate by $6,585.

We did not receive any public comments on these information collection requirements. Therefore, we are finalizing the burden estimate as proposed, with the technical correction noted.

2. ICRs Regarding Exceptions Process Related to the Prohibition of Expansion of Facility Capacity (§ 411.362)

As discussed in section XV. of the CY 2012 OPPS/ASC proposed rule (76 FR 42349 through 42354) and this final rule with comment period, we proposed to add a new § 411.362(c) to establish and implement the process by which an applicable hospital or high Medicaid facility may apply for an exception to the prohibition on expansion of facility capacity. We proposed that a physician-owned hospital would be allowed to request an exception under proposed § 411.362(c) by providing information to CMS regarding the hospital's baseline number of operating rooms, procedure rooms, and beds for which the hospital is licensed as of March 23, 2010, and specifying the increase in the number of operating rooms, procedure rooms and beds it is requesting under the exceptions process. We proposed that an applicable hospital requesting an exception would have to satisfy eligibility criteria for 3 of the most recent fiscal years for which data are

available. In addition, the hospital would have to provide supporting documentation to CMS regarding the criteria it must satisfy. We estimated that 265 physician-owned hospitals would request an exception.

As discussed in section XV. of this final rule with comment period, we received a comment contending that 3 fiscal years worth of data was excessive. After consideration of this public comment, in this final rule with comment, we are modifying the regulations at § 411.362(c)(2)(ii), (iv), and (v) to require applicable hospitals to satisfy the respective criteria for the most recent fiscal year for which data are available. Therefore, we have revised our proposed estimates. We estimate that it will take each hospital 6 hours and 45 minutes to complete the request process at the cost of approximately $365.65 for each hospital. Overall, the annual burden for this process is estimated at approximately 1,789 hours, at the cost of approximately $96,897.25. These estimates do not include time or cost burden estimates for hospitals to read and provide rebuttal statements in response to community input comments, which is included in the final regulation, and the associated time and costs for the hospital to send them to CMS. Due to the voluntary nature of this criterion, time and cost burden estimates are difficult to anticipate, as this is an unknown variable.

REVISED ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation Section(s)	OMB Control No.	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Labor Cost of Reporting ($)	Total Capital/ Maintenance Costs ($)	Total Cost ($)
§ 489.20	0938-1034	2,597	1,966	0.019	138,032*	18.50	2,551,148	0	2,557,733
§ 411.362	0938-New	265	265	6.45	1,789	44.81	96,897	0	96,897
Total		2,862	2,231		139,821				2,654,630

*Represents the revised burden estimate associated with the requirement. It does not reflect the burden currently approved under OCN 0938-1034.

C. Associated Information Collections Not Specified in Regulatory Text

In the CY 2012 OPPS/ASC proposed rule, we made reference to proposed associated information collection requirements that were not discussed in the regulation text contained in the proposed rule. The following is a discussion of those requirements for the proposals that we are adopting in this final rule with comment period.

1. Hospital Outpatient Quality Reporting (Hospital OQR) Program

As previously stated in section XIV. of the CY 2012 OPPS/ASC proposed rule and this final rule with comment period, the Hospital OQR Program has been generally modeled after the quality data reporting program for the Hospital IQR Program. We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72064 through 72110 and 72111 through 72114) for a detailed discussion of Hospital OQR Program information collection requirements we have previously finalized.

2. Hospital OQR Program Measures for the CY 2012, CY 2013, CY 2014, and CY 2015 Payment Determinations

a. Previously Adopted Hospital OQR Program Measures for the CY 2012, CY 2013, and CY 2014 Payment Determinations

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766), we retained the 7 chart-abstracted measures we used in CY 2009 and adopted 4 new claims-based imaging measures for the CY 2010 payment determination, bringing the total number of quality measures for which hospitals must submit data to 11 measures. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60637), we required hospitals to continue to submit data on the same 11 measures for the CY 2011 payment determination. The burden associated with the aforementioned data submission requirements is currently approved under OCN: 0938–1109 and expires October 31, 2013.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72071 through 72094), we adopted measures for the CY 2012, CY 2013, and CY 2014 payment determinations.

For the CY 2012 payment determination, we retained the 7 chart-abstracted measures and the 4 claims-based imaging measures we used for the CY 2011 payment determination. We also adopted 1 structural HIT measure that tracks HOPDs' ability to receive lab results electronically, and 3 claims-based imaging efficiency measures. These actions bring the total number of measures for the CY 2012 payment determination for which hospitals must submit data to 15 measures. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72112 through 72113), we discussed the burden associated with these information collection requirements.

For the CY 2013 payment determination, we required that hospitals continue to submit data for all of the quality measures that we adopted for the CY 2012 payment determination. We also adopted 1 structural HIT measure assessing the ability to track clinical results between visits, 6 new chart-abstracted measures on the topics of HOPD care transitions and ED efficiency, as well as 1 chart-abstracted ED–AMI measure that we proposed for the CY 2012 payment determination but which we decided to finalize for the CY 2013 payment determination. These actions bring the total number of quality measures for the CY 2013 payment determination for which hospitals must submit data to 23 measures.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72071 through 72094), for the CY 2014

payment determination, we retained the CY 2013 payment determination measures, but did not adopt any additional measures. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72112 through 72113), we discussed the burden associated with these information collection requirements.

The 23 measures that we adopted in the CY 2011 OPPS/ASC final rule with comment period to be used for the CY 2012 through CY 2014 payment determinations are listed in the table below.

BILLING CODE 4120–01–P

Hospital OQR Program Measurement Set Adopted in the CY 2011 OPPS/ASC Final Rule with Comment Period to be Used for the CY 2012, CY 2013, and CY 2014 Payment Determinations
OP-1: Median Time to Fibrinolysis
OP-2: Fibrinolytic Therapy Received Within 30 Minutes
OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
OP-4: Aspirin at Arrival
OP-5: Median Time to ECG
OP-6: Timing of Antibiotic Prophylaxis
OP-7: Prophylactic Antibiotic Selection for Surgical Patients
OP-8: MRI Lumbar Spine for Low Back Pain
OP-9: Mammography Follow-up Rates
OP-10: Abdomen CT – Use of Contrast Material
OP-11: Thorax CT – Use of Contrast Material
OP-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data
OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non Cardiac Low Risk Surgery
OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)
OP-15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache
OP-16: Troponin Results for Emergency Department acute myocardial infarction (AMI) patients or chest pain patients (with Probable Cardiac Chest Pain) Received Within 60 minutes of Arrival
OP-17: Tracking Clinical Results between Visits
OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
OP-19: Transition Record with Specified Elements Received by Discharged Patients
OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional
OP-21: ED- Median Time to Pain Management for Long Bone Fracture
OP-22: ED- Patient Left Without Being Seen
OP-23: ED- Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 minutes of Arrival

b. Additional Hospital OQR Program Measures for CY 2014

In the CY 2011 OPPS/ASC final rule with comment period, we did not adopt any new measures for the CY 2014 payment determination. In this final rule with comment period, we are adding, for the CY 2014 payment determination, 1 chart-abstracted measure and 2 structural measures (including hospital outpatient volume data for selected outpatient surgical procedures). Thus, for the CY 2014 payment determination, there will be a total of 26 measures. The complete measure set we are adopting for the CY 2014 payment determination, including measures we have previously adopted, is shown below.

BILLING CODE 4120–01–P

CY 2014 Hospital OQR Program Measure Set Reflecting Measures Previously Adopted and the Additions in this Final Rule with Comment Period
OP-1: Median Time to Fibrinolysis
OP-2: Fibrinolytic Therapy Received Within 30 Minutes
OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
OP-4: Aspirin at Arrival
OP-5: Median Time to ECG
OP-6: Timing of Antibiotic Prophylaxis
OP-7: Prophylactic Antibiotic Selection for Surgical Patients
OP-8: MRI Lumbar Spine for Low Back Pain
OP-9: Mammography Follow-up Rates
OP-10: Abdomen CT – Use of Contrast Material
OP-11: Thorax CT – Use of Contrast Material
OP-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data*
OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non Cardiac Low Risk Surgery *
OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)*
OP-15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache*
OP-16: Troponin Results for Emergency Department acute myocardial infarction (AMI) patients or chest pain patients (with Probable Cardiac Chest Pain) Received Within 60 minutes of Arrival **
OP-17: Tracking Clinical Results between Visits**
OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients**
OP-19: Transition Record with Specified Elements Received by Discharged Patients**
OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional**
Op-21: ED- Median Time to Pain Management for Long Bone Fracture **
OP-22: ED Patient Left Without Being Seen**
OP-23: ED- Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 minutes of Arrival **
OP-24: Cardiac Rehabilitation Patient Referral From an Outpatient Setting***
OP-25: Safety Surgery Checklist***
OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures***

CY 2014 Hospital OQR Program Measure Set Reflecting Measures Previously Adopted and the Additions in this Final Rule with Comment Period

Procedure Category	Corresponding HCPCS Codes
Gastrointestinal	40000 through 49999, G0104, G0105,G0121,C9716, C9724, C9725, 0170T
Eye	65000 through 68999, G0186, 0124T, 0099T, 0017T, 0016T, 0123T, 0100T, 0176T, 0177T, 0186T, 0190T, 0191T, 0192T, 76510, 0099T
Nervous System	61000 through 64999, G0260, 0027T, 0213T, 0214T, 0215T, 0216T, 0217T, 0218T, 0062T
Musculoskeletal	20000 through 29999, 0101T, 0102T, 0062T, 0200T, 0201T
Skin	10000 through 19999, G0247, 0046T, 0268T, G0127, C9726, C9727
Genitourinary	50000 through 58999, 0193T, 58805
Cardiovascular	33000 through 37999
Respiratory	30000 through 32999

*New measure for the CY 2012 payment determination.

**New measure for the CY 2013 payment determination.

***New measure for the CY 2014 payment determination adopted in this final rule with comment period.

BILLING CODE 4120–01–C

We will calculate the seven claims-based measures using Medicare FFS claims data and do not require additional hospital data submissions. With the exception of OP–22, we are using the same data submission requirements related to the chart-abstracted quality measures that are submitted directly to CMS that we used for the CY 2011 and CY 2012 payment determinations. For the four structural measures, including the collection of all-patient volume for selected outpatient procedures, hospitals will enter data into a Web-based collection tool during a specified collection period once annually. Under the Hospital OQR Program requirements, hospitals must complete and submit a notice of participation form for the Hospital OQR Program if they have not already done so or have withdrawn from participation. By submitting this document, hospitals agree that they will allow CMS to publicly report the measures for which they have submitted data under the Hospital OQR Program.

For the CY 2014 payment determination, the burden associated with these requirements (including those previously adopted) is the time and effort associated with completing the notice of participation form, collecting and submitting the data on the 26 measures. For the 15 chart-abstracted measures (including those measures for which data are data is submitted directly to CMS, as well as the OP–22 measure for which data will be submitted via a Web-based tool rather than via an electronic file), we estimate that there will be approximately 3,200 respondents per year. For hospitals to collect and submit the information on the chart-abstracted measures we estimate it will take 35 minutes per sampled case. Based upon the data submitted for the CY 2011 payment determination and our estimates for the additional proposed measures, we estimate there will be a total of 1,947,429 cases per year, approximately 609 cases per year per respondent. The estimated annual burden associated with the submission requirements for these chart-abstracted measures is 1,136,000 hours (1,947,429 cases per year × 0.583 hours per case).

For the structural measures, excluding the proposed all-patient volume for selected surgical procedures measure, we estimate that each participating hospital will spend 10 minutes per year to collect and submit the required data, making the estimated annual burden associated with these measures 1,600 hours (3,200 hospitals × 0.167 hours per measure × 3 structural measures per hospital).

For the collection of all-patient volume for selected outpatient surgical procedures, because hospitals must determine their populations for data reporting purposes and most hospitals are voluntarily reporting population and sampling data for Hospital OQR Program purposes, we believe the only additional burden associated with this proposed requirement would be the reporting of the data using the Web-based tool. We estimate that each participating hospital will spend 10 minutes per year to collect and submit the data, making the estimated annual burden associated with this measure 533 hours (3,200 hospitals × 0.167 hours

per measure × 1 all-patient volume measure per hospital).

Comment: One commenter believed that the estimates within the proposed rule are reasonable for the chart-abstraction of cases, but that they underestimate the true burden by overlooking the time burden for startup and biannual maintenance education of the measure specifications, educational research for cases that do not fit within the specifications manual, education regarding electronic tool usage, coordination of data submission and data quality checks by management and/or information technology personnel, and recruitment of abstraction personnel by management. The commenter believed that the effect of these additional, required activities will double or triple the burden estimated within the original proposal document and should not be overlooked.

Response: We thank the commenter for bringing our attention to these additional sources of burden and for their support of our estimates related to the abstraction of cases. We will consider whether future estimates will require consideration of the factors listed.

c. Hospital OQR Program Measures for CY 2015

In this final rule with comment period, for the CY 2015 payment determination, we are retaining the requirement that hospitals must complete and submit a notice of participation form for the Hospital OQR Program. For the CY 2015 payment determination, we also are retaining the measures used for CY 2014 payment determination (including the measures adopted in this final rule with comment period) and not adding any additional measures at this time.

For the CY 2015 payment determination, the burden associated with these requirements is the time and effort associated with completing the notice of participation form, collecting and submitting the data on the proposed measures, and collecting and submitting all-patient volume data for selected outpatient surgical procedures. For the chart-abstracted measures, we estimate that there will be approximately 3,200 respondents per year. For hospitals to collect and submit the information on the chart-abstracted measures where data is submitted directly to CMS, we estimate it will take 35 minutes per sampled case. Based upon the data submitted for the CY 2011 payment determination and our estimates for the additional measures, we estimate there will be a total of 1,947,429 cases per year, approximately 609 cases per year per respondent. The estimated annual burden associated with the aforementioned proposed submission requirements for the chart-abstracted data is 1,136,000 hours (1,947,429 cases per year × 0.583 hours per case). For the structural measures, we estimate that each participating hospital will spend 10 minutes per year to collect and submit the data, making the estimated annual burden associated with these measures 1,603 hours (3,200 hospitals × 0.167 hours per hospital × 3 structural measures per hospital).

For the collection of all-patient volume data for selected outpatient surgical procedures, because hospitals must determine their populations for data reporting purposes and most hospitals are voluntarily reporting population and sampling data for Hospital OQR purposes, we believe the only additional burden associated with this requirement will be the reporting of the data using the Web-based tool. We estimate that each participating hospital will spend 10 minutes per year to collect and submit the data, making the estimated annual burden associated with this measure 533 hours (3,200 hospitals × 0.167 hours per hospital).

We invited public comment on the burden associated with the information collection requirements but did not receive any public comment.

We did not receive any additional comments on these information collection requirements.

3. Hospital OQR Program Validation Requirements for CY 2013

In this final rule with comment period, we are retaining most of the requirements related to data validation for CY 2013 that we adopted in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72103 through 72106) for CY 2012, with some revisions. While these requirements are subject to the PRA, they are currently approved under OCN: 0938–1109 and expire October 31, 2013.

Similar to our approach for the CY 2012 Hospital IQR Program payment determination (75 FR 72103 through 72106), we are validating data from randomly selected hospitals for the CY 2013 payment determination, but we are reducing the number of hospitals from 800 to 450. We note that, because hospitals would be selected randomly, every hospital participating in the Hospital OQR Program would be eligible each year for validation selection.

In the CY 2011 OPPS/ASC proposed rule and final rule with comment period (75 FR 46381 and 72106, respectively), we discussed additional data validation conditions under consideration for CY 2013 and subsequent years. In this final rule with comment period, we are finalizing a policy under which we will select for validation up to 50 additional hospitals based upon targeting criteria.

For each selected hospital, generally we will randomly select up to 48 patient episodes of care per year (12 per quarter) for validation purposes from the total number of cases that the hospital successfully submitted to the OPPS Clinical Warehouse during the applicable time period. However, if a selected hospital submitted less than 12 cases in one or more quarters, only those cases available would be validated.

The burden associated with the CY 2013 requirement is the time and effort necessary to submit validation data to a CMS contractor. We estimate that it would take each of the sampled hospitals approximately 12 hours to comply with these data submission requirements. To comply with the requirements, we estimate each hospital must submit up to 48 cases for the affected year for review. All selected hospitals must comply with these requirements per year, which would result in a total of up to 24,000 charts being submitted by the sampled hospitals. The estimated annual burden associated with the data validation process for CY 2013 is approximately 6,000 hours.

We are maintaining the deadline of 45 days for hospitals to submit requested medical record documentation to a CMS contractor to support our validation process.

We invited public comment on the burden associated with these information collection requirements. We received comments regarding increased burden related to reducing the deadline for hospitals to submit requested medical record documentation from 45 to 30 days. We discuss these comments and state in section XIV.G.3.d. of this final rule with comment period that we have decided to not finalize our proposal to reduce the time for hospitals to submit medical record documentation, and that we are instead retaining our policy of 45 days after request.

4. Hospital OQR Program Reconsideration and Appeals Procedures

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68779), we adopted a mandatory reconsideration process that applied to the CY 2010 payment decisions. In the CY 2010 OPPS/ASC final rule with comment

period (74 FR 60654 through 60655), we continued this process for the CY 2011 payment update. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72106 through 72108), we continued this process for the CY 2012 payment update with some modifications. We eliminated the requirement that the reconsideration request form be signed by the hospital CEO to facilitate electronic submission of the form and reduce hospital burden. We are continuing this process for the CY 2013 and future years' payment determinations. While there is burden associated with filing a reconsideration request, 5 CFR 1320.4 of the Paperwork Reduction Act of 1995 regulations excludes collection activities during the conduct of administrative actions such as redeterminations, reconsiderations, and/or appeals.

We did not receive any comments on these information collection requirements.

5. ASC Quality Reporting Program

In this final rule with comment period, we are adopting five claims-based measures for collection beginning on October 1, 2012; these measures will be used for the CY 2014 payment determination. We will collect quality measure data for the five claims-based measures by using Quality Data Codes (QDCs) placed on submitted claims beginning with services furnished from October 1, 2012 through December 31, 2012. The five measures are:

- Patient Burns (NQF #0263)
- Patient Falls (NQF #0266)
- Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267)
- Hospital Transfer/Admission (NQF #0265)
- Prophylactic Intravenous (IV) Antibiotic Timing (NQF #0264)

Approximately 71 percent of ASCs participate in Medical Event Reporting, which includes reporting on the first four proposed claims-based measures listed above. Between January 1995 and December 2007, ASCs reported 126 events, an average of 8.4 events per year (Florida Medical Quality Assurance, Inc. and Health Services Advisory Group.: Ambulatory Surgery Center Environmental Scan (July 2008) (Contract No. GS–10F–0096T)). Thus, we estimate the burden to report QDCs on this number of claims per year for the first four claims-based measures to be nominal due to the small number of cases (less than 1 case per month per ASC).

The remaining claims-based measure is prophylatic IV antibiotic timing. We estimate the burden associated with submitting QDCs for this measures to be 231,851 hours (2,788,640 claims per year × 50 percent of claims requiring QDC information × 0.167 hours per claim). We refer readers to the HHS Report to Congress: Medicare Ambulatory Surgical Center Value-Based Purchasing Implementation Plan, available at the Web site: *https://www.cms.gov/ASCPayment/downloads/C_ASC_RTC%202011.pdf* as the source for the number of ASCs and number of claims per year to calculate ASC burden estimates.

For CY 2015 payment determination, we are retaining the five measures we are adopting for CY 2014 payment determination and we are adding two structural measures.

For the structural measures, ASCs will enter required information using a Web-based collection tool between July 1, 2013 and August 15, 2013. For the Safe Surgery Checklist Use structural measure, we estimate that each participating ASC will spend 10 minutes per year to collect and submit the required data, making the estimated annual burden associated with this measure 864 hours (5,175 ASCs × 1 measure × 0.167 hours per ASC).

For the ASC Facility Volume Data on Selected ASC Surgical Procedures structural measure, we estimate that each participating ASC will spend 10 minutes per year to collect and submit the required data, making the estimated annual burden associated with this measure, 864 hours (5,175 ASCs × 1 measure 0.167 hours per ASC).

Comments received regarding burden related to the collection of these data are discussed in section XIV.K.3., 4, and 5. of this final rule with comment period.

6. 2012 Electronic Reporting Pilot for Eligible Hospitals and CAHs

Under 42 CFR 495.6(f)(9), we require eligible hospitals and CAHs participating in the Medicare EHR Incentive Program (which would include those participating in the 2012 Electronic Reporting Pilot) to successfully report hospital CQMs to CMS in the manner specified by CMS. Although eligible hospitals and CAHs may continue to attest CQMs in 2012, they may also choose to participate in the 2012 Electronic Reporting Pilot for Hospitals and CAHs which we are finalizing in this final rule with comment period. Eligible hospitals and CAHs participating in the 2012 Electronic Reporting Pilot must submit CQM data on all 15 CQMs (listed in Table 10 of the Medicare and Medicaid EHR Incentive Program final rule (75 FR 44418 through 44420)) to CMS, via a secure portal based on data obtained from the eligible hospital's or CAH's certified EHR technology.

Eligible hospitals and CAHs are required to report on core and menu set criteria for Stage 1 meaningful use. The reporting of clinical quality measures is part of the core set. We estimate that it would take an eligible hospital or CAH 0.5 hour to submit the required CQM information under the 2012 Electronic Reporting Pilot. Therefore, the estimated total burden should all 4,922 Medicare eligible hospitals and CAHs (3,620 acute care hospitals and 1,302 CAHs) participate in the 2012 Electronic Reporting Pilot is 2,461 hours.

We believe that an eligible hospital or CAH might assign a Computer and Information Systems Manager to submit the CQM information on their behalf. We estimate the cost burden for an eligible hospital or CAH to submit the CQMs and hospital quality requirements is $29.64 (0.5 hour × $59.27 (mean hourly rate for computer and information systems managers based on the 2010 Bureau of Labor Statistics) and the total estimated annual cost burden for all eligible hospitals and CAHs to submit the required CQMs is $145,863 ($29.64 × 4,922 hospitals and CAHs).

We solicited public comments on the estimated numbers of eligible hospitals and CAHs that may register for the 2012 Electronic Reporting Pilot and that would submit the CQM information via the 2012 Electronic Reporting Pilot. We also invited public comments on the type of personnel or staff that would mostly likely submit on behalf of eligible hospitals and CAHs.

We did not receive any comments on these information collection requirements.

7. Additional Topics

In addition to soliciting public comments as part of the OMB approval process for the proposed information collection requirements associated with the Hospital OQR Program, in the proposed rule we sought public comment on several issues that may ultimately affect the burden associated with the Hospital OQR Program. Specifically, in the proposed rule, we proposed to retain measures for the CY 2015 payment determinations, to adopt new measures for the CY 2014 and CY 2015 payment determinations, and we sought comments on other possible measures under consideration for adoption into the Hospital OQR Program. We also sought public comments on collecting chart-abstracted data for one measure for the CY 2013 payment determination via a Web-based tool, and on the continued use of an extraordinary circumstance extension or

waiver for reporting quality data, and additional data validation conditions that we are considering adopting beginning with the CY 2014 payment determination.

We also sought public comment on our proposals for an ASC Quality Reporting Program for the ASC payment determinations for CYs 2014, 2015 and 2016.

We invited public comments on these potential information collection requirements.

Comments and responses for the proposed policies and burden associated with these proposed information collection requirements are discussed in section XIV. of this final rule with comment period.

XIX. 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 final rule with comment period, and, when we proceed with a subsequent document(s), we will respond to those comments in the preamble to that document.

XX. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this final rule with comment period 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 (UMRA) (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Contract with America Advancement Act of 1996 (Pub. L. 104–121) (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. This rule has been designated as an ''economically'' significant rule under section 3(f)(1) of Executive Order 12866 and a major rule under the Contract with America Advancement Act of 1996 (Pub. L. 104–121). Accordingly, the rule has been reviewed by the Office of Management and Budget. We have prepared a regulatory impact analysis that, to the best of our ability, presents the costs and benefits of this final rule with comment period. In the proposed rule (76 FR 42371), we solicited public comments on the regulatory impact analysis provided.

2. Statement of Need

This final rule with comment period is necessary to update the Medicare hospital outpatient prospective payment rates and the ambulatory surgical center (ASC) prospective payment rates for CY 2012. The final rule with comment period is necessary to adopt changes to payment policies and payment rates for outpatient services furnished by hospitals and CMHCs for CY 2012. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the OPPS conversion factor used to determine the APC payment rates. We also are required under section 1833(t)(9)(A) of the Act to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act. In addition, we must review the clinical integrity of payment groups and relative weights at least annually.

This final rule with comment period is also necessary to update the ASC payment rates for CY 2012. The final rule with comment period is necessary to enable CMS to adopt changes to payment policies and payment rates for covered surgical procedures and covered ancillary services that are performed in an ASC for CY 2012. Because the ASC payment rates are based on the OPPS relative weights for the majority of the procedures performed in ASCs, the ASC payment rates are updated annually to reflect annual changes to the OPPS relative weights. In addition, because the services provided in ASCs are identified by HCPCS codes which are reviewed and revised either quarterly or annually, depending on the HCPCS codes, it is necessary to update the ASC payment rates annually to reflect these changes to HCPCS codes. In addition, we are required under section 1833(i)(1) of the Act to review and update the list of surgical procedures that can be performed in an ASC not less frequently than every 2 years.

Section 1833(t)(17) of the Act requires that subsection (d) hospitals that fail to meet quality reporting requirements under the Hospital OQR Program to incur a reduction of 2.0 percentage points to their OPD fee schedule increase factor. In section XIV. of this final rule with comment period, we are adopting additional policies affecting the Hospital OQR Program for CY 2013, CY 2014, and CY 2015 that hospitals will have to meet in order to receive the full OPD fee schedule increase factor. In the proposed rule, we solicited public comments on these proposed additional policies. Any public comments that we received are addressed in section XIV. of this final rule with comment period.

This final rule with comment period is necessary to further implement section 6001(a)(3) of the Affordable Care Act. In section XV. of this final rule with comment period, we are adopting a process for a hospital to request an exception to the prohibition on expansion of facility capacity under the whole hospital and rural provider exceptions to the physician self-referral prohibition. We also adopt amendments to the patient safety requirements in the provider agreement regulations. In the proposed rule, we solicited public comments on these proposed changes. Any public comments that we received are addressed in section XV. of this final rule with comment period.

Section 1886(o)(1)(B) of the Act directs the Secretary to begin making value-based incentive payments under the Hospital VBP Program to hospitals for discharges occurring on or after October 1, 2012. In section XVI. of this final rule with comment period, we are adding one chart-abstracted measure for the FY 2014 payment determination under the Hospital VBP Program. In the proposed rule, we solicited public comments on this proposed additional measure. Any public comments that we received are addressed in section XVI. of this final rule with comment period.

Section 109(b) of the MIEA–TRHCA states that the Secretary may implement a quality reporting system for ASCs in a manner so as to provide for a reduction of 2.0 percentage points in any annual update with respect to the year involved, for failure to report on quality measures. In section XIV.K. of this final rule with comment period, we are establishing an ASC Quality Reporting Program with the collection of five quality measures beginning in CY 2012. In the proposed rule, we solicited public comments on this program. Any public comments that we received are addressed in section XIV.K. of this final rule with comment period.

3. Overall Impacts for OPPS and ASC Provisions

We estimate that the effects of the OPPS provisions that will be implemented by this final rule with comment period will result in expenditures exceeding $100 million in any 1 year. We estimate the total increase, from changes in this final rule with comment period, in expenditures under the OPPS for CY 2012 compared to CY 2011 to be approximately $600 million. Because this final rule with comment period for the OPPS is ''economically significant'' as measured by the $100 million threshold, we have prepared a regulatory impact analysis that, to the best of our ability, presents the costs and benefits of this rulemaking. Table 59 of this final rule with comment period displays the redistributional impact of the CY 2012 changes on OPPS payment to various groups of hospitals and for CMHCs.

We estimate that the effects of the ASC provisions that will be implemented by this final rule with comment period for the ASC payment system will result in expenditures exceeding $100 million in any 1 year. We estimate the total increase, from changes in this final rule with comment period, in expenditures under the ASC payment system for CY 2012 compared to CY 2011 to be approximately $45 million. Because this final rule with comment period for the ASC payment system is ''economically significant'' as measured by the $100 million threshold, we have prepared a regulatory impact analysis of changes to the ASC payment system that, to the best of our ability, presents the costs and benefits of this rulemaking. Table 61 and Table 62 of this final rule with comment period display the redistributional impact of the CY 2012 changes on ASC payment, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

4. Detailed Economic Analyses

a. Effects of OPPS Changes in This Final Rule With Comment Period

We are updating the OPPS payment rates and revising several OPPS payment policies for CY 2012. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the conversion factor used to determine the APC payment rates. We also are required under section 1833(t)(9)(A) of the Act to review, not less frequently than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act. In addition, we must review the clinical integrity of payment groups and weights at least annually. Consistent with our historical practice in this final rule with comment period, we are updating the conversion factor and the wage index adjustment for hospital outpatient services furnished beginning January 1, 2012, as we discuss in sections II.B. and II.C., respectively, of this final rule with comment period. We discuss our implementation of section 10324 of the Affordable Care Act, as amended by HCERA, authorizing a wage index of 1.00 for certain frontier States. We also are revising the relative APC payment weights using claims data for services furnished on and after January 1, 2010, through and including December 31, 2010, and updated cost report information. We are continuing the current payment adjustment for rural SCHs, including EACHs. Finally, we list the 19 drugs and biologicals in Table 32 of this final rule with comment period that we are removing from pass-through payment status for CY 2012.

We estimate that the update change to the conversion factor and other adjustments (but not including the effects of outlier payments, the pass-through estimates, and the application of the frontier State wage adjustment for CY 2012) will increase total OPPS payments by 1.9 percent in CY 2012. The changes to the APC weights, the changes to the wage indices, the continuation of a payment adjustment for rural SCHs, including EACHs, and the payment adjustment for cancer hospitals will not increase OPPS payments because these changes to the OPPS are budget neutral. However, these updates will change the distribution of payments within the budget neutral system as shown in Table 59 below and described in more detail in this section. We also estimate that the total change in payments between CY 2011 and CY 2012, considering all payments, including changes in estimated total outlier payments, pass-through payments, and the application of the frontier State wage adjustment outside of budget neutrality, in addition to the application of the OPD fee schedule increase factor after all adjustments required by sections 1833(t)(3)(F) and 1833(t)(3)(G) of the Act, will increase total estimated OPPS payments by 1.9 percent.

(1) Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the CY 2012 policy changes on various hospital groups. We post on the CMS Web site our hospital-specific estimated payments for CY 2012 with the other supporting documentation for this final rule with comment period. To view the hospital-specific estimates, we refer readers to the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS/*. At the Web site, select ''regulations and notices'' from the left side of the page and then select ''CMS–1525–FC'' from the list of regulations and notices. The hospital-specific file layout and the hospital-specific file are listed with the other supporting documentation for this final rule with comment period. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 59 below. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A.2. of this final rule with comment period for a discussion of the hospitals whose claims we do not use for ratesetting and impact purposes.

We estimate the effects of the individual policy changes by estimating payments per service, while holding all other payment policies constant. We use the best data available, but do not attempt to predict behavioral responses to our policy changes. In addition, we do not make adjustments for future changes in variables such as service volume, service-mix, or number of encounters. In the proposed rule, as we have done in previous proposed rules, we solicited public comment and information about the anticipated effects of our proposed changes on providers and our methodology for estimating them. Any public comments that we received are addressed in the applicable sections of this final rule with comment period that discuss the specific policies.

(2) Estimated Effects of This Final Rule With Comment Period on Hospitals

Table 59 below shows the estimated impact of this final rule with comment period on hospitals. Historically, the first line of the impact table, which estimates the proposed change in payments to all facilities, has always included cancer and children's hospitals, which are held harmless to their pre-BBA amount. We also include CMHCs in the first line that includes all providers because we include CMHCs in our weight scalar estimate. As discussed in section II.F. of this final rule with comment period, we are finalizing an adjustment for certain cancer hospitals as required under section 3138 of the Affordable Care Act. Because these hospitals will continue to be eligible to receive hold harmless payments (under current law), we now include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs, and we also include a

column that shows the impact on other hospitals of the budget neutral adjustment accounting for the payment adjustment to cancer hospitals.

We present separate impacts for CMHCs in Table 59 because CMHCs are paid only for partial hospitalization services and CMHCs are a different provider type from hospitals. In CY 2011, we are paying CMHCs under APC 0172 (Level I Partial Hospitalization (3 services) for CMHCs) and APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs), and we are paying hospitals for partial hospitalization services under APC 0175 (Level I Partial Hospitalization (3 services) for hospital-based PHPs) and APC 0176 (Level II Partial Hospitalization (4 or more services) for hospital-based PHPs). For CY 2012, we are continuing this APC payment structure and basing payment fully on the median costs calculated using claims and cost report data for the type of provider for which rates are being set, that is, hospital or CMHC. We display the impact on CMHCs of this policy below, and we discuss the impact on hospitals as part of our discussion of the impact of changes on hospitals for CY 2012.

The estimated increase in the total payments made under the OPPS is determined largely by the increase to the conversion factor set under the methodology in the statute. The distributional impacts presented do not include assumptions about changes in volume and service mix. Section 1833(t)(3)(C)(iv) of the Act provides that, for purposes of this subparagraph subject to paragraph (17) and subparagraph (F) of this paragraph, the OPD fee schedule increase factor is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act. The market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, which we refer to as the IPPS market basket percentage increase in this discussion, is 3.0 percent. However, section 1833(t)(3)(F)(i) of the Act reduces that 3.0 percent by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is 1.0 percentage point (which is also the MFP adjustment for FY 2012 as adopted in the FY 2012 IPPS/LTCH PPS final rule), and sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(ii) of the Act further reduce the market basket percentage increase by 0.1 percentage point, resulting in the OPD fee schedule increase factor of 1.9 percent, which we are using in the calculation of the CY 2012 OPPS conversion factor. We refer readers to section II.B. of this final rule with comment period for a detailed discussion of the calculation of the conversion factor and the source of its components. Section 10324 of the Affordable Care Act, as amended by HCERA, further authorized additional expenditures outside budget neutrality for hospitals in certain frontier States that have a wage index of 1.00. The amounts attributable to this frontier State wage index adjustment are incorporated in the CY 2012 estimates in Table 59. Additionally, in response to public comments on the proposed rule, we are providing the payment impact of the rural floor and the imputed floor with budget neutrality at the State level in Table 60, as discussed in section II.C. of this final rule with comment period.

Table 59 shows the estimated redistribution of hospital and CMHC payments among providers as a result of the following factors: APC reconfiguration and recalibration; wage indices and the rural adjustment; the combined impact of the APC recalibration, wage and rural adjustment effects, and the OPD fee schedule increase factor update to the conversion factor; the effect of the budget neutral adjustment to payments made to the 11 dedicated cancer hospitals that meet the classification criteria in section 1886(d)(1)(B)(v) of the Act; the frontier State wage index adjustment; and estimated redistribution considering all payments for CY 2012 relative to all payments for CY 2011, including the impact of changes in estimated outlier payments, and changes to the pass-through payment estimate. We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we are not making any changes to the policy for CY 2012. Because the updates to the conversion factor (including the update of the OPD fee schedule increase factor, that is, the IPPS market basket percentage increase less the productivity adjustment required by section 1833(t)(3)(F)(i) of the Act and less the adjustment required by sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(ii) of the Act; the subtraction of the estimated cost of the cancer hospital payment adjustment; the subtraction of the estimated cost of the rural adjustment; and the subtraction of the estimated cost of projected pass-through payment for CY 2012) are applied uniformly across services, observed redistributions of payments in the impact table for hospitals largely depend on the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services would change), and the impact of the wage index changes on the hospital. However, total payments made under this system and the extent to which this final rule with comment period will redistribute money during implementation also will depend on changes in volume, practice patterns, and the mix of services billed between CY 2011 and CY 2012 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the OPPS rates for CY 2012 will have a positive effect for providers paid under the OPPS, resulting in a 1.9 percent estimated increase in Medicare payments. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPPS ratio between payment and cost and removing payments to CMHCs suggest that these changes will result in a 1.9 percent estimated increase in Medicare payments to all other hospitals.

To illustrate the impact of the CY 2012 changes, our analysis begins with a baseline simulation model that uses the final CY 2011 relative weights, the FY 2011 final IPPS wage indices that include reclassifications, and the final CY 2011 conversion factor. Column 2 in Table 59 shows the independent effect of the changes resulting from the reclassification of services among APC groups and the recalibration of APC relative weights, based on 12 months of CY 2010 OPPS hospital claims data and the most recent cost report data. We modeled the effect of the APC recalibration changes for CY 2012 by varying only the relative weights (the final CY 2011 relative weights versus the CY 2012 relative weights calculated using the service-mix and volume in the CY 2010 claims used for this final rule with comment period) and calculating the percent difference in the relative weight. Column 2 also reflects the effect of the changes resulting from the APC reclassification and recalibration changes and any changes in multiple procedure discount patterns or conditional packaging that occur as a result of the changes in the relative magnitude of payment weights.

Column 3 reflects the independent effects of the updated wage indices, including the application of budget neutrality for the rural floor policy on a nationwide basis. This column excludes the effects of the frontier State wage index adjustment, which is not budget neutral and is included in Column 6. We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we are not making any changes to the policy for CY 2012. We modeled the independent effect of updating the wage indices by varying

only the wage indices, holding APC relative weights, service-mix, and the rural adjustment constant and using the CY 2012 scaled weights and a CY 2011 conversion factor that included a budget neutrality adjustment for the effect of changing the wage indices between CY 2011 and CY 2012.

Column 4 demonstrates the independent effect of the cancer hospital payment adjustment. The cancer hospital payment adjustment will be provided at cost report settlement rather than through an adjustment to APC payments on a claims basis as we proposed. Under this final rule with comment period, we will examine each cancer hospital's data at cost report settlement, determine the cancer hospital's PCR (before the cancer hospital payment adjustment) and in turn determine the lump sum necessary (if any) to make the cancer hospital's PCR equal to the target PCR. To the extent at cost report settlement a cancer hospital's PCR (before the cancer hospital payment adjustment) is above the target PCR, a cancer hospital will receive an aggregate payment equal to zero. We refer readers to section II.F. of this final rule with public comment for complete discussion of our policy for CY 2012 with regard to the payment adjustment for dedicated cancer hospitals. We refer readers to Table 13 in section II.F. for the estimated CY 2012 percentage payment adjustment that will be provided to each cancer hospital at cost report settlement. The cancer hospital payment adjustment is estimated to result in an aggregate increase in OPPS payments to cancer hospitals of 34.5 percent. After accounting for TOPs, the estimated aggregate increase in OPPS payments for CY 2012 is approximately 11.3 percent, after all CY 2012 payment updates have been included.

Column 5 demonstrates the combined ''budget neutral'' impact of APC recalibration (that is, Column 2), the wage index update (that is, Column 3), as well as the impact of updating the conversion factor with the OPD fee schedule increase factor, the 3.0 percent hospital market basket percentage increase less the productivity adjustment required by section 1833(t)(3)(F)(i) of the Act, which is 1.0 percentage point, and less the 0.1 percentage point reduction required by sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(ii) of the Act, which resulted in an OPD fee schedule increase factor of 1.9 percent. We modeled the independent effect of the budget neutrality adjustments and the OPD fee schedule increase factor by using the relative weights and wage indices for each year, and using a CY 2011 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indices.

Column 6 demonstrates the cumulative impact of the budget neutral adjustments from Columns 2 through 4, and the OPD fee schedule increase factor of 1.9 percent reflected in Column 5, combined with the non-budget neutral frontier State wage index adjustment, discussed in section II.C. of this final rule with comment period. This differs from Column 5 solely based on application of the non-budget neutral frontier State wage index adjustment.

Column 7 depicts the full impact of the CY 2012 policies on each hospital group by including the effect of all the changes for CY 2012 (including the APC reconfiguration and recalibration shown in Column 2) and comparing them to all estimated payments in CY 2011. Column 7 shows the combined budget neutral effects of Columns 2 through 4, plus the impact of the frontier State wage index adjustment; the change to the fixed-dollar outlier threshold from $2,100 to $1,900 as discussed in section II.G. of this final rule with comment period; the change in the Hospital OQR Program payment reduction for the small number of hospitals in our impact model that failed to meet the reporting requirements (discussed in section XIV.E. of this final rule with comment period); and the impact of increasing the estimate of the percentage of total OPPS payments dedicated to transitional pass-through payments. Of the 107 hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2011 update (and assumed, for modeling purposes, to be the same number for CY 2012), we included 34 hospitals in our model because they had both CY 2010 claims data and recent cost report data. We estimate that the cumulative effect of all changes for CY 2012 will increase payments to all providers by 1.9 percent for CY 2012. We modeled the independent effect of all changes in Column 7 using the final relative weights for CY 2011 and the relative weights for CY 2012. We used the final conversion factor for CY 2011 of $68.876 and the CY 2012 conversion factor of $70.016 discussed in section II.B. of this final rule with comment period in this model.

Column 7 also contains simulated outlier payments for each year. We used the one year charge inflation factor used in the FY 2012 IPPS/LTCH PPS final rule of 3.89 percent (1.0389) to increase individual costs on the CY 2010 claims, and we used the most recent overall CCR in the July 2011 Outpatient Provider-Specific File (OPSF) (76 FR 51794) to estimate outlier payments for CY 2011. Using the CY 2010 claims and a 3.89 percent charge inflation factor, we currently estimate that outlier payments for CY 2011, using a multiple threshold of 1.75 and a fixed-dollar threshold of $2,100 should be approximately 0.93 percent of total payments. Outlier payments of 0.93 percent are incorporated in the CY 2012 comparison in Column 7. We used the same set of claims and a charge inflation factor of 7.94 percent (1.0794) and the CCRs in the July 2011 OPSF, with an adjustment of 0.9903, to reflect relative changes in cost and charge inflation between CY 2010 and CY 2012, to model the CY 2012 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a final fixed-dollar threshold of $1,900.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 59 shows the total number of facilities (4,161), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2010 hospital outpatient and CMHC claims data to model CY 2011 and CY 2012 payments, by classes of hospitals, for CMHCs and for dedicated cancer hospitals. We excluded all hospitals and CMHCs for which we could not accurately estimate CY 2011 or CY 2012 payment and entities that are not paid under the OPPS. The latter entities include CAHs, all-inclusive hospitals, and hospitals located in Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and the State of Maryland. This process is discussed in greater detail in section II.A. of this final rule with comment period. At this time, we are unable to calculate a disproportionate share (DSH) variable for hospitals not participating in the IPPS. Hospitals for which we do not have a DSH variable are grouped separately and generally include freestanding psychiatric hospitals, rehabilitation hospitals, and long-term care hospitals. We show the total number (3,895) of OPPS hospitals, excluding the hold-harmless cancer and children's hospitals and CMHCs, on the second line of the table. We excluded cancer and children's hospitals because section 1833(t)(7)(D) of the Act permanently holds harmless cancer hospitals and children's hospitals to their ''pre-BBA amount'' as specified under the terms of the statute, and therefore, we removed them from our impact analyses. We show the isolated impact on 204 CMHCs at the bottom of the impact table and discuss that impact separately below.

Column 2: APC Changes Due to Reassignment and Recalibration

This column shows the combined effects of the reconfiguration, recalibration, and other policies (such as setting payment for separately payable drugs and biologicals at ASP+4 percent with an accompanying reduction in the amount of cost associated with packaged drugs and biologicals and changes in payment for PHP services). Overall, we estimate that changes in APC reassignment and recalibration across all services paid under the OPPS will increase payments to urban hospitals by 0.2 percent. We estimate that both large and other urban hospitals will experience an increase of 0.2 percent, all attributable to recalibration. We estimate that urban hospitals billing fewer than 21,000 lines for OPPS services will experience decreases ranging from 0.6 percent to 5.5 percent. The decrease of 5.5 percent for urban hospitals billing fewer than 5,000 lines per year is attributable to the decline in the payment for APC 0034 (Mental Health Services Composite), for which the payment rate is set at the payment rate for APC 0176 (Level II Partial Hospitalization (4 or more services) for hospital-based PHPs). Urban hospitals billing 21,000 or more lines for OPPS services will experience increases of 0.2 to 0.5 percent.

Overall, we estimate that rural hospitals will experience an increase of 0.1 percent as a result of changes to the APC structure. We estimate that rural hospitals of all bed sizes will experience no change or increases of 0.1 to 0.3 percent as a result of the APC recalibration. We estimate that rural hospitals that report fewer than 5,000 lines for OPPS services will experience a decrease of 0.7 percent, while rural hospitals that report 5,000 or more lines for OPPS services will experience no change or increases of 0.3 to 0.7 percent in payment as a result of the APC recalibration.

Among teaching hospitals, we estimate that the impact resulting from APC recalibration will include a decrease of 0.1 percent for major teaching hospitals and an increase of 0.3 percent for minor teaching hospitals. We estimate that non-teaching hospitals will experience an increase of 0.2 percent.

Classifying hospitals by type of ownership suggests that voluntary, proprietary, and governmental hospitals will experience increases of 0.1 to 0.2 percent as a result of the APC recalibration. Finally, we estimate that hospitals for which DSH payments are not available will experience a decrease of 6.0 percent and that urban hospitals for which DSH is not available will experience a decrease of 6.3 percent. Hospitals for which DSH is not available furnish a large number of psychiatric services and we believe that the decline in payment for APC 0176 is the cause for this estimated decline in payment.

Column 3: New Wage Indices and the Effect of the Rural Adjustment

This column estimates the impact of applying the FY 2012 IPPS wage indices for the CY 2012 OPPS without the influence of the frontier State wage index adjustment, which is not budget neutral. The frontier State wage index adjustment is reflected in the combined impact shown in Columns 6 and 7. We are continuing the rural payment adjustment of 7.1 percent to rural SCHs for CY 2012, as described in section II.E.2. of this final rule with comment period. We estimate that the combination of updated wage data and nationwide application of rural floor budget neutrality will redistribute payment among regions. We also updated the list of counties qualifying for the section 505 out-migration adjustments. Overall, we estimate that urban hospitals will experience no change from CY 2011 to CY 2012, although large urban hospitals will experience an increase of 0.1 percent as a result of the updated wage indices. Rural hospitals will experience decreases of 0.2 to 0.4 percent as a result of the updated wage indices. We estimate that urban hospitals located in the West South Central, Pacific and Puerto Rico regions will experience increases of 0.1 to 0.4 percent. Urban regions other than New England will experience no change or decreases of 0.1 to 0.8 percent. Hospitals in urban New England are expected to see an increase of 4.2 percent as a result of the implementation of the rural floor. We refer readers to section II.C. of this final rule with comment period for more information and Table 60 for estimated impact of the rural floor and the imputed floor with budget neutrality at the State level. Overall, we estimate that rural hospitals will experience a decrease of 0.3 percent as a result of changes to the wage index for CY 2012. We estimate that hospitals in rural Middle Atlantic, West North Central, and Pacific States will experience increases of 0.1 to 1.0 percent, while other rural regions will experience decreases from 0.1 to 0.8 percent.

Column 4: Cancer Hospital Payment Adjustment

This column estimates the budget neutral impact of applying the hospital-specific CY 2012 cancer hospital payment adjustment authorized by section 3138 of the Affordable Care Act, which is estimated to result in an aggregate increase in OPPS payments to dedicated cancer hospitals of 11.3 percent for the CY 2012 OPPS after accounting for TOPs. We estimate that all other hospitals will experience a payment decrease of 0.2 percent in CY 2012 as a result of the budget neutral payment adjustment for the dedicated cancer hospitals.

Column 5: All Budget Neutrality Changes Combined With the OPD Fee Schedule Increase

We estimate that, for most classes of hospitals, the addition of the OPD fee schedule increase factor of 1.9 percent will mitigate the negative impacts created by the budget neutrality adjustments made in Columns 2 and 3.

While most classes of hospitals will receive an increase that is more in line with the 1.9 percent overall increase after the update is applied to the budget neutrality adjustments, urban hospitals that bill fewer than 11,000 lines and hospitals that do not report DSH or for which DSH information is not available will experience decreases. In particular, urban hospitals that report fewer than 5,000 lines will experience a cumulative decrease, after application of the OPD fee schedule increase factor and the budget neutrality adjustments, of 3.4 percent, largely as a result of the decrease in payment for APC 0034 (Mental Health Services Composite). Similarly, urban hospitals for which DSH is not available, and for which DSH is zero will experience decreases of 0.1 to 4.0, also largely as a result of the decrease in payment for APC 0034. OPPS payment for APC 0034 is continuing to be set to the payment rate of APC 0176 (Level II Partial Hospitalization (4 or more services) for hospital-based PHPs), which experienced a decline based on updated cost report and hospital claims data.

Overall, we estimate that these changes will increase payments to urban hospitals by 1.9 percent. We estimate that large urban hospitals and ''other'' urban hospitals will also experience increases of 2.0 and 1.9 percent, respectively. Hospitals in urban New England will experience an increase of 5.7 percent, largely as a result of the change in wage index shown under column 3 and discussed above. We estimate that rural hospitals will experience a 1.5 percent increase as a result of the OPD fee schedule increase factor and other budget neutrality adjustments.

Among teaching hospitals, we estimate that the impacts resulting from the OPD fee schedule increase factor and other budget neutrality adjustments will include an increase of 1.9 percent for major teaching hospitals, minor teaching hospitals and non-teaching hospitals.

Classifying hospitals by type of ownership suggests that proprietary hospitals will experience an estimated increase of 1.7 percent, while voluntary hospitals will experience an estimated increase of 2.0 percent and government hospitals will experience an estimated increase of 1.5 percent.

Column 6: All Adjustments With the Frontier State Wage Index Adjustment

This column shows the impact of all budget neutrality adjustments, application of the 1.9 percent OPD fee schedule increase factor, and the non-budget neutral impact of applying the frontier State wage adjustment (that is, the frontier State wage index change in addition to all changes reflected in Column 4). In general, we estimate that all facilities and all hospitals will experience a combined increase of 2.0. Hospitals in the rural Mountain region will experience an increase of 2.8 percent, most of which is attributable to the frontier State wage adjustment. Similarly, hospitals in the rural West North Central region will experience an increase of 2.7 percent, while hospitals in the urban West North Central will experience an increase of 2.5 percent, most of which also is attributable to the frontier State wage adjustment.

Column 7: All Changes for CY 2012

Column 7 compares all changes for CY 2012 to estimated final payment for CY 2011, including the changes in the outlier threshold, payment reductions for hospitals that failed to meet the Hospital OQR Program reporting requirements, and the difference in pass-through estimates that are not included in the combined percentages shown in Column 5. This column includes estimated payment for a few hospitals receiving reduced payment because they did not meet their Hospital OQR Program reporting requirements; however, we estimate that the anticipated change in payment between CY 2011 and CY 2012 for these hospitals will be negligible. (We further discuss the estimated impacts of hospitals' failure to meet these requirements in section XX.A.4.d. of this final rule with comment period.) Overall, we estimate that facilities will experience an increase of 1.9 percent under this final rule with comment period in CY 2012 relative to total spending in CY 2011. The projected 1.9 percent increase for all facilities in Column 7 of Table 59 reflects the 1.9 percent OPD fee schedule increase factor, less 0.07 percent for the change in the pass-through estimate between CY 2011 and CY 2012, plus 0.07 percent for the difference in estimated outlier payments between CY 2011 (0.93 percent) and CY 2012 (1.0 percent), less 0.09 percent due to the section 508 wage adjustment, plus 0.10 percent due to the frontier State wage index adjustment. When we exclude cancer and children's hospitals (which are held harmless to their pre-BBA amount) and CMHCs, the estimated increase is 1.9 percent after rounding. We estimate that the combined effect of all changes for CY 2012 will increase payments to urban hospitals by 1.9 percent. We estimate that large urban hospitals will experience a 2.0 percent increase, while ''other'' urban hospitals will experience an increase of 1.9 percent. We estimate that urban hospitals that bill less than 5,000 lines of OPPS services will experience a decrease of 2.9 percent, largely attributable to the decline in payment for APC 0034 (Mental Health Services Composite). We estimate that urban hospitals that bill 11,000 or more lines of OPPS services will experience increases between 1.0 percent and 2.3 percent, while urban hospitals that report between 5,000 and 10,999 lines will experience a decrease of 0.3 percent.

Overall, we estimate that rural hospitals will experience a 1.5 percent increase as a result of the combined effects of all changes for CY 2012. We estimate that rural hospitals that bill less than 5,000 lines of OPPS services will experience an increase of 0.6 percent and that rural hospitals that bill 5,000 or more lines of OPPS services will experience increases ranging from 1.5 to 2.7 percent.

Among teaching hospitals, we estimate that the impacts resulting from the combined effects of all changes will include an increase of 1.9 percent for major teaching hospitals and non-teaching hospitals. Minor teaching hospitals will experience an increase of 1.8 percent.

In our analysis, we also have stratified hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals will experience an increase of 2.0 percent, proprietary hospitals will experience an increase of 1.7 percent, and governmental hospitals will experience an increase of 1.6 percent.

(3) Estimated Effects of This Final Rule With Comment Period on CMHCs

The last line of Table 59 demonstrates the isolated impact on CMHCs. In CY 2011, CMHCs are paid under four APCs for services under the OPPS: APC 0172 (Level I Partial Hospitalization (3 services) for CMHCs); APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs); APC 0175 (Level I Partial Hospitalization (3 services) for hospital-based PHPs); and APC 0176 (Level II Partial Hospitalization (4 or more services) for hospital-based PHPs). We implemented these four APCs for CY 2011. We adopted payment rates for each APC based on the cost data derived from claims and cost reports for the provider type to which the APC is specific and provided a transition to CMHC rates based solely on CMHC data for the two CMHC PHP per diem rates. For CY 2012, we are continuing the four APC provider-specific structure we adopted for CY 2011 and are finalizing our proposal to base payment fully on the cost data for the type of provider furnishing the service. We modeled the impact of this APC policy assuming that CMHCs will continue to provide the same number of days of PHP care, with each day having either 3 services or 4 or more services, as seen in the CY 2010 claims data used for this CY 2012 OPPS/ASC final rule with comment period. We excluded days with 1 or 2 services because our policy only pays a per diem rate for partial hospitalization when 3 or more qualifying services are provided to the beneficiary. Because the relative payment weights for APC 0172 and APC 0173 for CMHCs both decline in CY 2012 due to CMHC cost data for partial hospitalization services provided by CMHCs, we estimate that there will be a 32.4 percent decrease in payments to CMHCs due to these APC policy changes (shown in Column 2).

Column 3 shows that the estimated impact of adopting the CY 2012 wage index values will result in a decrease of 0.3 percent to CMHCs. Column 4 shows that CMHCs will experience a 0.2 percent reduction as a result of the cancer hospital payment adjustment. We note that all providers paid under the OPPS, including CMHCs, will receive a 1.9 percent OPD fee schedule increase factor. Column 5 shows that combining this OPD fee schedule increase factor, along with changes in APC policy for CY 2012 and the CY 2012 wage index updates, results in an estimated decrease of 30.8 percent. Column 6 shows that adding the frontier State wage adjustment results in no change to the cumulative 30.8 percent decrease. Column 7 shows that adding

the changes in outlier and pass-though payments will result in no change to the 30.8 percent decrease in payment for CMHCs. This reflects all changes to CMHCs for CY 2012.

The impact of the changes to hospital payment rates for partial hospitalization services is reflected in the impact of all changes on hospitals. The impact of the decline in payment for APC 0034 appears most notably in small urban hospitals that furnish primarily outpatient psychiatric services and hospitals for which DSH is zero or not available.

All providers paid under the OPPS will receive a 1.9 percent OPD fee schedule increase factor under this policy. Combining this OPD fee schedule increase factor with changes in APC policy for CY 2012, the CY 2012 wage index updates, and with changes in outlier and pass-through payments, we estimate that the combined impact on hospitals within the OPPS system will be a 1.9 percent increase in total payment for CY 2012. Table 59 presents the estimated impact of the changes to the OPPS for CY 2012.

BILLING CODE 4120–01–P

TABLE 59.—ESTIMATED IMPACT OF THE FINAL CY 2012 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENTS SYSTEM

	Number of Hospitals (1)	APC Recalibration (2)	New Wage Index and Rural Adjustment (3)	New Cancer Hospital Adjustment (4)	Comb (cols 2, 3, & 4) with Market Basket Update (5)	Column 5 with Frontier Wage Index Adjustment (6)	All Changes (7)
ALL FACILITIES *	4,161	0.0	0.0	0.0	1.9	2.0	1.9
ALL HOSPITALS	3,895	0.2	0.0	-0.2	1.9	2.0	1.9
(excludes hospitals permanently held harmless and CMHCs)							
URBAN HOSPITALS	2,946	0.2	0.0	-0.2	1.9	2.0	1.9
LARGE URBAN	1,607	0.2	0.1	-0.2	2.0	2.0	2.0
(GT 1 MILL.)							
OTHER URBAN	1,339	0.2	0.0	-0.2	1.9	2.1	1.9
(LE 1 MILL.)							
RURAL HOSPITALS	949	0.1	-0.3	-0.2	1.5	1.7	1.5
SOLE COMMUNITY	384	0.0	-0.2	-0.2	1.5	2.0	1.5
OTHER RURAL	565	0.2	-0.4	-0.2	1.5	1.5	1.6
BEDS (URBAN)							
0 - 99 BEDS	1,029	-0.5	0.1	-0.2	1.2	1.4	1.3
100-199 BEDS	841	0.3	0.2	-0.2	2.1	2.2	2.1
200-299 BEDS	454	0.4	0.1	-0.2	2.2	2.4	2.2
300-499 BEDS	419	0.3	-0.2	-0.2	1.8	1.9	1.8
500 + BEDS	203	0.1	0.1	-0.2	1.9	1.9	1.9
BEDS (RURAL)							
0 - 49 BEDS	349	0.0	-0.1	-0.2	1.5	1.8	1.6
50- 100 BEDS	355	0.0	-0.3	-0.2	1.5	1.7	1.5
101- 149 BEDS	140	0.3	-0.2	-0.2	1.7	1.9	1.8
150- 199 BEDS	57	0.1	-0.5	-0.2	1.3	1.8	1.3
200 + BEDS	48	0.1	-0.3	-0.2	1.5	1.5	1.5
VOLUME (URBAN)							
LT 5,000 Lines	594	-5.5	0.4	-0.2	-3.4	-3.3	-2.9
5,000 - 10,999 Lines	148	-2.0	0.1	-0.2	-0.3	0.0	-0.3
11,000 - 20,999 Lines	229	-0.6	0.0	-0.2	1.0	1.0	1.0
21,000 - 42,999 Lines	476	0.3	-0.1	-0.2	1.9	1.9	1.8

	Number of Hospitals (1)	APC Recalibration (2)	New Wage Index and Rural Adjustment (3)	New Cancer Hospital Adjustment (4)	Comb (cols 2, 3, & 4) with Market Basket Update (5)	Column 5 with Frontier Wage Index Adjustment (6)	All Changes (7)
42,999 - 89,999 Lines	713	0.5	0.2	-0.2	2.3	2.4	2.3
GT 89,999 Lines	786	0.2	0.0	-0.2	1.9	2.0	1.9
VOLUME (RURAL)							
LT 5,000 Lines	66	-0.7	-0.7	-0.2	0.3	2.9	0.6
5,000 - 10,999 Lines	70	0.7	0.3	-0.2	2.7	2.8	2.7
11,000 - 20,999 Lines	167	0.3	-0.2	-0.2	1.8	2.0	1.7
21,000 - 42,999 Lines	285	0.3	-0.2	-0.2	1.8	2.0	1.8
GT 42,999 Lines	361	0.0	-0.3	-0.2	1.4	1.6	1.5
REGION (URBAN)							
NEW ENGLAND	150	-0.2	4.2	-0.2	5.7	5.7	5.5
MIDDLE ATLANTIC	355	0.1	0.0	-0.2	1.8	1.8	1.6
SOUTH ATLANTIC	449	0.3	-0.5	-0.2	1.5	1.5	1.6
EAST NORTH CENT.	473	0.3	-0.7	-0.2	1.3	1.3	1.2
EAST SOUTH CENT.	183	0.6	-0.8	-0.2	1.5	1.5	1.6
WEST NORTH CENT.	190	0.1	-0.1	-0.2	1.7	2.5	1.8
WEST SOUTH CENT.	498	0.3	0.1	-0.2	2.1	2.1	2.1
MOUNTAIN	208	0.1	-0.2	-0.2	1.6	2.0	1.7
PACIFIC	394	0.1	0.2	-0.2	2.0	2.0	2.1
PUERTO RICO	46	0.2	0.4	-0.2	2.3	2.3	2.3
REGION (RURAL)							
NEW ENGLAND	25	-0.9	-0.3	-0.2	0.5	0.5	0.7
MIDDLE ATLANTIC	67	-0.2	0.1	-0.2	1.6	1.6	1.7
SOUTH ATLANTIC	162	0.3	-0.2	-0.2	1.7	1.7	1.8
EAST NORTH CENT.	128	0.0	-0.8	-0.2	0.9	0.9	0.7
EAST SOUTH CENT.	170	0.6	-0.6	-0.2	1.7	1.7	1.7
WEST NORTH CENT.	101	-0.3	0.1	-0.2	1.5	2.7	1.7
WEST SOUTH CENT.	200	0.5	-0.1	-0.2	2.1	2.1	2.1
MOUNTAIN	67	0.1	-0.7	-0.2	1.0	2.8	1.1
PACIFIC	29	0.1	1.0	-0.2	2.7	2.7	2.9
TEACHING STATUS							
NON-TEACHING	2,896	0.2	-0.1	-0.2	1.9	2.0	1.9
MINOR	708	0.3	-0.1	-0.2	1.9	2.1	1.8
MAJOR	291	-0.1	0.3	-0.2	1.9	1.9	1.9

	Number of Hospitals (1)	APC Recalibration (2)	New Wage Index and Rural Adjustment (3)	New Cancer Hospital Adjustment (4)	Comb (cols 2, 3, & 4) with Market Basket Update (5)	Column 5 with Frontier Wage Index Adjustment (6)	All Changes (7)
DSH PATIENT PERCENT							
0	11	-1.6	-0.2	-0.2	-0.1	-0.1	0.5
GT 0 - 0.10	353	0.0	0.2	-0.2	1.9	2.0	1.9
0.10 - 0.16	357	0.3	-0.3	-0.2	1.6	1.7	1.6
0.16 - 0.23	734	0.3	-0.1	-0.2	1.9	2.1	1.9
0.23 - 0.35	1,040	0.3	0.0	-0.2	2.0	2.1	2.0
GE 0.35	785	0.1	0.1	-0.2	1.9	1.9	2.0
DSH NOT AVAILABLE **	615	-6.0	0.6	-0.2	-3.8	-3.7	-3.6
URBAN TEACHING/DSH							
TEACHING & DSH	903	0.2	0.1	-0.2	1.9	2.0	1.9
NO TEACHING/DSH	1,456	0.4	0.0	-0.2	2.1	2.1	2.1
NO TEACHING/NO DSH	10	-1.6	-0.2	-0.2	-0.1	-0.1	0.5
DSH NOT AVAILABLE**	577	-6.3	0.7	-0.2	-4.0	-3.9	-3.8
TYPE OF OWNERSHIP							
VOLUNTARY	2,061	0.2	0.1	-0.2	2.0	2.1	2.0
PROPRIETARY	1,273	0.1	-0.1	-0.2	1.7	1.7	1.7
GOVERNMENT	561	0.1	-0.3	-0.2	1.5	1.5	1.6
CMHCs	204	-32.4	-0.3	-0.2	-30.8	-30.8	-30.8
Cancer Hospitals	11	0.6	0.3	11.3	14.1	14.1	13.7

Column (1) shows total hospitals and/or CMHCs.

Column (2) shows the impact of changes resulting from the reclassification of HCPCS codes among APC groups and the final recalibration of APC weights based on CY 2010 hospital claims data.

Column (3) shows the budget neutral impact of updating the wage index by applying the FY 2012 hospital inpatient wage index.

Column (4) shows the budget neutral impact of the cancer hospital payment adjustment which is estimated to result in an aggregate increase in OPPS payments to cancer hospitals of $71 million when TOPs are included..

Column (5) shows the impact of all budget neutrality adjustments and the addition of the 1.9 percent OPD fee schedule increase factor (3.0 percent reduced by 1.0 percentage point for the productivity adjustment and further reduced by 0.1 percentage point in order to satisfy statutory requirements set forth in the Affordable Care Act).

		Number of Hospitals (1)	APC Recalibration (2)	New Wage Index and Rural Adjustment (3)	New Cancer Hospital Adjustment (4)	Comb (cols 2, 3, & 4) with Market Basket Update (5)	Column 5 with Frontier Wage Index Adjustment (6)	All Changes (7)
Column (6) shows the non-budget neutral impact of applying the frontier State wage adjustment, after application of the CY 2012 final OPD fee schedule increase factor.								
Column (7) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate and adds final outlier payments. This column also shows the expiration of section 508 wages on September 30, 2011 and the application of the frontier State wage adjustment for CY 2012.								
*These 4,161 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.								
** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.								

In response to public comments we received on the proposed rule, we are providing the payment impact of the rural floor and imputed floor with budget neutrality at the State level in Table 60. Column 1 of the table displays the number of hospitals located in each State. Column 2 displays the number of hospitals in each State that will be receiving the rural floor or imputed floor wage index for CY 2012. Column 3 displays the percentage of total payments each State receives or contributes to fund the rural floor and the imputed floor with national budget neutrality. This column compares the post-reclassification CY 2012 wage index of providers before the rural floor and the imputed floor adjustment and the post-reclassification CY 2012 wage index of providers with the rural floor and the imputed floor adjustment. Column 4 displays an estimated payment amount that each State will gain or lose due to the application of the rural floor and the imputed floor with national budget neutrality.

TABLE 60.—ESTIMATED PAYMENTS DUE TO RURAL FLOOR AND IMPUTED FLOOR WITH NATIONAL BUDGET NEUTRALITY

State	Number of hospitals	Number of hospitals receiving rural floor or imputed floor	Percentage change in payments due to application of rural floor and imputed floor with budget neutrality	Difference (in millions)
Alabama	104	0	-0.5	-3.0
Alaska	6	4	3.3	1.7
Arizona	71	0	-0.5	-2.6
Arkansas	56	0	-0.5	-2.0
California	316	114	0.2	6.6
Colorado	55	10	0.3	1.5
Connecticut	35	15	1.6	8.3
Delaware	8	1	-0.5	-0.7
Florida	192	6	-0.4	-7.7
Georgia	125	0	-0.5	-4.9
Hawaii	14	0	-0.5	-0.5
Idaho	19	0	-0.4	-0.7
Illinois	139	0	-0.5	-8.4
Indiana	114	2	-0.4	-4.4
Iowa	35	5	-0.3	-1.4
Kansas	58	1	-0.5	-1.8
Kentucky	73	1	-0.4	-3.3
Louisiana	140	0	-0.4	-2.6
Maine	24	0	-0.4	-1.3
Massachusetts	82	83	7.6	92.1
Michigan	119	0	-0.5	-7.8
Minnesota	54	0	-0.5	-3.2
Mississippi	67	0	-0.4	-2.1
Missouri	92	3	-0.4	-4.2
Montana	14	1	-0.4	-0.6
Nebraska	24	0	-0.5	-1.2
Nevada	33	0	-0.5	-0.9
New Hampshire	14	9	1.3	3.7
New Jersey	79	53	1.4	14.0

State	Number of hospitals	Number of hospitals receiving rural floor or imputed floor	Percentage change in payments due to application of rural floor and imputed floor with budget neutrality	Difference (in millions)
New Mexico	34	0	-0.5	-0.9
New York	157	2	-0.5	-8.6
North Carolina	95	6	-0.4	-6.3
North Dakota	9	0	-0.4	-0.6
Ohio	157	13	-0.3	-5.1
Oklahoma	98	2	-0.5	-2.3
Oregon	34	3	-0.4	-1.4
Pennsylvania	186	24	-0.3	-4.5
Puerto Rico	46	12	0.0	0.0
Rhode Island	13	0	-0.5	-0.6
South Carolina	63	0	-0.5	-3.0
South Dakota	19	0	-0.4	-0.6
Tennessee	109	11	-0.3	-2.5
Texas	404	7	-0.5	-11.8
Utah	37	2	-0.4	-1.0
Vermont	7	0	-0.4	-0.5
Virginia	78	2	-0.4	-4.2
Washington	53	3	-0.3	-2.5
Washington, D.C.	11	0	-0.5	-0.7
West Virginia	39	4	-0.3	-0.9
Wisconsin	72	3	-0.4	-3.0
Wyoming	12	0	-0.4	-0.2

BILLING CODE 4120–01–C

(4) Estimated Effect of This Final Rule with Comment Period on Beneficiaries

For services for which the beneficiary pays a copayment of 20 percent of the payment rate, the beneficiary share of payment will increase for services for which the OPPS payments will rise and will decrease for services for which the OPPS payments will fall. For example, for a service assigned to Level IV Needle Biopsy/Aspiration Except Bone Marrow (APC 0037) in the CY 2011 OPPS, the national unadjusted copayment is $228.76, and the minimum unadjusted copayment is $215.24, 20 percent of the national unadjusted payment rate of $1,076.14. For CY 2012, the national unadjusted copayment for APC 0037 is $227.40, a decline from the copayment in effect for CY 2011. The minimum unadjusted copayment for APC 0037 is $215.00 or 20 percent of the CY 2012 national unadjusted payment rate for APC 0037 of $1,074.99. The minimum unadjusted copayment will decline because the CY 2011 payment rate for APC 0037 will decline for CY 2012. For further discussion on the calculation of the national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.I. of this final rule with comment period. In all cases, the statute limits beneficiary liability for copayment for a procedure to the hospital inpatient deductible for the applicable year. The CY 2011 hospital inpatient deductible is $1,132 (75 FR 68799 through 68800). The amount of the CY 2012 hospital inpatient deductible is $1,156.

In order to better understand the impact of changes in copayment on beneficiaries, we modeled the percent change in total copayment liability using CY 2010 claims. We estimate, using the claims of the 4,161 hospitals and CMHCs on which our modeling is based, that total beneficiary liability for copayments will decrease as an overall percentage of total payments, from 22.0 percent in CY 2011 to 21.8 percent in CY 2012 due largely to changes in service-mix.

(5) Effects on Other Providers

The relative weights and payment amounts established under the OPPS affect the payments made to ASCs as discussed in section XIII. of this final

rule with comment period. No types of providers other than hospitals, CMHCs and ASCs are affected by the changes in this final rule with comment period.

(6) Effects on the Medicare and Medicaid Programs

The effect on the Medicare program is expected to be $600 million in additional program payments for OPPS services furnished in CY 2012. The effect on the Medicaid program is expected to be limited to increased copayments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries. We refer readers to our discussion of the impact on beneficiaries under section XX.A.4.a.(4). of this final rule with comment period.

(7) Alternatives Considered

Alternatives to the changes we are making and the reasons for our selected alternatives are discussed throughout this final rule with comment period. Some of the major issues discussed in this final rule with comment period and the alternatives considered are discussed below.

• Alternatives Considered for Payment of the Acquisition and Pharmacy Overhead Costs of Drugs and Biologicals That Do Not Have Pass-Through Status

We are finalizing our proposal, with modification, that, for CY 2012, the OPPS will make payment for separately payable drugs and biologicals at ASP+4 percent, and this payment will continue to represent combined payment for both the acquisition and pharmacy overhead costs of separately payable drugs and biologicals. In addition, because we are continuing to make a pharmacy overhead adjustment for CY 2012, we believe it is appropriate to account for inflation that has occurred since the overhead redistribution amount of $200 million was applied in CY 2011. Further, in order to enhance the intra-rulemaking stability of the ASP+X amount between the proposed rule and this final rule with comment period, we are modifying the proposed redistribution amount of $215 million in order to keep the mathematical relationship between the redistribution amount and amount of total drug costs (instead of the dollar amount, as was our policy in CY 2010 and 2011) the same between the proposed rule and the final rule. This approach, described briefly below and in greater depth in section V.B.3 of this final rule with comment period, results in a total CY 2012 redistribution amount of $240.3 million, or $169 million (or 35 percent) in pharmacy overhead cost currently attributed to coded packaged drugs, and $71.3 million (or 10.7 percent) in pharmacy overhead cost attributed to uncoded packaged drugs.

Therefore, as discussed in further detail in section V.B.3. of this final rule with comment period, we believe that approximately $169 million in pharmacy overhead cost for packaged drugs and biologicals with a separately-reported HCPCS code, and $71.3 million pharmacy overhead cost attributed to packaged uncoded drugs and biologicals should, instead, be attributed to separately payable drugs and biologicals to provide an adjustment for the pharmacy overhead costs of these separately payable products. As a result, we also are finalizing our proposal to reduce the cost of packaged drugs and biologicals that is included in the payment for procedural APCs to offset the $240.3 million adjustment to payment for separately payable drugs and biologicals. We are finalizing our proposal that any redistribution of pharmacy overhead cost that may arise from CY 2012 final rule claims data will occur only from some drugs and biologicals to other drugs and biologicals, thereby maintaining the estimated total cost of drugs and biologicals under the OPPS.

We considered three alternatives for payment of the acquisition and pharmacy overhead costs of drugs and biologicals that do not have pass-through status for CY 2012. The first alternative we considered was to compare the estimated aggregate cost of separately payable drugs and biologicals in our claims data to the estimated aggregate ASP dollars for separately payable drugs and biologicals, using the ASP as a proxy for average acquisition cost, to calculate the estimated percent of ASP that would serve as the best proxy for the combined acquisition and pharmacy overhead costs of separately payable drugs and biologicals (70 FR 68642), but without redistribution of estimated pharmacy overhead costs. Under this methodology without redistribution, using July 2011 ASP information and costs derived from CY 2010 OPPS claims data, we estimated the combined acquisition and overhead costs of separately payable drugs and biologicals to be ASP–2 percent. As discussed in section V.B.3. of this final rule with comment period, we also determined that the combined acquisition and overhead costs of packaged drugs are 192 percent of ASP. We did not choose this alternative because we believe that this analysis indicates that hospital charging practices reflected in our standard drug payment methodology have the potential to ''compress'' the calculated costs of separately payable drugs and biologicals to some degree when there is no redistribution of estimated pharmacy overhead costs. Further, we recognize that the attribution of pharmacy overhead costs to packaged or separately payable drugs and biologicals through our standard drug payment methodology of a combined payment for acquisition and pharmacy overhead costs depends, in part, on the treatment of all drugs and biologicals each year under our annual drug packaging threshold. Changes to the packaging threshold may result in changes to payment for the overhead cost of drugs and biologicals that do not reflect actual changes in hospital pharmacy overhead cost for those products.

The second alternative we considered and the one we proposed for CY 2012 is to continue our pharmacy overhead redistribution methodology and to apply an inflation allowance and redistribute $215 million in overhead costs from packaged coded and uncoded drugs and biologicals to separately payable drugs and biologicals. Using this approach, we proposed to adjust the CY 2010 and 2011 pharmacy overhead and handling redistribution amount of $200 million using the PPI for Pharmaceuticals for Human Use, resulting in a proposed CY 2012 redistribution amount of $215 million and payments of ASP+4 percent. In the final rule, redistributing $215 million in overhead between packaged drugs and biologicals to separately payable drugs and pharmaceuticals would have resulted in a combined payment of ASP+3 percent for the acquisition and pharmacy overhead costs, a 1-percent decrease in the ASP+X amount from the proposed ASP+4 percent. However, as we discuss in section V.B.3.b of this final rule with comment period, we determined that this decline of the methodologically derived ASP+X percent is due to increasing the interim claims data used in the proposed rule calculations to a whole year's data for the final rule while keeping the drug overhead redistribution amount constant. Further, after additional analysis, we believe that this decline in the ASP+X amount for the final rule due to the inclusion of a whole year's data will always occur if we were to continue to use a fixed overhead redistribution amount while updating the amount of total costs included in the analysis for the final rule to include a whole year worth of total cost data. Therefore, because we believe another policy may promote more stability than the ASP+X percent calculation when based on a fixed

redistribution amount, and because we believe that our proposals should always reflect the expected value of the final to the best of our ability, we did not finalize our proposal to redistribute a fixed $215 million pharmacy overhead amount for this final rule with comment period.

The third option that we considered, and the one that we selected for CY 2012, is to continue the overhead redistribution methodology that we finalized in the CY 2010 OPPS/ASC final rule with comment period, employed in CY 2011, and proposed in CY 2012, but with a modification. Specifically, in this CY 2012 OPPS/ASC final rule with comment period, in order to enhance intra-rulemaking stability, we will instead keep the proportions of overhead redistribution to total drug and biological costs constant between the proposed rule and the final rule, but change the dollar amount of the transfer. Consequently, instead of redistributing the proposed $215 million in costs for coded and uncoded packaged drugs and biologicals ($54 million in redistributed costs for uncoded packaged drugs and biologicals, or 10.7 percent of total drug and biological costs; and $161 million for coded packaged drugs and biologicals, or 35 percent of total costs) we will update the redistribution amounts to keep the proportion of redistributed costs constant between the proposed rule and the final rule. Therefore, for CY 2012 we will redistribute $169 million (or 35 percent) of coded packaged drug and biological overhead cost, and $71.3 million (or 10.7 percent) of uncoded packaged drug and biological overhead cost, resulting in a total redistribution amount of $240.3 million. This option keeps the percentage of coded packaged and uncoded packaged overhead cost that is redistributed constant between the proposed rule and the final rule, and results in a final CY 2012 ASP+X percent of ASP+4 percent that is identical to the ASP+X percent in the proposed rule.

We chose this alternative because we believe that it substantially enhances the intra-rulemaking stability for the ASP+X amount between the proposed rule and the final rule. We believe that this redistribution amount provides an appropriate redistribution of pharmacy overhead costs associated with drugs and biologicals, based on the analyses discussed in section V.B.3. of this final rule with comment period.

• OPPS Payment Adjustment for Certain Cancer Hospitals

Section 3138 of the Affordable Care Act instructs the Secretary to conduct a study to determine if outpatient costs, including the cost of drugs and biologicals, incurred by cancer hospitals described in section 1886(d)(1)(B)(v) of the Act with respect to ambulatory classification groups exceed the costs incurred by other hospitals furnishing services under this subsection (section 1833(t) of the Act). Further, section 3138 of the Affordable Care Act provides that if the cancer hospitals' costs with respect to APC groups are determined to be greater than the costs of other hospitals paid under the OPPS, the Secretary shall provide an appropriate budget neutral payment adjustment under section 1833(t)(2)(E) of the Act to reflect these higher costs.

As discussed in detail in section II. F. of this final rule with comment period, using the claims and cost report data that we used under the modeled proposed CY 2011 OPPS, we constructed our traditional provider-level database of costs, modeled payments, units, service mix, wage index and other provider information that we typically use to establish class adjustments under the OPPS. We observed that cancer hospitals were more costly with respect to APC groups than other hospitals paid under the OPPS, having a standardized cost per discounted unit of $150.12 compared to a standardized cost per discounted unit of $94.14 for all other hospitals.

Having reviewed the cost data from the standard analytic database and determined that cancer hospitals are more costly with respect to APC groups than other hospitals within the OPPS system, we are finalizing our proposal, with modification after consideration of the public comments we received, to provide a payment adjustment for cancer hospitals for CY 2012 based on a comparison of costliness relative to payments using cost report data. Specifically, the cancer hospital payment adjustment amounts will be provided on an aggregate basis at cost report settlement and will be equal to the amount of additional payment needed for a resulting PCR that is equal to the weighted average PCR for other hospitals furnishing services under section 1833(t) of the Act, which we refer to as the ''target PCR''. The target PCR for CY 2012, which is calculated using the most recently submitted or settled cost report data that is available at the time of this final rule, is 0.91. Based on this target PCR, OPPS payments to cancer hospitals are estimated to increase by 34.5 percent and total payments to cancer hospitals, including TOPs, are estimated to increase by 11.3 percent in CY 2012.

We considered three alternatives for the proposed OPPS payment adjustment for certain cancer hospitals. The first alternative we considered was to use our standard payment regression model instead of cost report data to identify an appropriate payment adjustment for cancer hospitals. We used this approach in our CY 2006 OPPS final rule with comment period to establish the 7.1 percent payment adjustment for rural SCHs (70 FR 68556 through 68561). However, in constructing our analysis of cancer hospitals' costs relative to other hospitals, we considered whether our standard analytical approach would lead to valid results. The analyses presented in the CY 2006 OPPS proposed and final rules were designed to establish an adjustment for a large class of rural hospitals. In contrast, section 3138 of the Affordable Care Act is specifically limited to identifying an adjustment for 11 cancer hospitals to the extent that their costs with respect to APC groups exceeded the costs incurred by other hospitals furnishing services under section 1833(t) of the Act. With such a small sample size (11 out of approximately 4,000 hospitals paid under the OPPS), we were concerned that the standard explanatory and payment regression models used to establish the rural hospital adjustment would lead to imprecise estimates of payment adjustments for this small group of hospitals. Further, section 3138 of the Affordable Care Act specifies explicitly that cost comparisons between classes of hospitals must include the cost of drugs and biologicals. In our CY 2006 analysis of rural hospitals, we excluded the cost of drugs and biologicals in our model because the extreme units associated with proper billing for some drugs and biologicals can bias the calculation of a service-mix index, or volume weighted average APC relative weight, for each hospital (70 FR 42698). Therefore, we chose not to pursue our standard combination of explanatory and payment regression modeling to determine a cancer hospital adjustment.

The second alternative we considered was to provide the same adjustment to all cancer hospitals based on the difference between the weighted average PCR for all cancer hospitals (0.674) and the weighted average PCR for all other hospitals (0.907). This class adjustment, instead of a hospital-specific adjustment, would provide a 34.6 percent payment increase for each cancer hospital. Because this alternative did not seem equitable to other hospitals furnishing services under OPPS as it would result in a PCR for

most cancer hospitals that is higher than the weighted average PCR of other hospitals furnishing services under OPPS and a much larger budget neutrality adjustment, we did not select this alternative.

The third alternative we considered, and the one we selected for CY 2012, is to provide an aggregate payment amount at cost report settlement that is equal to the amount of additional payment needed for a resulting PCR equal to the target PCR for those cancer hospitals that have a PCR that is less than the target PCR. For a cancer hospital with an individual PCR that is above the target PCR (before the cancer hospital payment adjustment), the aggregate payment amount provided at cost report settlement is equal to zero. For purposes of calculating the aggregate adjustment amounts to be provided in CY 2012, we chose to rely on this straightforward assessment of payments and costs from the cost report data because of the concerns outlined above with respect to the small number of hospitals, and because of the challenges associated with accurately including drug and biological costs in our standard regression models.

• Alternatives Considered for the Supervision of Hospital Outpatient Therapeutic Services

We are finalizing our proposal to establish the APC Panel as the independent advisory body that will recommend to CMS the appropriate supervision level for individual hospital outpatient therapeutic services. We will modify the Panel's scope and composition in order to create a body that is prepared to address supervision standards and reflects the range of parties subject to the standards. We will issue final decisions on the required supervision levels, taking the Panel's recommendations into consideration, through a subregulatory process that will include a period of informal public notice and comment.

We considered several alternatives with respect to the number and nature of the representatives that we are adding to the APC Panel. Stakeholders requested that we add four positions for representatives of CAHs and an additional four seats for small rural hospitals that are paid under the OPPS. We did not choose this alternative because we do not believe that it would maintain balanced membership on the Panel in accordance with the FACA requirements.

The alternative that we considered and chose was to add four positions that will be divided evenly among representatives of CAHs and small rural PPS hospitals. We chose this alternative because we believe that it will lead to balanced Panel membership in accordance with the FACA requirements. Because currently there is little representation of small rural PPS hospitals on the Panel, we believe that additional representation of these providers is appropriate.

We also considered an alternative with respect to how CMS will issue final decisions on required supervision levels. We considered subjecting our decisions to notice and comment rulemaking because most public commenters requested this option. We did not choose this alternative because we believe that a more flexible process that allows more frequent evaluations and reduces administrative burden will best meet the needs of hospitals and beneficiaries. Public commenters who responded to the proposed rule and to the CY 2011 OPPS/ASC final rule with comment period requested that CMS provide such flexibility. In addition, there is precedent for setting outpatient supervision levels using a subregulatory process. Our final policy is similar to the process that the agency uses to set the supervision levels for outpatient diagnostic services under the MPFS, which are then adopted for the OPPS. In contrast to the process for diagnostic services, we are providing a period of public notice and comment to increase transparency and opportunity for public input.

In summary, the APC Panel has an exemplary history of providing valuable advice to CMS with regard to the payment and clinical issues associated with the APC groupings of hospital outpatient therapeutic services under the OPPS. We believe that extension of the function of the Panel to providing advice on supervision of individual hospital outpatient therapeutic services will result in both full consideration of the views of all types of hospitals and the best advice considering the full spectrum of hospital stakeholders.

b. Effects of ASC Payment System Changes in This Final Rule With Comment Period

On August 2, 2007, we published in the **Federal Register** the final rule for the revised ASC payment system, effective January 1, 2008 (72 FR 42470). In that final rule, we adopted the methodologies to set payment rates for covered ASC services to implement the revised payment system so that it would be designed to result in budget neutrality as required by section 626 of Public Law 108–173; established that the OPPS relative payment weights would be the basis for payment and that we would update the system annually as part of the OPPS rulemaking cycle; and provided that the revised ASC payment rates would be phased in over 4 years. During the 4-year transition to full implementation of the ASC payment rates, payments for surgical procedures performed in ASCs that were on the CY 2007 ASC list of covered surgical procedures were made using a blend of the CY 2007 ASC payment rate and the ASC payment rate calculated according to the ASC standard ratesetting methodology for the applicable transitional year. In CY 2008, we paid ASCs using a 25/75 blend, in which payment was calculated by adding 75 percent of the CY 2007 ASC rate for a surgical procedure on the CY 2007 ASC list of covered surgical procedures and 25 percent of the CY 2008 ASC rate calculated according to the ASC standard ratesetting methodology for the same procedure. In CY 2009, we paid ASCs using a 50/50 blend, in which payment was calculated by adding 50 percent of the CY 2007 ASC rate for a surgical procedure on the CY 2007 ASC list of covered surgical procedures and 50 percent of the CY 2009 ASC rate calculated according to the ASC standard ratesetting methodology for the same procedure. For CY 2010, we transitioned the blend to a 25/75 blend of the CY 2007 ASC rate and the CY 2010 ASC payment rate calculated according to the ASC standard ratesetting methodology. In CY 2011, we are paying ASCs for all covered surgical procedures, including those on the CY 2007 ASC list, at the ASC payment rates calculated according to the ASC standard ratesetting methodology.

ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XIII. of this final rule with comment period, we set the CY 2012 ASC relative payment weights by scaling CY 2012 ASC relative payment weights by the ASC scaler of 0.9466. The estimated effects of the updated relative payment weights on payment rates during this second year of full implementation of the ASC payment rates calculated according to the ASC standard ratesetting methodology are varied and are reflected in the estimated payments displayed in Tables 61 and 62 below.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system, which is the consumer price index for all urban consumers (CPI–U), be reduced by the productivity adjustment. The Affordable Care Act 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). We calculated the CY 2012 ASC conversion factor by adjusting the CY 2011 ASC conversion factor by 1.0004 to account for changes in the pre-floor and pre-reclassified hospital wage indices between CY 2011 and CY 2012 and by applying the CY 2012 MFP-adjusted CPI–U update factor of 1.6 percent (2.7 percent CPI–U minus a productivity adjustment of 1.1 percentage points). The CY 2012 ASC conversion factor is $42.627.

(1) Limitations of Our Analysis

Presented here are the projected effects of the changes for CY 2012 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2010 and CY 2012 with precision. We believe that the net effect on Medicare expenditures resulting from the CY 2012 changes will be small in the aggregate for all ASCs. However, such changes may have differential effects across surgical specialty groups as ASCs continue to adjust to the payment rates based on the policies of the revised ASC payment system. We are unable to accurately project such changes at a disaggregated level. Clearly, individual ASCs will experience changes in payment that differ from the aggregated estimated impacts presented below.

(2) Estimated Effects of This Final Rule With Comment Period on Payments to ASCs

Some ASCs are multispecialty facilities that perform the gamut of surgical procedures, from excision of lesions to hernia repair to cataract extraction; others focus on a single specialty and perform only a limited range of surgical procedures, such as eye, digestive system, or orthopedic procedures. The combined effect on an individual ASC of the update to the CY 2012 payments will depend on a number of factors, including, but not limited to, the mix of services the ASC provides, the volume of specific services provided by the ASC, the percentage of its patients who are Medicare beneficiaries, and the extent to which an ASC provides different services in the coming year. The following discussion presents tables that display estimates of the impact of the CY 2012 update to the revised ASC payment system on Medicare payments to ASCs, assuming the same mix of services as reflected in our CY 2010 claims data. Table 61 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2011 payments to estimated CY 2012 payments, and Table 62 shows a comparison of estimated CY 2011 payments to estimated CY 2012 payments for procedures that we estimate will receive the most Medicare payment in CY 2012.

Table 61 shows the estimated effects on aggregate Medicare payments under the revised ASC payment system by surgical specialty or ancillary items and services group. We have aggregated the surgical HCPCS codes by specialty group, grouped all HCPCS codes for covered ancillary items and services into a single group, and then estimated the effect on aggregated payment for surgical specialty and ancillary items and services groups. The groups are sorted for display in descending order by estimated Medicare program payment to ASCs. The following is an explanation of the information presented in Table 61.

- Column 1—*Surgical Specialty or Ancillary Items and Services Group* indicates the surgical specialty into which ASC procedures are grouped or the ancillary items and services group which includes all HCPCS codes for covered ancillary items and services. To group surgical procedures by surgical specialty, we used the CPT code range definitions and Level II HCPCS codes and Category III CPT codes as appropriate, to account for all surgical procedures to which the Medicare program payments are attributed.
- Column 2—*Estimated CY 2011 ASC Payments* were calculated using CY 2010 ASC utilization (the most recent full year of ASC utilization) and CY 2011 ASC payment rates. The surgical specialty and ancillary items and services groups are displayed in descending order based on estimated CY 2011 ASC payments.
- Column 3—*Estimated CY 2012 Percent Change* is the aggregate percentage increase or decrease in Medicare program payment to ASCs for each surgical specialty or ancillary items and services group that will be attributable to updates to ASC payment rates for CY 2012 compared to CY 2011.

As seen in Table 61, we estimate that the update to ASC rates for CY 2012 will result in a 1 percent change in aggregate payment amounts for eye and ocular adnexa procedures, a 4 percent increase in aggregate payment amounts for digestive system procedures, and a 0 percent change in aggregate payment amounts for nervous system procedures.

Generally, for the surgical specialty groups that account for less ASC utilization and spending, we estimate that the payment effects of the CY 2012 update are variable. For instance, we estimate that, in the aggregate, payment for genitourinary system procedures and hematologic and lymphatic systems procedures will increase by 5 percent, whereas auditory system procedures will decrease by 2 percent under the CY 2012 rates.

An estimated increase in aggregate payment for the specialty group does not mean that all procedures in the group will experience increased payment rates. For example, the estimated increase for CY 2012 for genitourinary system procedures is likely due to an increase in the ASC payment weight for some of the high volume procedures, such as CPT code 50590 (Fragmenting of kidney stone) where estimated payment will increase by 29 percent for CY 2012.

Also displayed in Table 61 is a separate estimate of Medicare ASC payments for the group of separately payable covered ancillary items and services. The payment estimates for the covered surgical procedures include the costs of packaged ancillary items and services. Payment for New Technology Intraocular Lenses (NTIOLs) is captured under this category. Because the NTIOL class for reduced spherical aberration expired on February 26, 2011, and a new NTIOL class was not approved during CY 2011 or CY 2012 rulemaking, we redistributed the estimated payment dedicated to separately paid NTIOLs in CY 2011 while the NTIOL class was active to other services for CY 2012. Therefore, we estimate that aggregate payments for these items and services will decrease by 26 percent for CY 2012.

TABLE 61.—ESTIMATED IMPACT OF THE FINAL CY 2012 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2012 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical Specialty Group (1)	Estimated CY 2011 ASC Payments (in Millions) (2)	Estimated CY 2012 Percent Change (3)
Total	$3,369	2%
Eye and ocular adnexa	$1,440	1%
Digestive system	$685	4%
Nervous system	$431	0%
Musculoskeletal system	$415	2%
Genitourinary system	$149	5%
Integumentary system	$130	1%
Respiratory system	$43	2%
Cardiovascular system	$31	-3%
Ancillary items and services	$29	-26%
Auditory system	$10	-2%
Hematologic & lymphatic systems	$4	5%

Table 62 below shows the estimated impact of the updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2012. The table displays 30 of the procedures receiving the greatest estimated CY 2011 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2011 program payment.

- Column 1—*HCPCS code.*
- Column 2—*Short Descriptor of the HCPCS code.*
- Column 3—*Estimated CY 2011 ASC Payments* were calculated using CY 2010 ASC utilization (the most recent full year of ASC utilization) and the CY 2011 ASC payment rates. The estimated CY 2011 payments are expressed in millions of dollars.
- Column 4—*Estimated CY 2012 Percent Change* reflects the percent differences between the estimated ASC payment for CY 2011 and the estimated payment for CY 2012 based on the update.

As displayed in Table 62, 21 of the 30 procedures with the greatest estimated aggregate CY 2011 Medicare payment are included in the 3 surgical specialty groups that are estimated to account for the most Medicare payment to ASCs in CY 2011, specifically eye and ocular adnexa, digestive system, and nervous system surgical groups. Consistent with the estimated payment effects on the surgical specialty groups displayed in Table 61 the estimated effects of the CY 2012 update on ASC payment for individual procedures shown in Table 62 are varied.

The ASC procedure for which the most Medicare payment is estimated to be made in CY 2011 is the cataract removal procedure reported with CPT code 66984 (Cataract surg w/iol 1 stage). We estimate that the update to the ASC rates will result in a 1 percent increase for this procedure in CY 2012. The estimated payment effects on two of the other four eye and ocular adnexa procedures included in Table 62 are slightly more significant. We estimate that the payment rate for CPT code 67904 (Repair eyelid defect) will increase by 3 percent and payment for CPT code 67042 (Vit for macular hole) will increase by 4 percent.

We estimate that the payment rates for all of the digestive system procedures included in Table 62 will change by −1 to +5 percent in CY 2012. During the previous 4-year transition to the revised ASC payment system, payment for most of the high volume digestive system procedures decreased each year because, under the previous ASC payment system, the payment rates for many high volume endoscopy procedures were almost the same as the payments for the procedures under the OPPS.

The estimated effects of the CY 2012 update on the eight nervous system procedures for which the most Medicare ASC payment is estimated to be made in CY 2011 will be variable. Our estimates indicate that the CY 2012 update will result in payment increases of 2 to 3 percent for 7 of the 8 procedures. The nervous system procedure for which we estimate a negative effect on CY 2012 payments is CPT code 63650 (Implant neuroelectrodes) which is expected to have payment decrease of 3 percent.

The estimated payment effects for most of the remaining procedures listed in Table 62 will be neutral or will increase by 2 to 4 percent except CPT code 29826 (Shoulder arthroscopy/surgery), which is estimated to decrease by 37 percent, code 29827 (Arthroscop rotator cuff repr), which is estimated to increase by 23 percent, and CPT code 52000 (Cystoscopy), which is estimated to decrease by 5 percent. Musculoskeletal procedures in general are expected to account for a greater percentage of CY 2012 Medicare ASC spending as we estimate that payment for procedures in that surgical specialty group will increase under the revised payment system in CY 2012.

BILLING CODE 4120–01–P

TABLE 62.--ESTIMATED IMPACT OF THE FINAL CY 2012 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS Code* (1)	Short Descriptor (2)	Estimated CY 2011 ASC Payments (in millions) (3)	Estimated CY 2012 Percent Change (4)
66984	Cataract surg w/iol, 1 stage	$1,080	1%
43239	Upper GI endoscopy, biopsy	$155	-1%
45380	Colonoscopy and biopsy	$133	4%
45378	Diagnostic colonoscopy	$100	4%
45385	Lesion removal colonoscopy	$85	4%
66982	Cataract surgery, complex	$79	1%
62311	Inject spine l/s (cd)	$67	2%
64483	Inj foramen epidural l/s	$66	2%
66821	After cataract laser surgery	$56	0%
29826	Shoulder arthroscopy/surgery	$42	-37%
15823	Revision of upper eyelid	$39	0%
63650	Implant neuroelectrodes	$38	-3%
64493	Inj paravert f jnt l/s 1 lev	$32	2%
G0105	Colorectal scrn; hi risk ind	$32	5%
29881	Knee arthroscopy/surgery	$30	3%
64721	Carpal tunnel surgery	$30	3%
63685	Insrt/redo spine n generator	$26	3%
29880	Knee arthroscopy/surgery	$25	3%
G0121	Colon ca scrn not hi rsk ind	$25	5%
43235	Uppr gi endoscopy, diagnosis	$24	-1%
45384	Lesion remove colonoscopy	$24	4%
52000	Cystoscopy	$20	-5%
28285	Repair of hammertoe	$19	2%
64590	Insrt/redo pn/gastr stimul	$16	3%
62310	Inject spine c/t	$16	2%
67904	Repair eyelid defect	$16	3%
26055	Incise finger tendon sheath	$16	4%
29827	Arthroscop rotator cuf repr	$15	23%
67042	Vit for macular hole	$15	4%
50590	Fragmenting of kidney stone	$15	29%

*Note that HCPCS codes we are deleting for CY 2012 are not displayed in this table.

BILLING CODE 4120–01–C

The previous ASC payment system served as an incentive to ASCs to focus on providing procedures for which they determined Medicare payments would

support their continued operation. We note that, historically, the ASC payment rates for many of the most frequently performed procedures in ASCs were similar to the OPPS payment rates for the same procedures. Conversely, procedures with ASC payment rates that were substantially lower than the OPPS rates were performed least often in ASCs. We believed that the revised ASC payment system would encourage greater efficiency in ASCs and would promote significant increases in the breadth of surgical procedures performed in ASCs because it distributes payments across the entire spectrum of covered surgical procedures based on a coherent system of relative weights that are related to the clinical and facility resource requirements of those procedures.

The CY 2010 claims data that we used to develop the CY 2012 ASC payment system relative payment weights and rates reflect the third year of utilization under the revised payment system. Although the changes in the claims data are not large, the data reflect increased Medicare ASC spending for procedures that were newly added to the ASC list in CY 2008. Our estimates based on CY 2010 data indicate that for CY 2012 there will be especially noticeable increases in spending for the hematologic and lymphatic systems compared to the previous ASC payment system.

(3) Estimated Effects of This Final Rule With Comment Period on Beneficiaries

We estimate that the CY 2012 update to the ASC payment system will be generally positive for beneficiaries with respect to the new procedures that we are adding to the ASC list of covered surgical procedures and for those that we are designating as office-based for CY 2012. First, other than certain preventive services where coinsurance and the Part B deductible is waived to comply with sections 1833(a)(1) and (b) of the Act, the ASC coinsurance rate for all procedures is 20 percent. This contrasts with procedures performed in HOPDs, where the beneficiary is responsible for copayments that range from 20 percent to 40 percent of the procedure payment. Second, in almost all cases, the ASC payment rates under the revised payment system are lower than payment rates for the same procedures under the OPPS. Therefore, the beneficiary coinsurance amount under the ASC payment system almost always will be less than the OPPS copayment amount for the same services. (The only exceptions would be if the ASC coinsurance amount exceeds the inpatient deductible. The statute requires that copayment amounts under the OPPS not exceed the inpatient deductible.) Furthermore, the additions to the ASC list of covered surgical procedures will provide beneficiaries access to more surgical procedures in ASCs. Beneficiary coinsurance for services migrating from physicians' offices to ASCs may decrease or increase under the revised ASC payment system, depending on the particular service and the relative payment amounts for that service in the physician's office compared to the ASC. However, for those additional procedures that we are designating as office-based in CY 2012, the beneficiary coinsurance amount would be no greater than the beneficiary coinsurance in the physician's office because the coinsurance in both settings is 20 percent.

(4) Alternatives Considered

Alternatives to the changes we are making and the reasons that we have chosen specific options are discussed throughout this final rule with comment period. Some of the major ASC issues discussed in this final rule with comment period and the options considered are discussed below.

• Alternatives Considered for Office-Based Procedures

According to our final policy for the revised ASC payment system, we designate as office-based those procedures that are added to the ASC list of covered surgical procedures in CY 2008 or later years and that we determine are predominantly performed in physicians' offices based on consideration of the most recent available volume and utilization data for each individual procedure HCPCS code and, if appropriate, the clinical characteristics, utilization, and volume of related HCPCS codes. We establish payment for procedures designated as office-based at the lesser of the MPFS nonfacility practice expense payment amount or the ASC rate developed according to the standard methodology of the revised ASC payment system.

In developing this final rule with comment period, we reviewed CY 2010 utilization data for all surgical procedures added to the ASC list of covered surgical procedures in CY 2008 or later years and for those procedures for which the office-based designation is temporary in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72036 through 72038). Based on that review and as discussed in section XIII.C.1.b. of this final rule with comment period, we are finalizing our proposal to newly designate 10 surgical procedures as permanently office-based and finalizing our proposal to make temporary office-based designations for 8 procedures in CY 2012 that were designated as temporarily office-based for CY 2011. We considered two alternatives in developing this policy.

The first alternative we considered was to make no change to the procedure payment designations. This would mean that we would pay for the 10 procedures we proposed to designate as permanently office-based and the 8 procedures we proposed to designate as temporarily office-based at an ASC payment rate calculated according to the standard ratesetting methodology of the revised ASC payment system. We did not select this alternative because our analysis of the data and our clinical review indicated that all 10 procedures we proposed to designate as permanently office-based, as well as the 8 procedures that we proposed to designate temporarily as office-based, are considered to be predominantly performed in physicians' offices. Consistent with our final policy adopted in the August 2, 2007 final rule (72 FR 42509 through 42513), we were concerned that making payments at the standard ASC payment rate for the 10 procedures we proposed to designate as permanently office-based and the 8 procedures we proposed to designate as temporarily office-based could create financial incentives for the procedures to shift from physicians' offices to ASCs for reasons unrelated to clinical decisions regarding the most appropriate setting for surgical care. Further, consistent with our policy, we believe that when adequate data become available to make permanent determinations about procedures with temporary office-based designations, maintaining the temporary designation is no longer appropriate.

The second alternative we considered and the one we are selecting for CY 2012 is to designate 10 additional procedures as permanently office-based for CY 2012 and to designate 8 procedures as temporarily office-based in CY 2012 that were designated as temporarily office-based for CY 2011. We chose this alternative because our claims data and clinical review indicate that these procedures could be considered to be predominantly performed in physicians' offices. We believe that designating these procedures as office-based, which results in the CY 2012 ASC payment rate for these procedures potentially being capped at the CY 2012 physicians' office rate (that is, the MPFS nonfacility practice expense payment amount), if applicable, is an appropriate step to ensure that Medicare payment policy

does not create financial incentives for such procedures to shift unnecessarily from physicians' offices to ASCs, consistent with our final policy adopted in the August 2, 2007 final rule.

c. Accounting Statements and Tables

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), we have prepared two accounting statements to illustrate the impacts of this final rule with comment period. The first accounting statement, Table 63 below, illustrates the classification of expenditures for the CY 2012 estimated hospital OPPS incurred benefit impacts associated with the CY 2012 OPD fee schedule increase shown in this final rule with comment period, based on the FY 2012 President's Budget. The second accounting statement, Table 64 below, illustrates the classification of expenditures associated with the 1.6 percent CY 2011 update to the revised ASC payment system, based on the provisions of this final rule with comment period and the baseline spending estimates for ASCs in the FY 2012 President's Budget. Lastly, both tables classify all estimated impacts as transfers.

TABLE 63.--ACCOUNTING STATEMENT: CY 2012 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2011 TO CY 2012 ASSOCIATED WITH THE FINAL CY 2012 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	$600 million
From Whom to Whom	Federal Government to outpatient hospitals and other providers who received payment under the hospital OPPS
Total	$600 million

TABLE 64.--ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2011 TO CY 2012 AS A RESULT OF THE FINAL CY 2012 UPDATE TO THE REVISED ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	$45 million
From Whom to Whom	Federal Government to Medicare Providers and Suppliers
Total	$45 million

d. Effects of Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

In section XVI. of the CY 2009 OPPS/ASC final rule with comment period (73 FR 68758 through 68781), section XVI. of the CY 2010 OPPS/ASC final rule with comment period (74 FR 60629 through 60655), and section XVI. of the CY 2011 OPPS/ASC final rule with comment period (75 FR72064 through 72110), we discussed our requirements for subsection (d) hospitals to report quality data under the Hospital OQR Program in order to receive the full OPD fee schedule increase factor for CY 2010, CY 2011, and CY 2012–2014, respectively. In section XIV. of this final rule with comment period, we are finalizing our proposal to adopt additional policies affecting the Hospital OQR Program for CY 2013, CY 2014, and CY 2015.

We determined that 107 hospitals did not meet the requirements to receive the full OPD fee schedule increase factor for CY 2011. Most of these hospitals (over 90 of the 107) received little or no OPPS payment on an annual basis and did not participate in the Hospital OQR Program. We estimate that 120 hospitals may not receive the full OPD fee schedule increase factor in CY 2012. We are unable at this time to estimate the number of hospitals that may not receive the full OPD fee schedule increase factor in CY 2013, CY 2014 and CY 2015.

In section XVI.E.3.a. of the CY 2010 OPPS/ASC final rule with comment period (74 FR 60647 through 60650), for the CY 2011 payment update, as part of the validation process, we required hospitals to submit paper copies of requested medical records to a designated contractor within the required timeframe. Failure to submit requested documentation could result in a 2.0 percentage point reduction to a hospital's CY 2011 OPD fee schedule increase factor, but the failure to attain a validation score threshold would not.

In section XVI.D.3.b of the CY 2011 OPPS/ASC final rule with comment period, we finalized our proposal to validate data submitted by 800 hospitals of the approximately 3,200 participating hospitals for purposes of the CY 2012 Hospital OQR Program payment determination. We stated our belief that

this approach was suitable for the CY 2012 Hospital OQR Program because it would: Produce a more reliable estimate of whether a hospital's submitted data have been abstracted accurately; provide more statistically reliable estimates of the quality of care delivered in each selected hospital as well as at the national level; and reduce overall hospital burden because most hospitals would not be selected to undergo validation each year. We adopted a threshold of 75 percent as the threshold for the validation score because we believed this level was reasonable for hospitals to achieve while still ensuring accuracy of the data. Additionally, this level is consistent with what we adopted in the Hospital Inpatient Quality Reporting (IQR) Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program)) (75 FR 50225 through 50229). As a result, we believed that the effect of our validation process for CY 2012 would be minimal in terms of the number of hospitals that would not meet all program requirements.

In this final rule with comment period, we are finalizing our proposal to validate data submitted by up to 500 of the approximately 3,200 participating hospitals for purposes of the CY 2013 Hospital OQR Program payment determination. Under our policy for the CY 2011 and CY 2012 payment determinations, and under our proposal for CY 2013, we stated that we would conduct a measure level validation by assessing whether the measure data submitted by the hospital matches the independently reabstracted measure data.

As stated above, we are unable to estimate the number of hospitals that may not receive the full OPD fee schedule increase factor in CY 2013. We also are unable to estimate the number of hospitals that would fail the validation documentation submission requirement for the proposed CY 2013 payment update.

The validation requirements for CY 2011, CY 2012, and the validation requirement proposed for CY 2013 will result in medical record documentation for approximately 7,300 cases for CY 2011, 9,600 cases per quarter for CY 2012, and approximately 6,000 cases per quarter for CY 2013, respectively, being submitted to a designated CMS contractor. We will pay for the cost of sending this medical record documentation to the designated CMS contractor at the rate of 12 cents per page for copying and approximately $1.00 per case for postage. We have found that an outpatient medical chart is generally up to 10 pages. Thus, as a result of validation requirements effective for the CY 2011 and CY 2012 payment determinations, and finalized for the CY 2013 payment determination, respectively, we will have expenditures of approximately $16,060 for CY 2011, $21,120 per quarter for CY 2012, and approximately $13,200 per quarter for CY 2013. Again, because we will pay for the data collection effort, we believe that a requirement for medical record documentation for 7,300 total cases for CY 2011, a maximum of 12 cases per quarter for 800 hospitals for CY 2012, and a maximum of 12 cases per quarter for up to 500 hospitals for CY 2013 represents a minimal burden to Hospital OQR Program participating hospitals.

In previous years, medical record documentation was requested by a CMS contractor and hospitals were given 45 days from the date of the request to submit the requested documentation. In section XIV.G.3.d. of this final rule with comment period, for the CY 2013 payment determination, we are not finalizing our proposal to reduce the time from 45 days to 30 days for hospitals to submit requested medical record documentation to meet our validation requirement. Instead, we are maintaining the 45-day timeframe. The total burden would be a maximum of 12 charts for each of the four quarters that must be copied and mailed within a 45-day period after the end of each quarter.

e. Effects of Changes to Physician Self-Referral Regulations

Section 6001(a) of the Affordable Care Act amended the whole hospital and rural provider exceptions (sections 1877(d)(2) and (d)(3) of the Act, respectively) to impose additional restrictions on physician ownership or investment in hospitals. The amended whole hospital and rural provider exceptions provide that a hospital may not increase the number of operating rooms, procedure rooms, and beds beyond that for which the hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of this date, but did have a provider agreement in effect on December 31, 2010, the date of effect of such agreement). Section 6001(a)(3) of the Affordable Care Act added new section 1877(i)(3)(A)(i) of the Act to set forth that the Secretary shall establish and implement an exception process to the prohibition on expansion of facility capacity.

Most physician-owned hospitals are unable to qualify for the ownership and investment exception at section 1877(d)(1) of the Act. Section 1877(d)(1) of the Act provides an exception for ownership or investment in publicly traded securities in a corporation where there is stockholder equity exceeding $75 million at the end of the corporation's most recent fiscal year or on average during the previous 3 fiscal years; or the ownership involves mutual funds in a company that has assets greater than $75 million. Studies by the OIG and GAO have concluded that physician-owned hospitals tend to be smaller and are unable to meet the $75 million threshold.

The regulations we are finalizing at § 411.362(c) set forth the process for a hospital to request an exception to the prohibition on expansion of facility capacity. New § 411.362(c)(2) outlines the requirements for an applicable hospital request and § 411.362(c)(3) outlines the requirements for a high Medicaid facility request. Our new regulations require each hospital desiring an exception to access certain data and make estimates based on that data to determine if the hospital meets the relevant criteria. For example, a hospital is required to access data furnished by the CMS Healthcare Cost Report Information System (HCRIS) and by the Bureau of the Census, in addition to referencing data from the hospital's individual cost reports and making certain estimates on the basis of its cost report data. We believe the impact of these requirements on affected hospitals will be minimal.

Our new regulations require each hospital requesting an exception to provide documentation supporting its calculations to demonstrate that it satisfies the relevant criteria. Our new regulations further require each hospital to provide documentation to support information related to its number of operating rooms, procedure rooms, and beds. This information includes, for example, the number of operating rooms, procedure rooms, and beds for which the hospital is licensed as of the date that the hospital submits a request for an exception. Each hospital also is required to provide a detailed explanation regarding whether and how it satisfies each of the relevant criteria. We believe physician-owned hospitals will be minimally affected by these requirements.

Our regulations require each hospital requesting an exception to disclose on a public Web site for the hospital that it is requesting an exception. Our new regulations require each hospital to certify that it does not discriminate and does not permit physicians to discriminate against beneficiaries of Federal health care programs. In addition, under our new regulations, if CMS were to receive input from the

community related to a particular hospital's request for an exception, the hospital may submit a rebuttal statement in response to input from the community. We believe the impact of these requirements on physician-owned hospitals is minimal.

We believe the proposals that we are finalizing will affect a relatively small number of physician-owned hospitals. We estimate that 265 physician-owned hospitals are eligible to apply for an exception. We believe accurately estimating the number of hospitals choosing to request an exception would be impracticable. Further, we are not aware of any existing data or projections that may produce an estimate with reasonable certainty. As a result, we are choosing to estimate that each of the 265 eligible hospitals will request an exception in order to avoid underestimating the potential impact. We are not aware of any data that may indicate the potential increase in operation rooms, procedure rooms, or beds pursuant to exceptions potentially approved. We also have no data or projections that may help estimate the number of physicians that would be affected by this final rule with comment period as a result of their ownership interests in hospitals.

The requirements concerning the criteria and process for hospitals seeking an exception to the prohibition on expansion of facility capacity are consistent with the physician self-referral statute and regulations and the current practices of most hospitals. Thus, our requirements will present a negligible impact on physician-owned hospitals. Physician-owned hospitals will bear costs associated with requesting an exception to the prohibition on facility expansion. In part, because hospitals are currently undertaking the costs of producing a cost report, we believe that the cost of referencing the required data and making the required estimates will be negligible. In addition, we believe the costs of providing supporting documentation, certifying nondiscrimination against beneficiaries of Federal health care programs, and submitting other required information necessary to request an exception to CMS will be minimal.

We believe that beneficiaries may be positively impacted by these provisions. Specifically, an increase in operating rooms, procedure rooms, and beds may augment the volume or nature of services offered by physician-owned hospitals. An expansion in the number of hospital beds may also permit additional inpatient admissions and overnight stays. Increased operating rooms, procedure rooms, and beds may result in improved access to health care facilities and services. We believe that our regulatory changes are necessary to conform our regulations to the amendments to section 1877 of the Act. We also believe the new regulations will help minimize anticompetitive behavior that can affect the decision as to where a beneficiary receives health care services and would possibly enhance the services furnished.

In the proposed rule, we solicited public comments on each of the issues outlined above that contain estimates of the costs and benefits of the proposed rule. We did not receive any public comments on our estimates.

f. Effects of Changes to Provider Agreement Regulations on Patient Notification Requirements

In section XV.D. of this final rule with comment period, we discuss our proposal concerning the requirement that all hospitals and critical access hospitals must furnish written notice to their patients at the beginning of their hospital stay or outpatient visit if a doctor of medicine or a doctor of osteopathy is not present in the hospital 24 hours a day, 7 days a week, and that the notice must indicate how the hospital will meet the medical needs of any patient who develops an emergency medical condition at a time when there is no physician present in the hospital. In this final rule with comment period, we are finalizing our proposal to modify the provider agreement regulations to reduce the categories of outpatients who must be notified if hospital does not have a doctor of medicine or doctor of osteopathy on site 24 hours a day/7 days a week. We are finalizing our proposal that only those outpatients who receive observation services, surgery, or services involving anesthesia must receive written notice. We are not making any changes to our patient safety requirements for physician-owned hospitals at § 411.362(b)(5)(i). We continue to believe that patients should be made aware of whether or not a doctor of medicine or a doctor of osteopathy is present in the hospital at all times, and the hospital's plans to address patient's emergency medical conditions when a doctor of medicine or a doctor of osteopathy is not present.

We believe our changes to the provider agreement regulations will result in only a minor change in the number of hospitals that are subject to the disclosure requirements, specifically those multicampus hospitals that currently have 24 hours a day, 7 days a week presence of a doctor of medicine or a doctor of osteopathy on one, but not all, of their campuses with inpatient services. We anticipate that very few multicampus hospitals will fall into this category. Rather, the primary impact of the regulations is a change in the number of annual written disclosures given by hospitals to patients. We believe the cost of implementing these provisions borne by hospitals will be limited to a one-time cost associated with completing minor revisions to portions of the hospitals policies and procedures related to patient admission and registration, as well as providing written notification to patients and affected staff. Therefore, we do not believe that these changes will have any significant economic impact on hospitals.

We do not anticipate that the proposals we are finalizing will have a significant economic impact on a substantial number of physicians, other health care providers and suppliers, or the Medicare or Medicaid programs and their beneficiaries. Specifically, we believe that this final rule with comment period will affect mostly hospitals, physicians, and beneficiaries. The changes we are finalizing concerning the disclosure of the presence of a doctor of medicine or a doctor of osteopathy in hospitals are consistent with the current practices of most hospitals. Thus, our physician presence disclosure proposal will present a negligible economic impact on the hospital.

Overall, we believe that beneficiaries will be positively impacted by these provisions. Specifically, disclosure of physician presence equips patients to make informed decisions about where they elect to receive care. Our new policies make no significant change that has the potential to impede patient access to health care facilities and services. In fact, we believe that our policies will help minimize anti-competitive behavior that can affect the decision as to where a beneficiary receives health care services and possibly the quality of the services furnished.

g. Effects of Additional Hospital VBP Program Requirements

Section 1886(o)(1)(B) of the Act directs the Secretary to begin making value-based incentive payments under the Hospital VBP Program to hospitals for discharges occurring on or after October 1, 2012. These incentive payments will be funded for FY 2013 through a reduction to the FY 2013 base operating MS–DRG payment amount for each discharge of 1 percent, as required by section 1886(o)(7)(B)(i) of the Act. The applicable percentage for FY 2014

is 1.25 percent, for FY 2015 is 1.5 percent, for FY 2016 is 1.75 percent, and for FY 2017 and subsequent years is 2.0 percent.

In section XVI.A.3. of this final rule with comment period, we are finalizing additional requirements for the FY 2014 Hospital VBP Program. Specifically, we are finalizing our proposal to add one chart-abstracted measure to the Hospital VBP measure set for the FY 2014 payment determination. Although this additional measure is chart-abstracted, it is required for the Hospital IQR Program. Therefore, its inclusion in the Hospital VBP Program does not result in any additional burden because the Hospital VBP Program uses data that are required for the Hospital IQR Program.

h. Effects of the 2012 Electronic Reporting Pilot

Under section XIV.J. of this final rule with comment period, we are finalizing our proposal to allow eligible hospitals and CAHs that are participating in the Medicare EHR Incentive Program to meet the CQM reporting requirement of the program for payment year 2012 by participating in the 2012 Electronic Reporting Pilot. This alternative will facilitate the use of an electronic infrastructure that supports the use of EHRs by hospitals and CAHs to meet the requirements in various CMS programs and reduce reporting burden simultaneously. Through this pilot, we are encouraging eligible hospitals and CAHs to take steps toward the adoption of EHRs that will allow for reporting of clinical quality data from EHRs to a CMS data repository. We expect that the submission of quality data through EHRs will provide a foundation for establishing the capacity of hospitals and CAHs to send, and for CMS, in the future, to receive, quality measures via hospital EHRs for the Hospital IQR Program's measures. Eligible hospitals and CAHs that choose to participate in this 2012 Electronic Reporting Pilot for the purpose of meeting the CQM reporting requirement of the Medicare EHR Incentive Program will be taking those first steps toward reporting clinical quality data in such a way.

i. Effect of Requirements for the Ambulatory Surgical Center (ASC) Quality Reporting Program

In section XIV.K. of this final rule with comment period, we are finalizing our proposal to adopt requirements for ASCs to report quality data under the ASC Quality Reporting Program in order to receive the full ASC annual payment update factor for CY 2014–2016.

We are unable at this time to estimate the number of ASCs that may not receive the full ASC annual payment update factor in CY 2014, CY 2015, and CY 2016.

B. Regulatory Flexibility Act (RFA) Analysis

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, we estimate that most hospitals, ASCs and CMHCs are small entities as that term is used in the RFA. For purposes of the RFA, most hospitals are considered small businesses according to the Small Business Administration's size standards with total revenues of $34.5 million or less in any single year. Most ASCs and most CMHCs are considered small businesses with total revenues of $10 million or less in any single year. For details, see the Small Business Administration's ''Table of Small Business Size Standards'' at *http://www.sba.gov/content/table-small-business-size-standards.*

In addition, section 1102(b) of the Social Security 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 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We estimate that this final rule with comment period may have a significant impact on approximately 704 small rural hospitals.

The analysis above, together with the remainder of this preamble, provides a regulatory flexibility analysis and a regulatory impact analysis.

C. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) 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. That threshold level is currently approximately $135 million. This final rule with comment period does not mandate any requirements for State, local, or tribal governments, nor will it affect private sector costs.

D. Conclusion

The changes we are finalizing will affect all classes of hospitals paid under the OPPS and will affect both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPPS will experience a modest increase or a minimal decrease in payment for services furnished under the OPPS in CY 2012. Table 59 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that will result in a 1.9 percent increase in payments for all services paid under the OPPS in CY 2012, after considering all changes to APC reconfiguration and recalibration, as well as the OPD fee schedule increase factor, wage index changes, including the frontier State wage index adjustment, the addition of an adjustment for dedicated cancer hospitals, estimated payment for outliers, and changes to the pass-through payment estimate. However, some classes of providers that are paid under the OPPS will experience significant gains and others will experience modest losses in OPPS payments in CY 2012. Specifically, we estimate that the 11 dedicated cancer hospitals that met the classification criteria in section 1883(d)(1)(B)(v) of the Act, as a class, will receive an increase in payments under the OPPS of 13.7 percent for CY 2012. In contrast, we estimate that CMHCs will see an overall decrease in payment of 30.8 percent as a result of the full transition in CY 2012 to payment rates for partial hospitalization services at CMHCs based on cost report and claims data submitted by CMHCs.

The updates to the ASC payment system for CY 2012 will affect each of the approximately 5,000 ASCs currently approved for participation in the Medicare program. The effect on an individual ASC will depend on its mix of patients, the proportion of the ASC's patients that are Medicare beneficiaries, the degree to which the payments for the procedures offered by the ASC are changed under the revised payment system, and the extent to which the ASC provides a different set of procedures in the coming year. Table 61 demonstrates the estimated distributional impact among ASC surgical specialties of the MFP-adjusted CPI–U update of 1.6 percent for CY 2012.

XXI. Federalism Analysis

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 costs on State and local governments, preempts State law, or otherwise has Federalism implications.

We have examined the OPPS and ASC provisions included in this final rule with comment period in accordance

with Executive Order 13132, Federalism, and have determined that they will not have a substantial direct effect on State, local or tribal governments, preempt State law, or otherwise have a Federalism implication. As reflected in Table 59 of this final rule with comment period, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) will increase by 1.6 percent under this final rule with comment period. While we do not know the number of ASCs or CMHCs with government ownership, we anticipate that it is small. We believe that the provisions related to payments to ASCs or CMHCs in CY 2012 will not affect payments to any ASCs or CMHCs owned by government entities.

The analyses we have provided in section XX.A. of this final rule with comment period, in conjunction with the remainder of this document, demonstrates that this final rule with comment period is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

This final rule with comment period will affect payments to a substantial number of small rural hospitals and a small number of rural ASCs, as well as other classes of hospitals, CMHCs, and ASCs, and some effects may be significant.

List of Subjects

42 CFR Part 410

Health facilities, Health professions, Laboratories, Medicare, Rural areas, X-rays.

42 CFR Part 411

Kidney diseases, Medicare, Physician referral, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 495

Computer technology, Electronic health records, Electronic transactions, Health, Health care. Health information technology, Health insurance, Health records, Hospitals, Laboratories, Medicaid, Medicare, Privacy, Reporting and recordkeeping requirements, Public health, Security.

For reasons stated in the preamble of this document, the Centers for Medicare & Medicaid Services is amending 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 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. Section 410.27 is revised to read as follows:

§ 410.27 Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service: Conditions.

(a) Medicare Part B pays for therapeutic hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service, which are defined as all services and supplies furnished to hospital or CAH outpatients that are not diagnostic services and that aid the physician or nonphysician practitioner in the treatment of the patient, including drugs and biologicals that cannot be self-administered, if—

(1) They are furnished—

(i) By or under arrangements made by the participating hospital or CAH, except in the case of a SNF resident as provided in § 411.15(p) of this subchapter;

(ii) As an integral although incidental part of a physician's or nonphysician practitioner's services;

(iii) In the hospital or CAH or in a department of the hospital or CAH, as defined in § 413.65 of this subchapter; and

(iv) Under the direct supervision (or other level of supervision as specified by CMS for the particular service) of a physician or a nonphysician practitioner as specified in paragraph (g) of this section, subject to the following requirements:

(A) For services furnished in the hospital or CAH, or in an outpatient department of the hospital or CAH, both on and off-campus, as defined in § 413.65 of this subchapter, ''direct supervision'' means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed;

(B) Certain therapeutic services and supplies may be assigned either general supervision or personal supervision. When such assignment is made, *general supervision* means the definition specified at § 410.32(b)(3)(i), and *personal supervision* means the definition specified at § 410.32(b)(3)(iii);

(C) Nonphysician practitioners may provide the required supervision of services that they may personally furnish in accordance with State law and all additional requirements, including those specified in §§ 410.71, 410.73, 410.74, 410.75, 410.76, and 410.77;

(D) For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, direct supervision must be furnished by a doctor of medicine or a doctor of osteopathy, as specified in §§ 410.47 and 410.49, respectively; and

(E) For *nonsurgical extended duration therapeutic services (extended duration services*), which are hospital or CAH outpatient therapeutic services that can last a significant period of time, have a substantial monitoring component that is typically performed by auxiliary personnel, have a low risk of requiring the physician's or appropriate nonphysician practitioner's immediate availability after the initiation of the service, and are not primarily surgical in nature, Medicare requires a minimum of direct supervision during the initiation of the service which may be followed by general supervision at the discretion of the supervising physician or the appropriate nonphysician practitioner. *Initiation* means the beginning portion of the nonsurgical extended duration therapeutic service which ends when the patient is stable and the supervising physician or the appropriate nonphysician practitioner determines that the remainder of the service can be delivered safely under general supervision.

(2) In the case of partial hospitalization services, also meet the conditions of paragraph (e) of this section.

(b) Drugs and biologicals are also subject to the limitations specified in § 410.129.

(c) Rules on emergency services furnished to outpatients by nonparticipating hospitals are specified in subpart G of Part 424 of this chapter.

(d) Rules on emergency services furnished to outpatients in a foreign country are specified in subpart H of Part 424 of this chapter.

(e) Medicare Part B pays for partial hospitalization services if they are—

(1) Prescribed by a physician who certifies and recertifies the need for the

services in accordance with subpart B of part 424 of this chapter; and

(2) Furnished under a plan of treatment as required under subpart B of part 424 of this chapter.

(f) Services furnished by an entity other than the hospital are subject to the limitations specified in § 410.42(a).

(g) For purposes of this section, ''nonphysician practitioner''' means a clinical psychologist, licensed clinical social worker, physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse-midwife.

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 3. The authority citation for Part 411 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, 1871, and 1877 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh and 1395nn).

■ 4. Section 411.362 is amended by—

■ a. Under paragraph (a), adding the definitions of ''Baseline number of operating rooms, procedure rooms, and beds'' and ''main campus of the hospital'' in alphabetical order.

■ b. Revising paragraph (b)(2).

■ c. Adding a new paragraph (c).

The revision and additions read as follows:

§ 411.362 Additional requirements concerning physician ownership and investment in hospitals.

(a) * * *

Baseline number of operating rooms, procedure rooms, and beds means the number of operating rooms, procedure rooms, and beds for which the applicable hospital or high Medicaid facility is licensed as of March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of such date, but does have a provider agreement in effect on December 31, 2010, the date of effect of such agreement).

Main campus of the hospital means ''campus'' as defined at § 413.65(a)(2).

* * * * *

(b) * * *

(2) *Prohibition on facility expansion.* The hospital may not increase the number of operating rooms, procedure rooms, and beds beyond that for which the hospital is licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of this date, but does have a provider agreement in effect on December 31, 2010, the effective date of such agreement), unless an exception is granted pursuant to paragraph (c) of this section.

* * * * *

(c) *Criteria for an individual hospital seeking an exception to the prohibition on facility expansion.*

(1) *General.* An applicable hospital or high Medicaid facility may request an exception from the prohibition on facility expansion up to once every 2 years from the date of a CMS decision on the hospital's most recent request.

(2) *Criteria for applicable hospital.* An applicable hospital is a hospital that satisfies all of the following criteria:

(i) *Population increase.* Is located in a county that has a percentage increase in population that is at least 150 percent of the percentage increase in population of the State in which the hospital is located during the most recent 5-year period for which data are available as of the date that the hospital submits its request. To calculate State and county population growth, a hospital must use Bureau of the Census estimates.

(ii) *Medicaid inpatient admissions.* Has an annual percent of total inpatient admissions under Medicaid that is equal to or greater than the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located during the most recent fiscal year for which data are available as of the date that the hospital submits its request. A hospital must use filed hospital cost report discharge data to estimate its annual percent of total inpatient admissions under Medicaid.

(iii) *Nondiscrimination.* Does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

(iv) *Average bed capacity.* Is located in a State in which the average bed capacity in the State is less than the national average bed capacity during the most recent fiscal year for which data are available as of the date that the hospital submits its request.

(v) *Average bed occupancy.* Has an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located during the most recent fiscal year for which data are available as of the date that the hospital submits its request. A hospital must use filed hospital cost report data to determine its average bed occupancy rate.

(3) *Criteria for high Medicaid facility.* A high Medicaid facility is a hospital that satisfies all of the following criteria:

(i) *Sole hospital.* Is not the sole hospital in the county in which the hospital is located.

(ii) *Medicaid inpatient admissions.* With respect to each of the 3 most recent fiscal years for which data are available as of the date the hospital submits its request, has an annual percent of total inpatient admissions under Medicaid that is estimated to be greater than such percent with respect to such admissions for any other hospital located in the county in which the hospital is located. A hospital must use filed hospital cost report discharge data to estimate its annual percentage of total inpatient admissions under Medicaid and the annual percentages of total inpatient admissions under Medicaid for every other hospital located in the county in which the hospital is located.

(iii) *Nondiscrimination.* Does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

(4) *Procedure for submitting a request.*

(i) A hospital must either mail an original and one copy of the written request to CMS or submit the request electronically to CMS. If a hospital submits the request electronically, the hospital must mail an original hard copy of the signed certification set forth in paragraph (c)(4)(iii) of this section to CMS.

(ii) A request must include the following information:

(A) The name, address, National Provider Identification number(s) (NPI), Tax Identification Number(s) (TIN), and CMS Certification Number(s) (CCN) of the hospital requesting an exception.

(B) The county in which the hospital requesting an exception is located.

(C) The name, title, address, and daytime telephone number of a contact person who will be available to discuss the request with CMS on behalf of the hospital.

(D) A statement identifying the hospital as an applicable hospital or high Medicaid facility and a detailed explanation with supporting documentation regarding whether and how the hospital satisfies each of the criteria for an applicable hospital or high Medicaid facility. The request must state that the hospital does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

(E) Documentation supporting the hospital's calculations of its baseline number of operating rooms, procedure rooms, and beds; the hospital's number of operating rooms, procedure rooms, and beds for which the hospital is

licensed as of the date that the hospital submits a request for an exception; and the additional number of operating rooms, procedure rooms, and beds by which the hospital requests to expand.

(iii) A request must include the following certification signed by an authorized representative of the hospital: ''With knowledge of the penalties for false statements provided by 18 U.S.C. 1001, I certify that all of the information provided in the request and all of the documentation provided with the request is true and correct to the best of my knowledge and belief.'' An authorized representative is the chief executive officer, chief financial officer, or other comparable officer of the hospital.

(5) *Community input and timing of complete request.* Upon submitting a request for an exception and until the hospital receives a CMS decision, the hospital must disclose on any public Web site for the hospital that it is requesting an exception. Individuals and entities in the hospital's community may provide input with respect to the hospital's request no later than 30 days after CMS publishes notice of the hospital's request in the **Federal Register**. Such input must take the form of written comments. The written comments must be either mailed or submitted electronically to CMS.

(i) If CMS does not receive written comments from the community, a request will be deemed complete at the end of the 30-day period.

(ii) If CMS receives written comments from the community, the hospital has 30 days after CMS notifies the hospital of the written comments to submit a rebuttal statement. A request will be deemed complete at the end of this 30-day period regardless of whether the hospital submits a rebuttal statement.

(6) A permitted increase under this section—

(i) May not result in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed exceeding 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds; and

(ii) May occur only in facilities on the hospital's main campus.

(7) *Publication of final decisions.* Not later than 60 days after receiving a complete request, CMS will publish the final decision in the **Federal Register**.

(8) *Limitation on review.* There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the process under this section (including the establishment of such process).

PART 416—AMBULATORY SURGICAL SERVICES

■ 5. The authority citation for Part 416 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and1395hh).

■ 6. Section 416.166 is amended by revising paragraph (b) to read as follows:

§ 416.166 Covered surgical procedures.

* * * * *

(b) *General standards.* Subject to the exclusions in paragraph (c) of this section, covered surgical procedures are surgical procedures specified by the Secretary and published in the **Federal Register** and/or via the Internet on the CMS Web site that are separately paid under the OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure.

* * * * *

■ 7. Section 416.171 is amended by—
■ a. Revising paragraph (b).
■ b. Revising paragraph (d).

The revisions read as follows:

§ 416.171 Determination of payment rates for ASC services.

* * * * *

(b) *Exception.* The national ASC payment rates for the following items and services are not determined in accordance with paragraph (a) of this section but are paid an amount derived from the payment rate for the equivalent item or service set under the payment system established in part 419 of this subchapter as updated annually in the **Federal Register** and/or via the Internet on the CMS Web site. If a payment rate is not available, the following items and services are designated as contractor-priced:

* * * * *

(d) *Limitation on payment rates for office-based surgical procedures and covered ancillary radiology services.* Notwithstanding the provisions of paragraph (a) of this section, for any covered surgical procedure under § 416.166 that CMS determines is commonly performed in physicians' offices or for any covered ancillary radiology service, excluding those listed in paragraphs (d)(1) and (d)(2) of this section, the national unadjusted ASC payment rates for these procedures and services will be the lesser of the amount determined under paragraph (a) of this section or the amount calculated at the nonfacility practice expense relative value units under § 414.22(b)(5)(i)(B) of this subchapter multiplied by the conversion factor described in § 414.20(a)(3) of this subchapter.

(1) The national unadjusted ASC payment rate for covered ancillary radiology services that involve certain nuclear medicine procedures will be the amount determined under paragraph (a) of this section.

(2) The national unadjusted ASC payment rate for covered ancillary radiology services that use contrast agents will be the amount determined under paragraph (a) of this section.

* * * * *

■ 8. Section 416.173 is revised to read as follows:

§ 416.173 Publication of revised payment methodologies and payment rates.

CMS publishes annually, through notice and comment rulemaking in the **Federal Register** and/or via the Internet on the CMS Web site, the payment methodologies and payment rates for ASC services and designates the covered surgical procedures and covered ancillary services for which CMS will make an ASC payment and other revisions as appropriate.

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 9. The authority citation for Part 419 continues to read as follows:

Authority: Secs. 1102, 1833(t), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395(t), and 1395hh).

■ 10. Section 419.32 is amended by:
■ a. Revising paragraph (b)(1)(iv)(A).
■ b. Removing the word ''and'' that appears at the end of paragraph (b)(1)(iv)(B)(1).
■ c. Removing the period and adding ''; and'' in its place at the end of paragraph (b)(1)(iv)(B)(2).
■ d. Adding a new paragraph (b)(1)(iv)(B)(3).

The revision and addition read as follows:

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

* * * * *

(b) * * *

(1) * * *

(iv)(A) For calendar year 2003 and subsequent years, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, reduced by the factor(s) specified in paragraph (b)(1)(iv)(B) of this section.

(B) * * *

(*3*) For calendar year 2012, a multifactor productivity adjustment (as determined by CMS) and 0.1 percentage point.

* * * * *

■ 11. Section 419.43 is amended by adding a new paragraph (i) to read as follows:

§ 419.43 Adjustments to national program payment and beneficiary copayment amounts.

* * * * *

(i) Payment adjustment for certain cancer hospitals.—(1) General rule. CMS provides for a payment adjustment for covered hospital outpatient department services furnished on or after January 1, 2012, by a hospital described in section 1886(d)(1)(B)(v) of the Act.

(2) Amount of payment adjustment. The amount of the payment adjustment under paragraph (i)(1) of this section is determined by the Secretary as follows:

(i) If a hospital described in section 1886(d)(1)(B)(v) of the Act has a payment-to-cost ratio (PCR) before the cancer hospital payment adjustment (as determined by the Secretary at cost report settlement) that is less than the weighted average PCR of other hospitals furnishing services under section 1833(t) of the Act (as determined by the Secretary at the time of the applicable CY Hospital Outpatient Prospective Payment System/Ambulatory Surgical Center final rule with comment period) (referred to as the Target PCR), for covered hospital outpatient department services, the aggregate payment amount provided at cost report settlement to such hospital is equal to the amount needed to make the hospital's PCR at cost report settlement (as determined by the Secretary) equal to the target PCR (as determined by the Secretary).

(ii) If a hospital described in section 1886(d)(1)(B)(v) of the Act has a payment-to-cost ratio (PCR) before the cancer hospital payment adjustment (as determined by the Secretary at cost report settlement) that is greater than the weighted average PCR of other hospitals furnishing services under section 1833(t) of the Act (as determined by the Secretary at the time of the applicable CY Hospital Outpatient Prospective Payment System/Ambulatory Surgical Center final rule with comment period) (referred to as the Target PCR), for covered hospital outpatient department services, the aggregate payment amount provided at cost report settlement to such hospital is equal to zero.

(3) Budget neutrality. CMS establishes the payment adjustment under paragraph (i)(1) of this section in a budget neutral manner.

■ 12. Section 419.70 is amended by—

■ a. Revising the introductory text of paragraph (d)(2).

■ b. Revising paragraph (d)(6).

The revisions read as follows:

§ 419.70 Transitional adjustments to limit decline in payments.

* * * * *

(d) * * *

(2) Temporary treatment for small rural hospitals on or after January 1, 2006. For covered hospital outpatient services furnished in a calendar year from January 1, 2006, through December 31, 2011, for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by 95 percent of that difference for services furnished during CY 2006, 90 percent of that difference for services furnished during CY 2007, and 85 percent of that difference for services furnished during CYs 2008, 2009, 2010, and 2011 if the hospital—

* * * * *

(6) Temporary treatment for sole community hospitals on or after January 1, 2010, and through December 31, 2011. For covered hospital outpatient services furnished on or after January 1, 2010, through December 31, 2011, for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by 85 percent of that difference if the hospital is a sole community hospital as defined in § 412.92 of this chapter or is an essential access community hospital as described under § 412.109 of this chapter.

* * * * *

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 13. The authority citation for Part 489 continues to read as follows:

Authority: Secs. 1102, 1819, 1820(e), 1861, 1864(m), 1866, 1869, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395i–3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395hh).

■ 14. Section 489.20 is amended by revising paragraph (w) to read as follows:

§ 489.20 Basic commitments.

* * * * *

(w)(1) In the case of a hospital as defined in § 489.24(b), to furnish written notice to all patients at the beginning of their planned or unplanned inpatient hospital stay or at the beginning of any planned or unplanned outpatient visit for observation, surgery or any other procedure requiring anesthesia, if a doctor of medicine or a doctor of osteopathy is not present in the hospital 24 hours per day, 7 days per week, in order to assist the patients in making informed decisions regarding their care, in accordance with § 482.13(b)(2) of this subchapter. For purposes of this paragraph, a planned hospital stay or outpatient visit begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned hospital admission for inpatient care or outpatient service. An unplanned hospital stay or outpatient visit begins at the earliest point at which the patient presents to the hospital.

(2) In the case of a hospital that is a main provider and has one or more remote locations of a hospital or one or more satellites, as these terms are defined in § 413.65(a)(2), § 412.22(h), or § 412.25(e) of this chapter, as applicable, the determination is made separately for the main provider and each remote location or satellite whether notice to patients is required. Notice is required at each location at which inpatient services are furnished at which a doctor of medicine or doctor of osteopathy is not present 24 hours per day, 7 days per week.

(3) The written notice must state that the hospital does not have a doctor of medicine or a doctor of osteopathy present in the hospital 24 hours per day, 7 days per week, and must indicate how the hospital will meet the medical needs of any patient who develops an emergency medical condition, as defined in § 489.24(b), at a time when there is no doctor of medicine or doctor of osteopathy present in the hospital.

(4) Before admitting a patient or providing an outpatient service to outpatients for whom a notice is required, the hospital must receive a signed acknowledgment from the patient stating that the patient understands that a doctor of medicine or doctor of osteopathy may not be present during all hours services are furnished to the patient.

(5) Each dedicated emergency department, as that term is defined in § 489.24(b), in a hospital in which a doctor of medicine or doctor of osteopathy is not present 24 hours per day, 7 days per week must post a notice conspicuously in a place or places likely to be noticed by all individuals entering the dedicated emergency department. The posted notice must state that the hospital does not have a doctor of medicine or a doctor of osteopathy present in the hospital 24 hours per day, 7 days per week, and must indicate how the hospital will meet the medical needs

of any patient with an emergency medical condition, as defined in § 489.24(b), at a time when there is no doctor of medicine or doctor of osteopathy present in the hospital.

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 15. 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).

■ 16. Section 495.8 is amended by—

■ a. Revising paragraph (b)(2)(ii).

■ b. Adding a new paragraph (b)(2)(vi).

The revision and addition read as follows:

§ 495.8 Demonstration of meaningful use criteria.

* * * * *

(b) * * *

(2) * * *

(ii) Reporting clinical quality information. For § 495.6(f)(9) ''Reporting hospital clinical quality measures to CMS or, in the case of Medicaid eligible hospitals, the States,'' report the hospital quality measures selected by CMS to CMS (or in the case of Medicaid eligible hospitals, the States) in the form and manner specified by CMS (or in the case of Medicaid eligible hospitals, the States).

* * * * *

(vi) Exception for Medicare eligible hospitals and CAHs for FY 2012—Participation in the Medicare EHR Incentive Program Electronic Reporting Pilot. In order to satisfy the clinical quality measure reporting objective in § 495.6(f)(9), aside from attestation, a Medicare eligible hospital or CAH may participate in the Medicare EHR Incentive Program Electronic Reporting Pilot.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; Program No. 93.774, Medicare—Supplementary Medical Insurance Program; and Program No. 93.778 (Medical Assistance)

Dated: October 26, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & MedicaidServices.

Dated: October 28, 2011

Kathleen Sebelius,

Secretary.

[FR Doc. 2011–28612 Filed 11–1–11; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 76 Wednesday,
No. 230 November 30, 2011

Part III

Department of Transportation

Federal Railroad Administration

49 CFR Part 214
Railroad Workplace Safety; Adjacent-Track On-Track Safety for Roadway Workers; Final Rule

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Part 214

[Docket No. FRA–2008–0059, Notice No. 4]

RIN 2130–AB96

Railroad Workplace Safety; Adjacent-Track On-Track Safety for Roadway Workers

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

ACTION: Final rule.

SUMMARY: FRA is amending its regulations on railroad workplace safety to further reduce the risk of serious injury or death to roadway workers performing work with potentially distracting equipment near certain adjacent tracks. In particular, this final rule requires that roadway workers comply with specified on-track safety procedures that railroads must adopt to protect those workers from the movement of trains or other on-track equipment on ''adjacent controlled track.'' FRA defines ''adjacent controlled track'' to mean ''a controlled track whose track center is spaced 19 feet or less from the track center of the occupied track.'' These on-track safety procedures are required for each adjacent controlled track when a roadway work group with at least one of the roadway workers on the ground is engaged in a common task with on-track, self-propelled equipment or coupled equipment on an occupied track. In addition, FRA is removing the provision on preemptive effect.

DATES: This final rule is effective May 1, 2012.

FOR FURTHER INFORMATION CONTACT: Kenneth Rusk, Staff Director, Track Division, Office of Safety Assurance and Compliance, FRA, 1200 New Jersey Avenue SE., RRS–15, Mail Stop 25, Washington, DC 20590 (telephone (202) 493–6236); or Anna Winkle, Trial Attorney, Office of Chief Counsel, FRA, 1200 New Jersey Avenue SE., RCC–12, Mail Stop 10, Washington, DC 20590 (telephone (202) 493–6166 or (202) 493–6052).

SUPPLEMENTARY INFORMATION: The NPRM issued as Notice No. 1 under this same docket number and published July 17, 2008, was withdrawn by Notice No. 2 published August 13, 2008. A second NPRM issued as Notice No. 3 under this same docket number was published November 25, 2009. All references to ''the NPRM'' in this final rule are to this second NPRM unless otherwise specified.

Table of Contents

I. Executive Summary
II. Overview of the Existing Roadway Worker Protection (RWP) Rule
  A. Applicability and Basic Definitions
  B. Authorized Methods of Establishing On-Track Safety
  C. Existing On-Track Safety Requirements for Roadway Work Groups With Respect to Adjacent Tracks
III. Notice of Safety Advisory 2004–01
IV. Recent Roadway Worker Accidents (1997–2010)
V. Joint Petition to FRA for an Emergency Order
VI. Current Rulemaking To Revise the RWP Rule
  A. Overview of the RSAC [Railroad Safety Advisory Committee]
  B. Proceedings in This Rulemaking to Date Generally
  C. Proceedings Concerning On-Track Safety Procedures for Adjacent Tracks
  D. Response to Comments on the November 25, 2009 NPRM
  1. On-Ground Work Performed to the Clear Side
  2. Hi-Rail Vehicles and Clarification of ''Common Task''
  3. Rail-Bound Geometry or Detector Cars
  4. Continuous Barrier
  5. Requests for Additional Exceptions to, or Relief From, the Requirements of Proposed § 214.336 or for a Narrowing of Its Scope
  a. Requested Exception Where There Is Only One Worker on the Ground
  b. Requested Revision of Proposed § 214.336(c) To Permit Work by the Machine Operator Within the Areas 25 Feet in Front of and 25 Feet Behind Equipment During Low-Speed Movements on an Adjacent-Controlled-Track
  c. Requested Revision of Proposed § 214.336(b)(2) to Permit a Roadway Work Group Component To Resume Work After the Head-End Has Passed the Component's Location
  d. Request To Raise the Threshold Speed in § 214.336(b) and § 214.336(c) From 25 MPH to 40 MPH for Passenger Trains
  6. Predetermined Place of Safety
  7. The Effect of the Proposed Rule on Dispatchers
VII. Section-by-Section Analysis
VIII. Regulatory Impact and Notices
  A. Executive Order 12866 and 13563 and DOT Regulatory Policies and Procedures
  B. Regulatory Flexibility Act and Executive Order 13272
  C. Paperwork Reduction Act
  D. Federalism Implications
  E. Environmental Impact
  F. Unfunded Mandates Reform Act of 1995
  G. Energy Impact
  H. Trade Impact
  I. Privacy Act

I. Executive Summary

As will be detailed in this final rule, the recent increase in roadway worker fatalities that have occurred on an adjacent track (*i.e.,* under the existing rule, any track within 25 feet of the centerline of the track to which the roadway work group was assigned to perform one or more roadway worker duties) has caused considerable concern at FRA and throughout the industry, even prompting the filing of a joint petition for emergency order under 49 U.S.C. 20104 on April 11, 2008. *See* 49 CFR part 214, subpart C (''Roadway Worker Protection Rule'' or ''RWP Rule'').[1] FRA had issued a notice of safety advisory to address this same issue in May of 2004; however, it appears that the salutary effects of the safety advisory, which produced a period of 16 months with no fatalities on an adjacent track, were not long-lasting, as four fatalities have since occurred on an adjacent track where a roadway work group, with at least one of the roadway workers on the ground, was engaged in a common task with on-track, self-propelled equipment on an occupied track. These amendments to the Roadway Worker Protection Rule are based on the consensus language developed through the Roadway Worker Protection Working Group of FRA's Railroad Safety Advisory Committee (RSAC), which is comprised of various representatives of the groups that are affected by this rule (including railroad management, railroad labor organizations, and contractors). Because incidents involving adjacent controlled tracks appear to present clear evidence of significant risk that is not effectively addressed by the existing regulation, FRA has concluded that moving forward with this final rule in advance of the other proposals contained in the RSAC consensus [2] is necessary and appropriate.

As will be discussed in more detail in Section II.C, below, until this final rule's amendments to § 214.335(c) become effective, the RWP Rule requires that roadway work groups engaged in ''large-scale maintenance or construction'' be provided with on-track safety in the form of ''train approach warning'' for

[1] The RWP rule was published on December 16, 1996, and became effective on January 15, 1997. *See* 61 FR 65959.

[2] While the consensus language relating to adjacent track issues that was developed through the RSAC was originally intended to be published as part of a larger NPRM, FRA decided to propose the adjacent-track-related provisions in a separate NPRM (which led to the issuance of this final rule) so that an appropriate provision would be in effect in a more timely fashion than if the provision were one of many in the larger rulemaking that would need to undergo internal review and approval and public notice and comment. The remaining provisions not related to adjacent track will be proposed in a separate NPRM at a later date, as part of the larger RWP rulemaking.

train or equipment movements on adjacent tracks if the adjacent tracks are not already included within the working limits. Applying the definition of ''adjacent tracks'' to the criteria discussed above, on-track safety is required for any tracks with track centers spaced less than 25 feet apart from the center of the track to which a roadway work group is assigned to perform ''large-scale maintenance or construction.'' The track to which the roadway work group is assigned to perform the large-scale maintenance or construction is commonly referred to as the ''occupied track.''

Although FRA did provide some guidance on the term ''large-scale maintenance or construction'' in the preamble of the 1996 final rule, many railroads were not providing on-track safety on adjacent tracks for surfacing operations, small tie renewal operations, or similar maintenance operations that, while smaller in scale, still included one or more pieces of on-track, self-propelled equipment. Fatalities occurred on the adjacent track during such operations when on-track safety was not established on the adjacent track or had been temporarily or permanently nullified or suspended to permit the passage of a train or other on-track equipment. This final rule makes the conditions that trigger the requirement for adjacent-track on-track safety more objective.

New § 214.236 requires that railroads adopt specified on-track safety procedures to protect certain roadway work groups from the movement of trains or other on-track equipment on ''adjacent controlled track.'' An ''adjacent controlled track'' is ''a controlled track whose track center is spaced 19 feet or less from the track center of the occupied track.'' The ''occupied track'' is ''the track on which on-track, self-propelled equipment or coupled equipment is authorized or permitted to be located while engaged in a common task with a roadway work group with at least one of the roadway workers on the ground.'' These on-track safety procedures are required for each adjacent controlled track when a roadway work group with at least one of the roadway workers on the ground is engaged in a common task with on-track, self-propelled equipment or coupled equipment on an occupied track.

As a general rule, the procedures in paragraph (b) of new § 214.336 require all on-ground work and equipment movement on the occupied track to stop and each roadway worker to occupy a predetermined place of safety upon receiving a notification or warning that there is an authorized train or other on-track equipment movement on an adjacent controlled track. A roadway worker affected by such movement is permitted to resume work only after the trailing-end of the movement has passed such worker. As further described, below, the final rule provides a limited exception to the general rule in paragraph (c) of this section (*i.e.,* by establishing different procedures to be used during low-speed movements on an adjacent controlled track than during higher-speed movements), and also establishes three categories of exceptions to the requirement to cease work in paragraphs (e)(1) through (e)(3) of this section. *See* §§ 214.336(c) and 214.336(e)(1) through (3).

Due to the lower risk associated with adjacent-controlled-track movements at low speeds (25 mph or less), certain work is permitted to continue after receiving a notification or warning of such a movement on an adjacent controlled track. The work permitted to continue is (1) equipment movement on the rails of the occupied track, and (2) on-ground work performed exclusively between the rails of the occupied track, provided that no on-ground work is performed within the areas 25 feet in front of and 25 feet behind any on-track, self-propelled equipment or coupled equipment permitted to move on the occupied track. *See* § 214.336(c).

There are three categories of exceptions to the requirement to cease work. *See* § 214.336(e)(1) through (3). The first two (''On-ground work performed on a side of the occupied track meeting specified condition(s)'' and ''Maintenance or repairs performed alongside machines or equipment on the occupied track'') permit work to continue if performed on a side of the occupied track where there should essentially be no danger posed by equipment movement on an adjacent track. *See* § 214.336(e)(1)(i) through (iii), regarding the side with no adjacent track, the side with working limits and no movements permitted within such working limits, and the side with an inter-track barrier. The third type of exception permits work to continue if it involves certain types of equipment (*i.e.,* hi-rail vehicles, automated inspection cars, and catenary maintenance tower cars) used for certain purposes (*e.g.,* inspection or minor correction purposes) that, as indicated by the fatality data, do not present a significant level of distraction. *See* § 214.336(e)(3)(i) through (iii). To help roadway workers and the regulated community at large better understand the exceptions and the interrelation of the various requirements of the sections, Table 1 in the rule text summarizes how the procedures apply to different factual scenarios. The diagrams (Figure 1) that follow Table 1 correspond to the same examples in the table, and help the reader to visualize the factual scenarios.

Given the importance of an on-track safety job briefing in roadway workers' understanding of the nature of the work that they will be conducting and the conditions under which they will conduct it, FRA has expanded the on-track safety job briefing requirements to cover the new procedures for adjacent-track on-track safety in § 214.336 (if applicable) and a discussion of adjacent tracks (if any), generally.

In addition, FRA is removing the provision on preemptive effect. This section was prescribed in 1996 and has become outdated and, therefore, misleading because it does not reflect post-1996 amendments to 49 U.S.C. 20106. FRA now believes that the section is unnecessary because 49 U.S.C. 20106 sufficiently addresses the preemptive effect of part 214.

This final rule will impose costs that are likely outweighed by the quantified safety benefits. For the 20-year period analyzed, the estimated quantified cost that will be imposed on industry totals $285.7 million (undiscounted) with a present value (PV) (7 percent) of $151.4 million, and a PV (3 percent) of $212.6 million. For the same 20-year period, the estimated quantified benefits total $286.2 million (undiscounted), with a PV (7 percent) of approximately $151.6 million and a PV (3 percent) of $212.9 million. The costs will primarily be imposed by a small increase in job briefing time and additional resources spent to provide on-track safety for the safe conduct of other than large-scale maintenance and construction of track located adjacent to (and within a certain distance of) one or more controlled tracks on which train movements may be occurring. Training costs will also accrue. The benefits will primarily accrue from a reduction in roadway worker casualties (fatalities and injuries). This analysis estimates that there will be 10.3 fewer roadway worker fatalities over the next 20 years. In addition, it estimates that this final rule will reduce roadway worker injuries by 182 over the next 20 years. Business benefits stemming from avoided train delays and property damages, as well as benefits from reduced safety stand downs [3] resulting from roadway worker

[3] Currently, when a railroad experiences a roadway worker fatality, the railroad leadership holds a ''safety stand down,'' during which all scheduled maintenance work is postponed so that the railroad managers and employees are able to

Continued

fatalities will also accrue. FRA finds that the estimated quantified benefits will exceed the estimated quantified costs.

The following table presents the quantified costs broken down by section of the RIA and by section of the rule:

Estimated cost of final rule	PV Rate, 3%*	PV Rate, 7%*
9.2 Job Briefings—§ 214.315	$1.94	$1.38
9.4 On-Track Safety—§ 214.336	207.60	147.83
9.4 Other (Signalmen, Lone Workers)—§§ 214.315/336	2.76	1.97
9.4 Training—§ 214.336	0.25	0.18
Total	212.55	151.36

* Dollars are in millions and are discounted over a 20-year period.

The table below presents the estimated benefits associated with this final rule by section of the RIA and by benefit category:

Estimated benefits of final rule	PV Rate, 3%*	PV Rate, 7%*
10.1 Casualty Mitigation (§ 214.336)—Fatality (Struck by Train)	$43.72	$31.13
10.2 Casualty Mitigation (§ 214.336)—Injury (Struck by Train)	71.62	51.00
10.3 Casualty Mitigation (§ 214.336)—Injury (Struck by Object Other Than Train)	15.30	10.90
10.4 Adjacent Track Revision	9.79	6.97
10.5 Damage Reduction	0.89	0.64
10.6 Reporting/Recordkeeping—Cost Savings	0.02	0.01
10.7 Business Industry Benefit	46.71	33.26
10.8 Reduction in Safety Stand Downs	19.98	14.23
10.9 Job Briefing Fatality Prevention (§ 214.315)	3.69	2.63
10.9 Job Briefing Injury Prevention (§ 214.315)	1.16	0.83
Total	212.88	151.59

* Dollars are in millions and are discounted over a 20-year period.

II. Overview of the Existing Roadway Worker Protection (RWP) Rule

A. Applicability and Basic Definitions

As background, since the RWP Rule [4] became effective in 1997, it has imposed certain safety requirements. In particular, the RWP Rule requires each railroad that operates rolling equipment on track that is part of the general railroad system of transportation to ''adopt and implement a program that will afford on-track safety to all roadway workers whose duties are performed on that railroad.'' *See* 49 CFR 214.3, 214.303(a).[5] ''On-track safety'' is defined in the RWP Rule as ''a state of freedom from the danger of being struck by a moving railroad train or other railroad equipment, provided by operating and safety rules that govern track occupancy by personnel, trains and on-track equipment.'' *See* § 214.7. The roadway workers that must be afforded on-track safety are any employees of a railroad, or of a contractor to a railroad, whose duties include ''inspection, construction, maintenance or repair of railroad track, bridges, roadway, signal and communication systems, electric traction systems, roadway facilities or roadway maintenance machinery on or near track or with the potential of fouling a track, and flagmen and watchmen/lookouts * * *.'' *See* § 214.7, ''Roadway worker.''

B. Authorized Methods of Establishing On-Track Safety

Several methods are authorized to be used to provide on-track safety for roadway workers, and many of those methods involve establishing ''working limits,'' which is defined in part as ''a segment of track with definite boundaries established in accordance with [part 214] upon which trains and engines may move only as authorized by the roadway worker having control over that defined segment of track.'' *See* §§ 214.7 and 214.319. Working limits may be established on controlled track (*i.e.,* ''track upon which the railroad's operating rules require that all movements of trains must be authorized by a train dispatcher or a control operator'') through exclusive track occupancy (§ 214.321), foul time (§ 214.323), or train coordination (§ 214.325). *See* §§ 214.7 and 214.319. Regardless of which method is chosen, the working limits are only permitted to be under the control of a qualified roadway worker in charge, and all affected roadway workers must be notified and either clear of the track or provided on-track safety through train approach warning (in accordance with § 214.329) before the working limits are released to permit the operation of trains or other on-track equipment through the working limits. *See id.*

Train approach warning is another common method of establishing on-track safety in which a trained and qualified watchman/lookout provides warning to roadway worker(s) of the approach of a train or on-track equipment in sufficient time to enable each roadway worker to move to and occupy a previously arranged place of safety not less than 15 seconds before a train moving at the maximum speed authorized on that track would arrive at the location of the roadway worker. *See* §§ 214.329 and 214.7 ''Watchman/

discuss the accident and reinforce pertinent safety practices, oftentimes through refresher training. A discussion of the cost savings that result from reduced safety stand downs is found in Section 10.8 of the Regulatory Impact Analysis (RIA).

[4] The RWP rule was published in the **Federal Register** on December 16, 1996 (61 FR 65959), and became effective on January 15, 1997.

[5] All references in this preamble to a section or other provision of a regulation are to a section, part, or other provision in title 49, Code of Federal Regulations unless otherwise specified.

lookout.'' Train approach warning is sometimes used as a temporary form of on-track safety when a roadway worker in charge needs to nullify the on-track safety previously established by working limits in order to permit a train or piece of on-track equipment to enter the roadway work group's working limits. Train approach warning permits the roadway workers to continue working for longer (than if working limits were the only form of on-track safety in effect) if the working limits span several miles and the train or equipment will not be passing by the work area for some time due to a speed restriction, the distance away, or the train or equipment halting its movement. It should be noted that switching temporarily to ''train approach warning'' is permissible only if the change was discussed in detail with the roadway work group, prior to the change occurring, in an updated on-track safety job briefing pursuant to § 214.315(d).

C. Existing On-Track Safety Requirements for Roadway Work Groups With Respect to Adjacent Tracks

Until the amendments to § 214.335(c) become effective, the provision of the 1996 RWP Rule requires that roadway work groups engaged in ''large-scale maintenance or construction'' be provided with on-track safety in the form of ''train approach warning'' for train or equipment movements on adjacent tracks if the adjacent tracks are not already included within the working limits. Under the current definition of ''adjacent tracks,'' on-track safety as discussed above is required for any tracks with track centers spaced less than 25 feet apart from the track center of the track to which a roadway work group is assigned to perform large-scale maintenance or construction. *See* §§ 214.7 and 214.335(c). The track to which the roadway work group is assigned to perform the large-scale maintenance or construction is commonly referred to as the ''occupied track.'' Thus, in triple-main track territory, if a roadway work group is occupying the middle track (*e.g.,* Main Track No. 2) in order to perform large-scale maintenance or construction, and the track centers of the tracks on either side of the occupied track are within 25 feet of the track center of the occupied track, then on-track safety is required to be established on both adjacent tracks (*e.g.,* Main Track Nos. 1 and 3). In some yards or territories, where track centers are spaced only 12 feet apart, an occupied track (*e.g.,* Yard Track No. 3) may have up to four adjacent tracks (*e.g.,* Yard Track Nos. 1, 2, 4, and 5). In such cases, the existing rule requires on-track safety to be established on all four adjacent tracks, in addition, of course, to the on-track safety required for the occupied track itself. *See* § 214.335(c) (61 FR 65976) and § 214.337(a).

Although the term ''large-scale maintenance or construction'' is not specifically defined in the 1996 regulation, FRA noted in the preamble to the 1996 final rule establishing the 1996 RWP Rule that the principle behind the reference to large-scale maintenance or construction was ''the potential for distraction, or the possibility that a roadway worker or roadway maintenance machine might foul the adjacent track and be struck by an approaching or passing train,'' and further stated that ''conditions in which the risk of distraction [were] significant'' required measures to provide on-track safety on adjacent tracks. *See* 61 FR 65971. To further clarify what is meant by the term ''large-scale maintenance or construction,'' FRA referenced the recommendation of the Roadway Worker Safety Advisory Committee, which described large-scale track maintenance and/or renovations, such as but not limited to, ''rail and tie gangs, production in-track welding, ballast distribution, and undercutting.'' *See id.* Under such guidance, many railroads were not providing on-track safety on adjacent tracks for surfacing operations, small tie renewal operations, or similar maintenance operations that, while smaller in scale (*e.g.,* because these were often single-task operations, rather than the multiple-task operations typical of production units), still included one or more pieces of on-track, self-propelled equipment. Fatalities occurred on the adjacent track during such operations when on-track safety was not established on the adjacent track or had been temporarily or permanently nullified or suspended to permit the passage of a train or other on-track equipment.

III. Notice of Safety Advisory 2004–01

After the occurrence of five roadway worker fatalities in one calendar year (2003), including one on an adjacent track, FRA responded on April 27, 2004, by issuing Notice of Safety Advisory 2004–01, which was later published in the **Federal Register** on May 3, 2004. *See* 69 FR 24220. FRA issued this safety advisory to recommend certain safety practices, to review existing requirements for the protection of roadway workers from traffic on adjacent tracks, and to heighten awareness to prevent roadway workers from inadvertently fouling a track when on-track safety is not provided. *See id.*

The safety advisory explained that the requirements of the RWP Rule, including the requirement to provide adjacent track on-track safety for large-scale maintenance or construction in § 214.335(c), are only minimum standards. The advisory emphasized that railroads and railroad contractors are free to prescribe additional or more-stringent standards consistent with the rule. *See id.* at 24222 and § 214.301(b).

FRA recommended that railroads and contractors to railroads develop and implement basic risk assessment procedures for use by roadway workers to determine the likelihood that a roadway worker or equipment would foul an adjacent track prior to initiating work activities, regardless of whether those activities were ''large-scale'' or ''small-scale.'' The advisory provided examples of relevant factors to consider in making such an assessment. These factors included whether the work could be conducted by individuals positioned between the rails of a track on which on-track safety has been established, as opposed to being positioned outside of the rails of such a track on a side of the track that has an adjacent track; whether there was a structure between the tracks to prevent intrusion (such as a fence between the tracks at a passenger train station and the tall beam of a through-plate girder bridge); the track-center distance, to ensure that the adjacent track would not be fouled if a worker were to inadvertently trip and fall; the nature of the work (inspection or repair); the sight distances; and the speed of trains on the adjacent track. *See* 69 FR 24222. FRA further noted that, upon completion of an on-site risk assessment, the on-track safety briefing required by § 214.315(a) would be the ideal instrument to implement preventive measures concerning adjacent tracks. *See id.*

In addition to the above recommendation concerning basic risk assessment, FRA recommended that railroads and contractors to railroads consider taking the following actions:

- Use of working limits for activities where equipment could foul adjacent track (whether large-scale or small-scale activities);
- Use rotation stops to mitigate the dangers associated with on-track equipment and trains passing on adjacent tracks;
- Review procedures for directing trains through adjacent track working limits, and enhance such procedures when necessary;
- Install adjacent track warning signs/devices in the operating cab of on-track machines to remind roadway maintenance machine operators to not

inadvertently depart the equipment onto a track where there may be trains and other on-track equipment passing;

• Provide additional training and monitoring to employees, emphasizing the need to cross tracks in a safe manner (*i.e.,* single file and after looking in both directions);

• Reinforce to individual roadway workers that it is critical not to foul a track except in the performance of duty and only when on-track safety has been established. This training could be accomplished through training sessions, as well as daily job briefings; and

• Institute peer-intervention measures by which workers are encouraged to intervene when observing another roadway worker engaging in potentially non-compliant and unsafe activity. *See id.*

IV. Recent Roadway Worker Accidents (1997–2010)

In the more than thirteen years since the RWP Rule went into effect on January 15, 1997, there have been nine roadway worker fatalities on an adjacent track. Seven of those fatalities have occurred on a controlled track that was adjacent to the track on which a roadway work group, with at least one of the roadway workers on the ground, was engaged in a common task with on-track, self-propelled equipment. FRA notes that there has been only one adjacent-track fatality where a roadway work group had been engaged in a common task with a lone hi-rail vehicle, defined in § 214.7 as ''a roadway maintenance machine that is manufactured to meet Federal Motor Vehicle Safety Standards and is equipped with retractable flanged wheels so that the vehicle may travel over the highway or on railroad tracks.'' [6] In addition, there have been no adjacent-track fatalities where a roadway work group had been engaged in a common task with a catenary maintenance tower car on the occupied track. This is likely because the duties normally performed by an employee operating a hi-rail vehicle or a catenary maintenance tower car tend to be less distracting to on-ground roadway workers and produce less dust and noise than a typical on-track roadway maintenance machine. Given the above, FRA proposed that adjacent-track on-track safety not be required for roadway work groups engaged in a common task with a hi-rail vehicle or a catenary maintenance tower car, as discussed in the section-by-section analysis of paragraphs (b)(2) and (3), respectively, in new § 214.336.

Of the seven fatalities that occurred under the circumstances described above and which this final rule is intended to address, three occurred during the period after the effective date of the 1996 RWP Rule and before the publication of the safety advisory on May 3, 2004, and four have occurred since that period. In the four-year period prior to May of 2004 (May 1, 2000–April 30, 2004), there has been one adjacent-track fatality known to have occurred under such circumstances, for a rate of .25 per year. In the four-year period since (May 1, 2004–April 30, 2008), there have been four adjacent-track fatalities, for a rate of one per year, which is four times the rate of the previous four-year period. While FRA recognizes that even one death can make rates change dramatically when the total number of deaths is small, the increase in the rate of these deaths despite the safety advisory continues to lead FRA to conclude that regulatory action is needed to avert an escalating number of deaths. Moreover, given the extensive participation in developing these consensus regulatory provisions by representatives of all of the key interests involved in this issue, it is contrary to the public interest to wait for all of the other issues in the larger RWP rulemaking to be resolved or to engage in lengthy periods for notice and public comment before acting to prevent more deaths.

The following is a brief summary of the results of FRA's investigations of the four most recent incidents that resulted in these unfortunate fatalities:

• *October 5, 2005:* A roadway surfacing gang tamper operator, with 28 years of service, was walking up to the front of the tamper to put away the light buggies as his surfacing gang, having just completed its work, was getting ready to travel to clear the number two main track. The operator was walking east on the side of the tamper between the two main tracks when he was struck by a westbound train on the adjacent track. The track centers were spaced approximately 13 feet apart, and the train was traveling at an estimated speed of 40 miles per hour (mph).

• *March 12, 2007:* A surfacing gang was occupying the number one main track in a double-main territory. The surfacing gang foreman (the roadway worker in charge), who earlier had notified the other members of the gang of pending movement on the adjacent track, was standing in the gage of the same adjacent track when he was struck by a train. It remains unclear why he was fouling the adjacent track at the time of the incident. The track centers were spaced approximately 13 feet, 6 inches apart, and the maximum authorized speed on the adjacent track was 50 mph. The foreman was the only roadway worker on the ground at the time of the incident.

• *February 10, 2008:* A train struck a roadway worker inside an interlocking on a triple-main track territory. The worker was part of a gang that consisted of approximately 10 workers that were engaged in the repair of a crossover on the middle main track with a tamper. Foul time was being used as adjacent-track on-track safety, but this on-track safety was removed by the roadway worker in charge, who gave permission to the dispatcher to permit a train to operate on the adjacent track through the roadway work group working limits. As the train entered the interlocking on a limited clear signal indication for a crossover move past the work area, one of the roadway workers attempted to cross the track in front of the train and was struck. The track centers were spaced approximately 13 feet apart, and the maximum authorized speed for the train on the adjacent track was 45 mph.

• *March 27, 2008:* A surfacing gang was working on double-main track territory. The surfacing gang foreman was standing in the foul of the adjacent track while his surfacing crew worked on the number two main track (the occupied track). A train operating on the adjacent track struck the foreman. No on-track safety was in effect on the adjacent track involved at the time of the incident. The track centers were spaced approximately 14 feet, 7 inches apart, and the maximum authorized speed on the adjacent track was 70 mph. The foreman was the only roadway worker on the ground at the time of the incident.

While the above discussion focuses on those fatalities that have occurred on an adjacent track where a roadway work group, with at least one of the roadway workers on the ground, was engaged in a common task with on-track, self-propelled equipment on an occupied track, it is important to discuss some of the common circumstances in all nine of the fatalities that have occurred on an adjacent track since the rule went into effect, as these circumstances were considered by FRA in its decision to issue the NPRM and this final rule. The first common circumstance is the type of track. All nine of the fatalities occurred on ''controlled'' track, rather than ''non-controlled'' track. This was taken into consideration in writing FRA's proposed and final definition of ''adjacent controlled track,'' which has

[6] In that case (which occurred on March 28, 2002, in Langhorne, PA), the roadway workers were under the impression that adjacent-track on-track safety was in effect, but it was not, due to a miscommunication.

been included in new § 214.336(a)(3) and would be limited to controlled tracks whose track centers are spaced 19 feet or less from the track center of the occupied track. The term would only be applicable to § 214.336 and would not replace the broader term ''adjacent tracks,'' which is defined in § 214.7.

Second, all nine of the fatalities occurred on an adjacent track that was quite closely-spaced to the track that the roadway work group was occupying. Six of the adjacent tracks had track centers that were spaced approximately 14 feet or less from the respective track centers of the tracks that the roadway work groups were occupying, and all nine of the adjacent tracks were spaced 15 feet or less from the track centers of the respective occupied tracks. This common circumstance was also taken into consideration in FRA's proposed and final definition of ''adjacent controlled track,'' which would have a narrower applicability for purposes of proposed and final § 214.336 than the term ''adjacent tracks,'' because it would not include tracks with track centers that were spaced more than 19 feet (but less than 25 feet) away from the track center of the occupied track.

The third common circumstance of the nine fatalities on adjacent track is the time of year. Four of the fatalities occurred during the first quarter (January-March), none of the fatalities occurred in the second and third quarters of the year (April-June and July-September, respectively), and the other five fatalities occurred during the fourth quarter (October–December). As noted earlier in Section I, above, because incidents involving adjacent controlled tracks appear to present clear evidence of significant risk that is not effectively addressed by the current regulation, FRA has concluded that moving forward with this rulemaking to address adjacent-track on-track safety in advance of the other proposals contained in the RSAC consensus is necessary and appropriate in order to reduce the risk of additional fatalities on adjacent track that are likely to occur late this year or early next year in the absence of further regulatory action.

V. Joint Petition to FRA for an Emergency Order

On April 11, 2008, the Brotherhood of Maintenance of Way Employes Division (BMWED) and the Brotherhood of Railroad Signalmen (BRS) filed a joint petition requesting that FRA issue an emergency order under 49 U.S.C. 20104(a) requiring adjacent-track protection for roadway work groups. The petition noted that similar requests, which were filed on October 7, 2005, November 7, 2003, and December 21, 1999, were denied by FRA. The petitioners expressed their belief that, under the existing provisions of the rule, roadway workers will continue to suffer preventable serious injuries and death. The petitioners asserted that FRA should require railroads and their contractors to establish on-track safety on adjacent tracks (''adjacent-track on-track safety'') for a wider range of work activities. In FRA's January 5, 2006 denial of the October 2005 petition, FRA noted that the RSAC working group tasked to review and revise the RWP Rule (''RWP Working Group'') was ''committed to presenting comprehensive draft language * * * that would more closely tailor the solution to the problem.'' And while the RWP Working Group did in fact draft this language, and both the Working Group and the full RSAC were able to reach consensus on such language, BMWED and BRS were concerned that the language, which has not been published as an NPRM, would not become a final rule for a considerable period of time, leaving the possibility for further preventable fatalities. BMWED and BRS urged FRA to issue an emergency order that would adopt the adjacent-track consensus language of the RWP RSAC.

On April 18, 2008, the American Train Dispatchers Association (ATDA) filed a letter in support of the BMWED and BRS joint petition. In the letter, ATDA agreed that preventable injuries and deaths continue to occur because of a lack of positive regulation mandating adjacent-track on-track safety and urged FRA to issue an emergency order based upon the RSAC-approved and consensus-based replacement language for § 214.235(c), as indicated in the joint petition.

As an emergency order does not require prior notice to the affected party or an opportunity to be heard prior to issuance of the order, Congress declared that such an order may be invoked only where an unsafe condition or practice ''causes an emergency situation involving a hazard of death or personal injury.'' 49 U.S.C. 20104. By letter dated June 4, 2008, FRA denied the joint petition for emergency order, noting that the increased rate of adjacent-track-related fatalities cited in the joint petition makes a strong case for regulatory action, but does not constitute an emergency situation ''that has developed suddenly and unexpectedly in which the danger is immediate.'' To address this serious safety concern, FRA decided to issue a separate NPRM with an abbreviated comment period, as further discussed in Section VI.C, below.

VI. Current Rulemaking To Revise the RWP Rule

A. Overview of the RSAC

In March 1996, FRA established RSAC, which provides a forum for developing consensus recommendations to FRA's Administrator on rulemakings and other safety program issues. The Committee includes representation from all of the agency's major stakeholder groups, including railroads, labor organizations, suppliers and manufacturers, and other interested parties. A list of member groups follows:

- American Association of Private Railroad Car Owners (AARPCO);
- American Association of State Highway and Transportation Officials (AASHTO);
- American Chemistry Council;
- American Petroleum Institute;
- American Public Transportation Association (APTA);
- American Short Line and Regional Railroad Association (ASLRRA);
- ATDA;
- Association of American Railroads (AAR);
- Association of Railway Museums;
- Association of State Rail Safety Managers (ASRSM);
- Brotherhood of Locomotive Engineers and Trainmen (BLET);
- BMWED;
- BRS;
- The Chlorine Institute, Inc.;
- Federal Transit Administration (FTA);*
- Fertilizer Institute;
- High Speed Ground Transportation Association (HSGTA);
- Institute of Makers of Explosives;
- International Association of Machinists and Aerospace Workers;
- International Brotherhood of Electrical Workers (IBEW);
- Labor Council for Latin American Advancement;*
- League of Railway Industry Women;*
- National Association of Railroad Passengers (NARP);
- National Association of Railway Business Women;*
- National Conference of Firemen & Oilers;
- National Railroad Construction and Maintenance Association (NRC);
- National Railroad Passenger Corporation (Amtrak);
- National Transportation Safety Board (NTSB);*
- Railway Supply Institute (RSI);
- Safe Travel America (STA);
- Secretaria de Comunicaciones y Transporte;*

- Sheet Metal Workers International Association (SMWIA);
- Tourist Railway Association, Inc.;
- Transport Canada;*
- Transport Workers Union of America (TWU);
- Transportation Communications International Union/BRC (TCIU/BRC);
- Transportation Security Administration (TSA);* and
- United Transportation Union (UTU).

*Indicates associate, non-voting membership.

When appropriate, FRA assigns a task to RSAC, and after consideration and debate, RSAC may accept or reject the task. If the task is accepted, RSAC establishes a working group that possesses the appropriate expertise and representation of interests to develop recommendations to FRA for action on the task. These recommendations are developed by consensus. A working group may establish one or more task forces to develop facts and options on a particular aspect of a given task. The individual task force then provides that information to the working group for consideration. If a working group comes to unanimous consensus on recommendations for action, the package is presented to the full RSAC for a vote. If the proposal is accepted by a simple majority of RSAC, the proposal is formally recommended to FRA. FRA then determines what action to take on the recommendation. Because FRA staff play an active role at the working group level in discussing the issues and options and in drafting the language of the consensus proposal, FRA is often favorably inclined toward the RSAC recommendation. However, FRA is in no way bound to follow the recommendation, and the agency exercises its independent judgment on whether the recommended rule achieves the agency's regulatory goal, is soundly supported, and is in accordance with policy and legal requirements. Often, FRA varies in some respects from the RSAC recommendation in developing the actual regulatory proposal or final rule. Any such variations would be noted and explained in the rulemaking document issued by FRA. If the working group or RSAC is unable to reach consensus on a recommendation for action, FRA moves ahead to resolve the issue through traditional rulemaking proceedings.

B. Proceedings in This Rulemaking to Date Generally

On January 26, 2005, the RSAC formed the RWP Working Group (''Working Group'') to consider specific actions to advance the on-track safety of employees of covered railroads and their contractors engaged in maintenance-of-way activities throughout the general system of railroad transportation, including clarification of existing requirements. The assigned task was to review the existing rule, technical bulletins, and a safety advisory dealing with on-track safety. The Working Group was to consider implications and, as appropriate, consider enhancements to the existing rule. The Working Group would report to the RSAC any specific actions identified as appropriate, and would report planned activity to the full Committee at each scheduled Committee meeting, including milestones for completion of projects and progress toward completion.

The Working Group is comprised of members from the following organizations:

- Amtrak;
- APTA;
- ASLRRA;
- ATDA;
- AAR, including members from BNSF Railway Company (BNSF), Canadian National Railway Company (CN), Canadian Pacific Railway, Limited (CP), Consolidated Rail Corporation (Conrail), CSX Transportation, Inc. (CSXT), The Kansas City Southern Railway Company (KCS), Norfolk Southern Corporation railroads (NS), and Union Pacific Railroad Company (UP);
- Belt Railroad of Chicago;
- BLET;
- BMWED;
- BRS;
- FRA;
- Indiana Harbor Belt Railroad (IHB);
- Long Island Rail Road (LIRR);
- Metro-North Commuter Railroad Company (Metro-North);
- Montana Rail Link;
- NRC;
- Northeast Illinois Regional Commuter Railroad Corporation (Metra);
- RailAmerica, Inc.;
- Southeastern Pennsylvania Transportation Authority (SEPTA);
- UTU; and
- Western New York and Pennsylvania Railroad (WNY&P).

The Working Group held 12 multi-day meetings. The group worked diligently and was able to reach consensus on 32 separate items.

C. Proceedings Concerning On-Track Safety Procedures for Adjacent Tracks

One of the items on which the Working Group was able to reach consensus dealt specifically with the adjacent-track on-track safety issue in § 214.335 On-track safety procedures for roadway work groups. The consensus language developed by the Working Group for this topic, which was approved by the full RSAC and formally recommended to FRA for paragraphs (c), (d), and (e), is as follows:

For paragraph (c)—''On-track safety is required for adjacent controlled track within 19 feet of the centerline of the occupied track when roadway work group(s) consisting of roadway workers on the ground and on-track self-propelled or coupled equipment are engaged in a common task on an occupied track.

- ''Except as provided by paragraph (c)(3) of this section, when trains are cleared through working limits on an adjacent controlled track, or when watchman/lookout warning in accordance with § 214.329 is the form of adjacent on-track safety, roadway workers shall occupy a predetermined place of safety and all on-ground work and equipment movement activity within the fouling space of the occupied track shall cease upon notification of pending adjacent track movement (working limits) or upon receiving the watchman/lookout warning.
- ''When single or multiple movements are cleared through adjacent controlled track working limits, on-ground work and equipment movement on the occupied track may resume only after all such movements on adjacent track have passed each component of the Roadway Work Group(s). If the train stops before passing all roadway workers, the employee in charge shall communicate with the engineer prior to allowing the work to resume.
- ''When single or multiple movements are cleared through adjacent controlled track working limits at a speed no greater than 25 mph, work performed exclusively between the rails of the occupied track, or to the field side of the occupied track with no adjacent track, may continue upon notification of each roadway worker of movement on adjacent track. On-ground work shall not be performed within 25 feet to the front or 25 feet to the rear of roadway maintenance machine(s) on the occupied track during such adjacent track movement.''

For paragraph (d), the Working Group recommended ''Equipment may not foul an adjacent controlled track unless protected by working limits and there are no movements authorized through the working limits by the roadway worker in charge.''

And for paragraph (e), the Working Group recommended ''The mandatory provisions for adjacent controlled track protection under this subpart are not applicable to work activities involving—

''A hi-rail vehicle as defined in § 214.7, provided such hi-rail vehicle is not coupled to railroad cars. Where multiple hi-rail vehicles are engaged in a common task, the on-track safety briefing shall include discussion of the nature of the work to be performed to determine if adjacent controlled track protection is necessary. Nothing in this subpart prohibits the roadway worker in charge of the hi-rail vehicle from establishing adjacent controlled track protection, as he/she deems necessary.

• ''On-ground roadway workers exclusively performing work on the field side of the occupied track.

• ''Catenary maintenance tower cars with roadway workers positioned on the ground within the gage of the occupied track for the sole purpose of applying or removing grounds. Nothing in this subpart prohibits the roadway worker in charge of the catenary maintenance tower car from establishing adjacent track protection, as he/she deems necessary.''

Upon reviewing the joint petition of the BRS and BMWED for an emergency order, the consensus language of the Working Group quoted above, and the relevant accident data concerning roadway workers fouling adjacent tracks, FRA decided to issue a separate NPRM [7] to lower the safety risk associated with roadway workers fouling adjacent tracks. Although FRA's safety advisory may have had an initial effect and have raised awareness enough to help keep the number of all categories of roadway worker fatalities in 2004 and through almost six months in 2005 at zero, the effect was not sustained enough to combat the rise of roadway worker fatality incidents since late June of 2005, when the first roadway worker fatality occurred after the issuance of the safety advisory, or since October of 2005, when the first adjacent track roadway worker fatality occurred.

In light of recent roadway worker fatality trends, FRA determined that the agency must propose a more prescriptive approach to prevent further fatalities. The need to mandate adjacent-track on-track safety was recognized by FRA, members of the Working Group, and members of the full RSAC. The consensus language developed by the Working Group and recommended by the full RSAC was expected to reduce the risk of roadway worker fatalities due to fouling an adjacent track while working in conjunction with on-track, self-propelled equipment or coupled equipment on an occupied track. As part of the process in drafting the NPRM in the larger RWP rulemaking, FRA circulated the consensus rule text concerning adjacent track and other items to the Working Group for errata review. Both AAR and BMWED submitted comments on this provision. To address these issues, and other potential ambiguities discovered upon a closer review of the rule text, FRA reorganized and modified the consensus text in issuing an NPRM.

FRA published an NPRM addressing adjacent-track on-track safety on July 17, 2008 (73 FR 41214), but formally withdrew the notice on August 13, 2008 (73 FR 47124). The withdrawal stated, in part—

> [i]n crafting the NPRM, FRA presented the RSAC consensus language in the preamble verbatim and transparently explained its rationale for all changes it made to the consensus language. As this was an NPRM, FRA sought comment on the entire proposal, including those portions that FRA sought to clarify.
>
> FRA recognizes that inadvertent errors do sometimes occur in formulating a proposal and expects that interested parties would provide comments to both FRA and all other interested parties through the established comment process detailed in the NPRM. Given the alleged discrepancies between the consensus language and the proposed rule, the need to clarify the essential issues and move toward resolution of the safety concern at hand, and the ex parte communications regarding this proposed rule, FRA has decided to withdraw this rulemaking and will take such further regulatory steps as safety requires.

Id. Due to the inherent dangers of roadway workers working in multiple-track territories among machines, FRA decided to revisit the issues and language of the withdrawn NPRM in light of the comments received, formal and informal (*i.e.,* phone calls and emails), and issue a revised NPRM, which was published on November 25, 2009 (74 FR 61633). In accordance with DOT's policy (Order No. 2100.2 (1970)), all communications (including informal phone calls and emails) between FRA employees and other parties since the publication of the July 17, 2008 NPRM and prior to its withdrawal were reduced to writing and placed in the public docket. While some comments were marked ''draft'' or received after the withdrawal of the NPRM, FRA posted them to the docket, since they were still taken into consideration in drafting the NPRM and this final rule. A summary of the comments on the July 17, 2008 NPRM and FRA's response to those comments appears in the preamble to the November 25, 2009 NPRM, and therefore is not repeated in the preamble to this final rule unless it is necessary to discussion of a pending issue.

A summary of the comments on the November 25, 2009 NPRM and any pertinent earlier comments and FRA's response to those comments follows in Section VI.D, below. However, there is one issue that was raised by AAR in its comments on the July 17, 2008 NPRM that merits further discussion in this section, namely the effective date of the rule. In its comments, AAR had urged FRA to make the effective date for training on the new requirements consistent with the railroads' training schedules. Specifically, AAR indicated that if a rule were published before October 1st of a calendar year, then training could be completed by July 1st of the next calendar year. In support of this recommended effective date, AAR explained that most employees are trained during the first six months of each year, many during the first quarter, when there is typically less demand for railroad services. AAR further noted that railroads spend considerable resources to ensure that their training materials are comprehensive and effective, and that training outside the normal training cycle could be counterproductive and could potentially lead to errors in implementation, as the trainers may have a more difficult time effectively conveying the information. The BMWED and BRS comments on the July 17, 2008 NPRM, though not expressly commenting on a particular effective date, expressed concern that the separate training and recordkeeping requirements proposed in § 214.336(c) would have shifted the burden for effective training from the employer to the employees, and would have infringed on the employees' right to quality, employer-provided training. FRA had proposed these separate training and recordkeeping requirements to serve as a stop-gap measure until the time of the employee's recurrent training pursuant to § 214.343(d). However, given the complexity of new § 214.336, FRA agrees that it would be best to allow the railroads additional time to create comprehensive and helpful training materials and to train their employees during the normal training cycle. As a result, FRA has decided to make the rule effective on May 1, 2012. This should help ensure uniformity and quality of training. Until this final rule becomes effective, FRA strongly encourages railroads and contractors to take measures to increase awareness on

[7] As noted in Section I of this preamble, the provisions related to on-track safety for certain adjacent tracks were originally intended to be published as part of a larger NPRM concerning part 214, but were proposed as a separate NPRM (which led to the issuance of this final rule) to expedite the effective date of such provisions.

the issue of the dangers posed by adjacent tracks, such as making it a topic of discussion at safety meetings or enhancing their on-track safety job briefings to include information about any adjacent tracks, on-track safety for such tracks, and identification of any roadway maintenance machines that will foul such tracks.

D. Response to Comments on the November 25, 2009 NPRM

FRA received four comments on the November 25, 2009 NPRM. Comments were submitted by a variety of affected parties, namely, BMWED and BRS (joint comments), AAR, APTA, and ATDA. FRA has extensively reviewed and evaluated the comments. In this section, FRA has responded to the comments regarding the following issues:

(1) On-ground work performed to the clear side;

(2) Hi-rail vehicles and clarification of ''common task'';

(3) Rail-bound geometry or detector cars;

(4) Continuous barrier;

(5) Requests for additional exceptions to, or relief from, the requirements of proposed § 214.336 or for a narrowing of its scope;

(6) Predetermined place of safety; and

(7) The effect of the proposed rule on dispatchers.

FRA has responded to some of the smaller concerns within the Section-by-Section Analysis at Section VII of this preamble.

1. On-Ground Work Performed to the Clear Side

BMWED and BRS raised several issues in their joint comments on the NPRM. First and foremost, however, was their concern with the concept and definition of the term ''clear side,'' which they believed was an ''unproven and novel concept'' that had not been discussed in the RSAC and the Working Group, and that was a ''dangerous surrogate for the consensus language defining 'Field Side' within the body of the text adopted by the Working Group in 214.335(c)(3).'' In the NPRM, FRA had proposed the term ''clear side'' as a shorthand to describe the side on which there should essentially be no danger posed by any other adjacent track, for purposes of the exception in paragraph (e)(1) of proposed § 214.336 for ''[o]ne or more on-ground roadway workers performing work while exclusively positioned on the clear side of the occupied track.'' In particular, FRA noted that, assuming compliance with the proposed rule, there would be no danger posed by any other adjacent track either because there is no adjacent track on that particular side of the occupied track or, even though there is an adjacent track on that side of the occupied track, working limits have been established in accordance with this subpart on the closest adjacent track on that side and, therefore, there are no movements authorized through the working limits on that adjacent track.

This proposed exception was based on paragraph (e)(2) of the consensus language, which read ''[o]n-ground roadway workers exclusively performing work on the field side of the occupied track.'' As discussed at length in the preamble of the NPRM (*see* 74 FR 61640), FRA believed that this language was broader than the consensus language in consensus paragraph (c)(3), which would have permitted work to continue ''to the field side of the occupied track with no adjacent track'' during a low-speed movement on an adjacent controlled track on the opposite side of the occupied track. Additionally, FRA noted that there were two field sides to each occupied track, beginning at each rail and continuing outward and away from the track center of the occupied track. However, in their joint comments on the NPRM, BMWED and BRS expressed their beliefs that the term ''field side'' was clear, and that each right-of-way (rather than each track) has only two field sides (*i.e.,* the outermost extremes of the right-of-way). It was their opinion that FRA was mistaken in its conclusion that there was a conflict between consensus paragraphs (c)(3) and (e)(2) because the term ''field side'' in (e)(2) clearly referred to the side of the occupied track *that had no adjacent track on that side;* without such a conflict, they believed there was no need to introduce the term ''clear side.''

FRA notes that the term ''field side'' is used by roadway workers inspecting track to indicate on which side of a rail a bolt was replaced (*e.g.,* field side vs. gage side), regardless of whether the track is in single-track territory or multiple-track territory. Given this use of the term and BMWED's and BRS' view that the term has been used differently in the common parlance of roadway workers, it is evident that the term ''field side'' was understood by different people to mean different things. FRA has considered this fact as well as the comments raised concerning the safety of permitting work to continue on a side of the occupied track that had an adjacent track.

FRA had originally proposed in the July 17, 2008 NPRM (later withdrawn) that work would be permitted to continue on that side as long as on-track safety (including train approach warning) had been established on that side. In response to the concerns raised by BMWED and BRS that it would be unsafe to permit work on that side if working limits are not specifically required on any adjacent track on that side (with no movements permitted through such limits), FRA adjusted its proposal in the November 25, 2009 NPRM so as to better ensure the safety of the workers on that side of the occupied track. *See* 74 FR 61640.

In this final rule, FRA has considered the additional comments received from BMWED and BRS on the proposed section, particularly on the use of the term ''clear side'' and ''field side'' and has removed both terms to eliminate any confusion. However, FRA still believes that it is safe to work on the side of an occupied track with working limits on the closest adjacent track on that side and no movements within such limits on that side, and that establishing the near running rail as a demarcation point is a ''bright line'' approach that will make it easier both for roadway workers and the regulated community at large to follow and for FRA to enforce. Thus, this final rule permits work while exclusively positioned on the side of the occupied track with one or more adjacent tracks, the closest of which has working limits on it and no movements permitted within such working limits by the roadway worker in charge. *See* § 214.336(e)(1)(ii) of the final rule.

2. Hi-Rail Vehicles and Clarification of ''Common Task''

In response to the exception proposed for hi-rail vehicles in the NPRM in paragraph (e)(2) of § 214.336, FRA received comments from BMWED and BRS indicating that the exception was written too broadly and should be amended so as to limit it to only those hi-rail vehicles being used for inspection or minor correction purposes. These commenters submitted that this was the intent of the consensus language, and that failing to impose this limitation would permit work to be performed by hi-rail vehicles that was equally as distracting (such as a thermite welding crew working out of the back of a large hi-rail vehicle work platform) as that performed by other types of on-track, self-propelled equipment or coupled equipment subject to the requirements of this section.

AAR requested clarification of the exception for hi-rail vehicles, noting that the language limiting the exception for hi-rail vehicles (*i.e.,* to those that are not operating on the same occupied track and within the limits of a roadway

work group as described in § 214.336(a)) should be modified so as to exclude from the exception only those hi-rail vehicles working on the occupied track within 300 feet in front of or behind any roadway maintenance machine of a roadway work group. AAR noted that there are circumstances where the working limits could extend between two control points for several miles, and that the hi-rail vehicle may be operated a considerable distance away from the roadway work group, but within the control points.

APTA raised a similar concern regarding the roadway workers' proximity to the on-track, self-propelled equipment, noting that proposed § 214.336 would require adjacent-track on-track safety for workers in a tie gang applying rail anchors on an occupied track where no power tools or roadway maintenance machines are in use within their hearing, and for an on-ground worker taking rail profile measurements behind a rail grinder. Because the fatalities recounted in the NPRM all suggest proximity to the on-track equipment as a defining factor, APTA suggested that FRA should narrowly define the phrase ''common task'' so as to exclude from the limitations of § 214.336(a) workers who are not in proximity to the on-track equipment and whose ability to see and hear approaching trains or other equipment on adjacent tracks is not limited by noise, lights, or other conditions.

FRA agrees with BMWED and BRS that the language in the NPRM would have permitted work to be performed by hi-rail vehicles that was equally as distracting, and thus has adopted BMWED's and BRS' suggestion in the final rule. *See* § 214.336(e)(3)(i). As explained in detail in the Section-by-Section Analysis at Section VII of this preamble, FRA has added a definition of the term ''minor correction purposes'' to paragraph (a)(3) of this section for additional clarity.

Additionally, in response to the concern raised by AAR (and a similar concern raised by APTA) that a hi-rail vehicle that is operated within the same working limits but a considerable distance away from the distractions of the roadway work group would not qualify for the exception, FRA has added language to permit the hi-rail vehicle exception to apply in this situation if both of the following conditions are met. The first is that the roadway worker in charge of the working limits has conducted an on-track safety job briefing with the principal (''non-excepted'') roadway work group and the entering (''excepted'') roadway work group and determined that adjacent-controlled-track on-track safety is not necessary for the entering ''excepted group'' (*i.e.,* a group that would otherwise qualify for one of the exceptions in paragraph (e)(3)).

The second condition that would need to be met in order to permit the hi-rail vehicle exception to still apply in the above scenario is that the entering group is not working in such proximity to the principal (''non-excepted'') group so that the ability of a roadway worker in the entering (''excepted'') group to hear or see approaching trains and other on-track equipment is impaired by background noise, lights, sight obstructions or any other physical conditions caused by the equipment of the principal group. FRA notes that this additional language was based in part on the existing on-track safety procedures for lone workers, and that the selected language would be enforced in a similar manner. *See* § 214.337(c)(6). Additionally, in recognition that, under the reverse scenario, the principal group could be the ''excepted group'' and the entering group could be the ''non-excepted group,'' FRA has written the language in such a manner so as to apply to both scenarios.

While the above approach is similar to what APTA suggested in its comments, FRA has decided not to apply this approach to any members of a roadway work group that includes equipment that triggers the requirements of § 214.336 and that is not subject to an exception, regardless of whether the individual roadway workers are in proximity of such equipment. FRA notes that unless those individual roadway workers comprise an entirely separate roadway work group with its own roadway worker in charge, it is safer to provide uniformity in procedures for the work group as a whole. This approach, as applied to an entering group, is also safer than AAR's suggestion that FRA permit the exception to apply to hi-rail vehicles that are at least 300 feet away from any roadway maintenance machine in the principal roadway work group, because it will capture distractions that impair the abilities of roadway workers from further than 300 feet away, due to factors such as the size of the on-track, self-propelled equipment or coupled equipment, and the amount of noise or dust generated by such equipment.

Because the concept of a ''common task'' is at the core of determining whether roadway workers are part of the same work group,[8] and thus subject to the same adjacent-controlled-track on-track safety procedures per the triggering language in paragraph (a), FRA believes that it is important to provide clarification as to this concept. While the term ''common task'' is not defined in part 214, FRA has provided guidance in the preamble to the 1996 RWP Rule concerning the term in the context of a ''lone worker'' who, by definition, is not engaged in a common task with another roadway worker. *See* § 214.7. This guidance may also be helpful in understanding the use of the term ''common task'' in the context of the new § 214.336. The preamble provides the following:

> Generally, a common task is one in which two or more roadway workers must coordinate and cooperate in order to accomplish the objective. Other considerations are whether the roadway workers are under one supervisor at the worksite; or whether the work of each roadway worker contributes to a single objective or result.
>
> For instance, a foreman and five trackmen engaged in replacing a turnout would be engaged in a common task. A signal maintainer assigned to adjust the switch and replace wire connections in the same turnout at the same time as the track workers would be considered a member of the work group for the purposes of on-track safety. On the other hand, a bridge inspector working on the deck of a bridge while a signal maintainer happens to be replacing a signal lens on a nearby signal would not constitute a roadway work group just by virtue of their proximity. FRA does not intend that a common task may be subdivided into individual tasks to avoid the use of on-track safety procedures required for roadway work groups.

61 FR 65965–66.

3. Rail-Bound Geometry or Detector Cars

In the NPRM, FRA had sought comment regarding whether the hi-rail vehicle exception should be expanded to include rail-bound geometry and detection equipment. *See* 74 FR 61641, 61648. As discussed in the NPRM, AAR had requested that the exception for hi-rail vehicles be expanded to include rail-bound geometry and detection equipment, since the level of distraction posed by this equipment is similar to that posed by hi-rail vehicles. AAR suggested that FRA expand the hi-rail vehicle exception by adding ''or self-propelled track geometry or detector car'' after ''a hi-rail vehicle.'' In seeking comments, FRA noted that ''it seems that the level of distraction is similar for a roadway worker on the ground who is field-verifying a measurement behind a

[8] A ''roadway work group'' is defined in § 214.7 as ''two or more roadway workers organized to work together on a common task.''

geometry car and a roadway worker on the ground who is replacing a bolt behind a hi-rail.'' 74 FR 61641.

BMWED and BRS responded that they believed that the distractions are dissimilar, in that the detector cars are larger (reducing visibility) and much louder than a hi-rail pickup, and could therefore reduce a person's ability to detect the approach of a train. Additionally, they noted that there are other roadway maintenance machines performing a common task with such detection equipment that will also be at risk. In contrast, APTA expressed support for expanding the hi-rail vehicle exception to self-propelled detector (and ''inspection-type'') cars, noting its belief that roadway workers engaged in a common task with self-propelled detector cars are performing work under the same circumstances as those engaged in a common task with hi-rail vehicles, and thus, should be granted the same exemption.

FRA has decided to adopt this exception in this final rule because the level of distraction posed by the task of inspecting or performing minor correction is the same. Additionally, FRA has considered that inspection or minor correction work performed by a roadway work group with this type of equipment would clearly not have triggered the requirement for adjacent-track on-track safety under existing § 214.335(c) (as this would not have been considered ''large scale maintenance or construction'').

4. Continuous Barrier

FRA requested comment in the NPRM as to whether a new exception should be added for locations where there is a physical barrier, such as a fence, between the occupied track and the adjacent track and, if so, whether it should be limited to where there is a continuous permanent or semi-permanent physical barrier of a certain height (such as a chain-linked fence at least 4' in height or a concrete barrier at least 32'' in height) between the occupied track and the adjacent controlled track. 74 FR 61642, 61648. FRA received three comments from interested parties on this issue.

BMWED and BRS opposed a new exception for fences, *etc.,* due to concerns that the fence and/or concrete barriers would not necessarily encompass the entire work environment of one or more roadway work groups, and would not prevent inadvertent fouling of the adjacent controlled track by roadway maintenance machines. The commenters noted in closing that if, however, FRA is inclined to grant this new exception, then FRA must establish clearly-prescribed minimum criteria for such a barrier, including that it be permanently-installed and continuous, of sufficient strength, without voids, openings, or defects and at least four feet in height, and FRA must require that all roadway workers are positioned or performing work ''exclusively within the confines'' of the barrier. The commenters believed that a minimum height requirement of four feet would be reasonable and necessary to prevent a roadway worker who stumbles from going over the top of a shorter barrier and landing in the foul of a live adjacent controlled track.

AAR suggested that an exception be added for ''[w]ork on an occupied track where there is a physical barrier between the occupied track and the adjacent track of sufficient height to prevent the worker from stepping over the barrier.'' APTA also supported the creation of an exception for locations that have permanent or semi-permanent barriers between the occupied and adjacent tracks, and noted that FRA should not be concerned about the use of plastic fencing for this purposes, as it has been used effectively in many passenger rail applications where short-term work is performed in multiple-track and shared-corridor alignments. APTA submitted that the plastic fencing is highly visible to workers on the ground and train operators alike, and its dielectric properties make it a preferred option in situations where work is performed near third rail or catenary power sources.

Having considered these comments and reviewed the fatality data, FRA has determined that it is safe to perform work on a side of the occupied track that has an inter-track barrier between it and the closest adjacent track on that side, provided that the inter-track barrier meets minimum requirements to ensure that it is sturdy enough to prevent a roadway worker from fouling the adjacent track. As a result, FRA has adopted a new exception for such inter-track barriers. *See* § 214.336(e)(1)(iii). FRA has incorporated several of the suggestions from the comments received and defined the term ''inter-track barrier'' to mean ''a continuous barrier of a permanent or semi-permanent nature that spans the entire work area, that is at least four feet in height, and that is of sufficient strength to prevent a roadway worker from fouling the adjacent track.'' *See* § 214.336(a)(3) (''inter-track barrier''). Further, FRA believes that this exception, as a practical matter, will be used primarily in commuter territories that already have permanent, sturdy chain-linked fences in place, often to prevent passengers from crossing the tracks. Most other semi-permanent barriers, such as concrete extra-tall jersey barriers (since standard jersey barriers are less than four feet in height), would be labor intensive to set up for a short work project. Regarding the use of plastic fencing, FRA notes that those fences are not typically permanently or semi-permanently installed, and FRA is also concerned that this material may be easily defeated by vandals with a pocket knife, thereby weakening the plastic fencing or leaving gaps in it through which a roadway worker could fall. As a result, FRA does not consider plastic fencing as an acceptable ''inter-track barrier'' for purposes of this section.

Finally, in order to address BMWED's concern that the inter-track barrier would not prevent inadvertent fouling of the adjacent controlled track by roadway maintenance machines, FRA has added clarifying language to the introductory text in paragraph (e) that cross-references the requirements in paragraph (f), concerning components of roadway maintenance machines fouling an adjacent controlled track. This language is intended to reiterate that, the exception in paragraph (e)(1)(iii) exempts the roadway workers from the procedures in paragraphs (a), (b), and (c) only; they must still follow the procedures in paragraph (f), which generally provides that components of roadway maintenance machines shall not foul an adjacent controlled track unless working limits have been established on the adjacent controlled track and there are no movements permitted within the working limits by the roadway worker in charge that would affect the roadway worker operating such machine.

5. Requests for Additional Exceptions to, or Relief From, the Requirements of Proposed § 214.336 or for a Narrowing of Its Scope

FRA received several comments requesting additional exceptions to, or relief from, the requirements of proposed § 214.336 or for a narrowing of its scope. Three of the requests were made by AAR, and the other two were made by APTA. Each request or set of similar requests is described and then addressed.

a. Requested Exception Where There Is Only One Worker on the Ground

AAR commented that FRA had disagreed with its draft comments on the withdrawn NPRM that FRA's proposal to apply adjacent-track protection requirements where there is only one worker on the ground is contrary to the intent of the Working

Group. AAR indicated that, even assuming FRA is correct, adjacent-track protection is not required when activities are performed between the rails of the occupied track or on the clear side, since employees undertaking such activities are not in danger from trains passing on adjacent track. AAR submitted that adjacent-track on-track safety serves no purpose for employees checking track characteristics (*e.g.,* cross level, gage, or profile), a machine operator re-supplying a machine with materials, a mechanic repairing a machine, or where a machine is just being fueled. AAR further stated that the last three activities described above do not even constitute roadway work, thus the proposed adjacent-track protection requirements would not apply. Accordingly, AAR proposed that FRA add an additional exception to proposed § 214.336(e) for ''a single employee performing work exclusively between the rails of the occupied track.'' AAR noted that it would not be opposed to limiting the exception by requiring that the employee must first communicate with the operator of the roadway machine.

Regarding AAR's request that FRA add an additional exception to proposed § 214.336(e) for ''a single employee performing work exclusively between the rails of the occupied track,'' FRA again notes, as it did in the NPRM, that an analysis of the agency's accident investigations of these types of incidents revealed that four of the seven fatalities that involved a roadway work group engaged in a common task with on-track, self-propelled equipment on an adjacent track occurred with only one of the roadway workers on the ground. FRA specifically chose the clarifying words ''one or more roadway workers on the ground'' because FRA believed that this was the intent of the Working Group, since there was no safety rationale for excluding roadway work groups that consisted of only two roadway workers. Further, FRA notes that a lot of the work performed in a common task with on-track, self-propelled equipment or coupled equipment, other than hi-rail vehicles and automated rail inspection cars being used for inspection or minor correction and catenary maintenance tower cars, does not lend itself to being performed within the gage of the track without breaking the plane of the rails. Additionally, the exception in § 214.336(e)(2) would permit a roadway worker to refuel a machine, provided that he or she is positioned on a side of the occupied track meeting specified conditions, with the machine effectively preventing the roadway worker from fouling the adjacent controlled track on the other side of such machine.

Additionally, FRA wants to make explicit that it disagrees with AAR's characterization of a machine operator re-supplying a machine with materials, a mechanic repairing a machine, or a machine being fueled as not constituting work subject to the RWP rules (or ''roadway work,'' as used in AAR's comments). The first activity is ''roadway work'' because the gathering or distribution of materials necessary to the performance of track maintenance duties is part of those duties, and the last activities are maintenance of roadway maintenance machinery. *See* § 214.7 (definition of ''roadway worker''). FRA also disagrees with AAR's characterization that adjacent-track on-track safety is not required when activities are performed between the rails of the occupied track, since employees undertaking such activities are not in danger from trains passing on adjacent track. Both the NPRM and final rule versions of paragraph (b) clearly require (or would have required) work to cease between the rails of the occupied track during adjacent-controlled-track movements authorized or permitted at speeds over 25 mph. FRA also notes that a train passing by at a speed over 25 mph presents a higher risk of injury to roadway workers from abnormal consist conditions or track construction/maintenance materials that may become airborne while the train passes the roadway workers.

b. Requested Revision of Proposed § 214.336(c) To Permit Work by the Machine Operator Within the Areas 25 Feet in Front of and 25 Feet Behind Equipment During Low-Speed Movements on an Adjacent Controlled Track

In its draft comments on the withdrawn NPRM, AAR had recommended that FRA permit the machine operator to perform work on the ground within 25 feet of the front or rear of the roadway maintenance machine that he or she was operating, during adjacent-controlled-track movements of 25 mph or less. AAR noted it would be impractical not to allow the operator to step off of his machine and walk directly behind it. Accordingly, AAR suggested that the proposed paragraph § 214.336(a)(2)(i) in the withdrawn NPRM (and later proposed as § 214.336(c) in the NPRM) be amended by adding after the word ''movement'' the phrase ''unless the employee is operating the machine.'' FRA noted its belief (without agreeing to the concept as a whole, contrary to what was suggested by AAR's comments on the NPRM) that the phrase ''unless the employee is the assigned operator of the machine'' would have better addressed AAR's concerns, since presumably the employee would place the machine in the idle position and set the brakes before alighting and, therefore, would not be operating or moving the machine from the ground. FRA sought comment as to whether this amendment should be added.

AAR commented that it supported the revised language suggested by FRA, with one slight modification in order to address a situation where two workers, such as an operator and a helper, are assigned to a machine. Thus, AAR suggested that FRA add the following language to paragraph (c), ''unless the employees are the assigned operators of the machines.''

BMWED and BRS submitted comments indicating that they are opposed to amending proposed § 214.336(c) by adding after the word ''movement'' the phrase ''unless the employee is the assigned operator of the machine.'' The risk from adjacent track movements associated with working on the occupied track within 25 feet to the front or rear of a roadway maintenance machine is not reduced simply because the roadway worker happens to be the ''assigned operator.'' The noise of the machine, the reduced visibility, and the distraction of performing work within 25 feet to the front or rear of the machine is the same for all roadway workers, regardless of whether or not the person is the assigned operator.

While FRA believes that the intent of this provision is mainly to prevent roadway workers from being struck by the machines or equipment, and generally agrees that if the machine is not being operated the main danger would be prevented; FRA does not believe that the danger would be adequately addressed if there is more than one assigned operator to a machine, as AAR stated is often the case. This presents a dangerous situation where one of the operators of a machine would be permitted to begin to operate a machine without first having to provide notice to the other operator(s), who would be permitted to work within the 25-foot areas in front of and behind the machine, and could potentially be positioned in a blind spot. Additionally, even if only one operator were permitted, if a roadway worker observed the operator in the 25-foot area and thought that because the machine was off or in idle it was safe to approach the machine within 25 feet and he positioned himself in a blind

spot, that roadway worker may be injured if the operator started the machine suddenly. Given all of the above, FRA has decided not to adopt this requested exception.

c. Requested Revision of Proposed § 214.336(b)(2) To Permit a Roadway Work Group Component To Resume Work After the Head-End Has Passed the Component's Location

AAR believes that work should be permitted to resume when the leading end of the equipment has passed, provided that the work is performed exclusively between the rails of the occupied track or on the clear side, and suggests that FRA adopt language to that effect in paragraph (b)(2) of § 214.336, noting that there is no evidence of employees walking into the sides of trains. With respect to FRA's review of the related meeting documents and its conclusion in the NPRM that railroad management's proposal appears to have conceded that the entire movement must pass before permitting work to resume, regardless of speed, AAR submits that it did not make any such concession.

FRA has decided that even if it were mistaken as to AAR's concession in this regard, each affected roadway worker whose work is not subject to an exception shall not be permitted to resume such work until after the entire movement (the trailing-end of the movement) has passed by the location of the roadway worker, due to the concerns raised by BMWED and BRS on this issue, namely that there are hazards presented to roadway workers by abnormal consist conditions (*e.g.,* ''shifted loads/shifted ladings, loose banding, dragging chains/binders, loose brake piping, loose/swinging boxcar doors, [and] fragmented brake shoes'') and by ''dust, rust, debris, stone, and track construction/maintenance materials'' which may become airborne while trains pass roadway workers.

d. Request To Raise the Threshold Speed in § 214.336(b) and § 214.336(c) From 25 MPH to 40 MPH for Passenger Trains

APTA commented that it believes that the threshold speed that determines whether the stricter procedures in § 214.336(b) apply should be raised from in excess of 25 mph for all trains to a minimum of 40 mph for passenger trains, noting that passenger trains have historically been permitted to operate at higher maximum authorized speeds than freight trains on the same track. APTA further noted that passenger trains can stop more quickly and easily than freight trains, and the roadway worker in charge is in the best position to gauge whether a slower speed is necessary for safe operations, based on local conditions and the type of work being performed.

FRA has decided not to adopt APTA's proposed change. FRA responds that because passenger trains are shorter and do not present the same dangers of shifted loads/shifted ladings as freight trains, the roadway worker in charge is likely to send the passenger train through the working limits at the maximum authorized speed. Thus, the amount of time that the work would not be permitted to continue on the side of the occupied track closest to the movement and between the rails of the occupied track would be minimal.

6. Predetermined Place of Safety

Both AAR and APTA requested in their comments that FRA provide clarification on what it considers a ''place of safety'' for purposes of the language in proposed § 214.336(b)(1) to require that each roadway worker cease work and ''occupy a predetermined place of safety.'' APTA requested that FRA affirmatively state that the occupied track may be designated as a place of safety for purposes of that proposed provision, and AAR noted its belief that ''a place of safety'' includes between the rails of the occupied track, and that it may be safer for the roadway workers to stay between the rails of the occupied track (particularly if the roadway workers are occupying a track located between two or more tracks), rather than to cross the other track(s) to reach an alternative location.

FRA agrees with AAR and APTA that under some circumstances, it may be safer for the roadway worker to stay between the rails of the occupied track, and that this is permitted to be an appropriate predetermined place of safety, as determined by the roadway worker in charge. In response to the comments made by APTA and AAR, FRA has provided clarification as to what is meant by ''a predetermined place of safety'' in Table 1 of this section. Specifically, FRA has added a note in Table 1, which provides that a ''predetermined place of safety'' (or ''PPOS''), as used in the table, means a specific location that an affected roadway worker must occupy upon receiving a watchman/lookout's warning of approaching movement(s) (''warning'') or a roadway worker in charge's notification of pending movement(s) on an adjacent track (''notification''), as designated during the on-track safety job briefing required by § 214.315. The PPOS may not be on a track, unless the track has working limits on it and no movements permitted within such working limits by the RWIC.[9] Thus, under these circumstances, the space between the rails of the occupied track may be designated as a place to remain in position or to otherwise occupy upon receiving a warning or notification. Additionally, in response to concerns raised by BMWED and BRS in their joint comments concerning the potential dangers of having contingent places of safety, note 1 further explains that the roadway worker in charge must determine any change to a PPOS, and communicate such change to all affected roadway workers through an updated on-track safety job briefing.

7. The Effect of the Proposed Rule on Dispatchers

FRA received comments from ATDA, submitted by Mr. Greg J. M. Godfrey (ATDA Local Chairman, New York Dispatchers), which are summarized in this paragraph. ATDA's comments favored increased railroad workplace safety, but noted that adoption of the proposed rule would result in additional requests for protection from the train dispatchers. The comments asserted that as a result of technological innovation to reduce workforce and the understaffing of other crafts (*e.g.,* a roadway worker may be forced to request foul time to complete work that could have been conducted with a watchman/lookout instead), the dispatchers are already under an enormous amount of pressure. ATDA stated its belief that this significant pressure is the reason for the rise in unfortunate incidents that could have been prevented through a sufficient workforce and that the train dispatcher will need additional support and additional desks if the final rule provides increased measures of protections for roadway workers. Finally, ATDA indicated that this situation entails a real cost that needs to be factored in and that train dispatching districts will need to be studied to ensure adequate focus can be maintained by the train dispatchers.

FRA notes in response that it believes this final rule will not result in a significant increase in the number of calls to a dispatcher, as the economic analysis assumes that the majority of the time, the roadway workers will be

[9] This is consistent with how FRA has applied a similar term, ''a previously determined place of safety'' (*see* § 214.337(c)(4)) in the context of on-track safety procedures for lone workers: ''The place of safety to be occupied by a lone worker upon the approach of a train may not be on a track, unless working limits are established on that track.'' *See* § 214.337(d).

utilizing train approach warning provided by watchmen/lookouts, rather than working limits established by a dispatcher. And in those circumstances where working limits need to be established, FRA anticipates that they will be established at the same time as the working limits for the occupied track are established; thus, FRA does not anticipate more than a *de minimis* increase in the workload of a dispatcher, especially since this rule will also eliminate many requests for working limits on adjacent tracks that are greater than 19 feet away from the occupied track (as measured from centerline to centerline).

VII. Section-by-Section Analysis

Amendments to 49 CFR Part 214, Railroad Workplace Safety

Subpart A—General

Section 214.4 Preemptive Effect

FRA has removed this section from 49 CFR part 214. This section was prescribed in 1996 and has become outdated and, therefore, misleading because it does not reflect post-1996 amendments to 49 U.S.C. 20106. *See* 61 FR 65975; Sec. 1710(c), Public Law 107–296, 116 Stat. 2319; Sec. 1528, Public Law 110–53, 121 Stat. 453. Although FRA considered updating this regulatory section, FRA now believes that the section is unnecessary because 49 U.S.C. 20106 sufficiently addresses the preemptive effect of part 214. In other words, providing a separate Federal regulatory provision concerning the proposed regulation's preemptive effect is duplicative of 49 U.S.C. 20106 and, therefore, unnecessary.

There has been no opportunity for public comment on this particular amendment in the final rule. FRA has determined, pursuant to section 4 of the Administrative Procedure Act (5 U.S.C. 553), that prior notice and an opportunity for comment on the removal of § 214.4 are not necessary. The amendment is administrative in nature and merely eliminates an outdated and incomplete restatement of the preemptive effect of part 214. As such, FRA finds that notice and public comment procedures are ''impracticable, unnecessary, or contrary to the public interest'' under 5 U.S.C. 553(b)(3)(B).

Section 214.7 Definitions

The existing version of § 214.7 simply lists various terms used in part 214 and provides a definition of each term. Unlike the ''definitions'' sections of most FRA safety regulations, the usual kind of introductory text (*e.g.,* ''As used in this part'' or ''In this part'') is missing.

In this final rule, § 214.7 has been amended by adding introductory text, ''Unless otherwise provided, as used in this part—'' prior to the list of definitions. This change is necessary for two reasons: (1) to clarify that the definitions apply to part 214 and not necessarily to other parts of the Code of Federal Regulations; and (2) to ensure that the addition of similar definitions (''adjacent track'' and ''adjacent controlled track'') that are applicable only to § 214.336 do not conflict in any way with the same terms in this ''general definitions'' section. Note, however, that the definition of ''adjacent tracks'' still applies to any other sections in part 214 that reference the term, either in its plural or singular form, unless otherwise provided in the section in which the term is used.

Subpart C—Roadway Worker Protection

Section 214.315 Supervision and Communication

Given the importance of an on-track safety job briefing in roadway workers' understanding of the nature of the work that they will be conducting and the conditions under which they will conduct it, the existing requirements in § 214.315 to hold a job briefing ''when an employer assigns duties to a roadway worker that call for that employee to foul a track'' have been expanded in revised § 214.315 of this final rule to cover the procedures for adjacent-controlled-track on-track safety in new § 214.336 if such procedures are required for that assignment or if adjacent-track on-track safety is deemed necessary by the roadway worker in charge (as provided in paragraph (d) of that section). With a few minor changes, the text concerning the additional components of an on-track safety job briefing that is adopted in this final rule is the same as the consensus language developed by the Working Group and recommended by the full RSAC. The consensus language relating to adjacent tracks was proposed as a new paragraph (a)(2) in existing § 214.315, to read as follows:

> (2) Information about any tracks adjacent to the track to be occupied, on-track safety for such tracks, and identification of roadway maintenance machines that will foul any adjacent track. In such cases, the briefing shall include procedural instructions addressing the nature of the work to be performed and the characteristics of the work location to ensure compliance with this part.

On December 18, 2007, FRA emailed the Working Group members and requested an errata review of a document in which FRA had compiled all of the consensus items. In its errata review comments, AAR requested that FRA clarify that the provision was not intended to require a discussion about the on-track safety of an adjacent track unless on-track safety was required on that track by part 214. FRA agreed that this was not the intent of the proposed requirement, and had added the language ''if required by this subpart or deemed necessary by the roadway worker in charge'' to the consensus rule text, which was proposed as new paragraph (a)(3) in the NPRM. The language concerning the discretion of the roadway worker in charge was added to emphasize that the roadway worker in charge would still be permitted to establish on-track safety on an adjacent track, regardless of whether it was controlled or non-controlled, if that on-track safety was reasonably necessary given the nature of the work that was to be performed. This proposed section would still have required the on-track safety job briefing to include information concerning any ''adjacent tracks'' (as defined in § 214.7), so as to serve as a warning to each roadway worker of the potential danger in fouling such a track, even if no on-track safety is required for that particular track because it does not meet the definition of ''adjacent controlled track'' in proposed § 214.336(a)(3). While the second sentence of the consensus language began with the phrase ''in such cases,'' FRA deleted that language, and had moved the rest of the language into a new paragraph (a)(4) in the NPRM, since the on-track safety job briefing must always address the nature of the work to be performed and the characteristics of the work location to ensure compliance with this subpart, regardless of whether there is an adjacent track present.

In the NPRM, FRA had further clarified in a proposed revision to introductory paragraph (a) that this section would list only the minimum items that would have to be discussed in an on-track safety briefing. In proposed § 214.315(a), the words ''at a minimum'' were added, and the rest of existing paragraph (a) was moved to proposed paragraphs (a)(1) and (a)(2). FRA received no comments on the proposed amendments to this section, and FRA has adopted the amendments to this section as proposed for the reasons stated above.

Section 214.335 On-Track Safety Procedures for Roadway Work Groups, General

Currently, § 214.335(c) reads as follows:

(c) Roadway work groups engaged in large-scale maintenance or construction shall be provided with train approach warning in accordance with § 214.327 for movements on adjacent tracks that are not included within working limits.

In this final rule, FRA has amended this section by deleting paragraph (c) and creating new requirements in a separate section to address on-track safety procedures for certain roadway work groups and adjacent tracks, § 214.336, for the reasons discussed below. This final rule also amends the heading of § 214.335 to reflect the general nature of the remaining requirements in that section.

Section 214.336 On-Track Safety Procedures for Certain Roadway Work Groups and Adjacent Tracks

Paragraph (a), Procedures; General

As discussed in Sections I and II.C, above, existing § 214.335(c), which is in effect until this final rule becomes effective, requires adjacent-track on-track safety for a roadway work group only if such work group is engaged in ''large-scale maintenance or construction.'' Under this criterion and the limited guidance provided in the preamble to the 1996 final rule that prescribed the provision, many railroads had not been providing on-track safety on adjacent tracks for surfacing operations, small tie-renewal operations, or similar maintenance operations that, while smaller in scale, still include on-track, self-propelled equipment that may be similarly or equally distracting to the roadway workers on the ground. New § 214.336 seeks to eliminate this interpretive issue by establishing new, more objective criteria for determining whether adjacent-track on-track safety is required for a roadway work group.

In developing language to address the increasing number of roadway worker fatalities on an adjacent track, the Working Group considered that most of the fatalities on an adjacent track occurred when a roadway work group with at least one of the roadway workers on the ground, was engaged in a common task with on-track, self-propelled equipment on an occupied track. In those circumstances, the potential for a roadway worker in the group to be distracted from the danger of an oncoming train was great due to the noise and dust generated by the operation of on-track, self-propelled equipment, the need to avoid entanglement in the operation of that equipment, and the need to monitor the quality of the work being performed. This set of factual circumstances became the basis for the new criteria for triggering the requirement to establish adjacent-track on-track safety in introductory paragraph (c)(1) of the consensus language, and in paragraph (a)(1) of new § 214.336, which, as a general rule, requires that on-track safety be established for each adjacent controlled track when a roadway work group with at least one of the roadway workers on the ground is engaged in a common task with on-track, self-propelled equipment or coupled equipment (including single-unit, self-propelled equipment or units connected to non-powered on-track equipment by tow bars) on an occupied track. In particular, the on-track safety must be provided in accordance with § 214.319 (Working limits, generally) (which includes § 214.321 (Exclusive track occupancy), § 214.323 (Foul time), and § 214.325 (Train coordination)), or § 214.329 (Train approach warning provided by watchmen/lookouts) and as more specifically described in this section.

This general rule is set forth in paragraph (a)(1), which also directs the reader to the exceptions described in paragraph (e). The more specific procedures for adjacent-controlled-track on-track safety are set forth in paragraphs (b) and (c), concerning movements on an adjacent controlled track at speeds over 25 mph, and at speeds of 25 mph or less, respectively. The language in RSAC-recommended paragraph (a) was also modified in light of the new definition of ''adjacent controlled track,'' namely by removing the reference to the 19-foot track center distance and placing it in the definition in paragraph (a)(3).

Paragraph (a)(2) addresses the special circumstances arising in territories with at least three tracks, if an occupied track is between two adjacent tracks, at least one of which is an adjacent controlled track. This paragraph differs from that proposed in the NPRM in that it now addresses two special circumstances, instead of one. The first, which was proposed in the NPRM as paragraph (a)(2) and is now set forth in paragraph (a)(2)(i) of this final rule, provides that if an occupied track has two adjacent controlled tracks, and one of these adjacent controlled tracks has one or more train or other on-track equipment movements authorized or permitted at a speed of 25 mph or less, and the other adjacent controlled track has one or more concurrent train or other on-track equipment movements authorized or permitted at a speed over 25 mph, the more restrictive procedures in paragraph (b) of this section apply. This special circumstance requires that all work (*i.e.,* both on-ground work and equipment movement) on or between the rails of the occupied track and on both sides of the occupied track cease, since, as will be further discussed below, there is no side of the occupied track meeting the specified conditions for an exception to these procedures. *See* § 214.336(e)(1).

The second special circumstance arising in territories with at least three tracks (if an occupied track is between two adjacent tracks, at least one of which is an adjacent controlled track), is set forth in new paragraph (a)(2)(ii). This paragraph provides that if an occupied track has an adjacent controlled track on one side (Side X), and a non-controlled track whose track center is spaced 19 feet or less from the track center of the occupied track on the other side (Side Y), the affected roadway workers must treat the non-controlled track on Side Y as an adjacent controlled track for purposes of this section. While this circumstance was not raised during the RSAC discussions or in either of the NPRMs, FRA was concerned that the additional confusion of working between two tracks that are spaced that closely to the occupied track (*i.e.,* with track centers spaced 19 feet or less from the track center of the occupied track) and requiring that the on-track safety procedures apply to one of the closely-spaced tracks (the controlled track on Side X), but not the other (the non-controlled track on Side Y), could result in fatalities on the non-controlled adjacent track (on Side Y). This approach is consistent with FRA's rationale for adopting the language in paragraph (e)(1)(ii) that imposes conditions on the exception for work performed on a side with one or more adjacent tracks so that work would be permitted on that side only if the danger posed by the closest track on that side had been essentially eliminated (*i.e.,* either the closest adjacent track on that side has working limits on it with no movement permitted within such working limits by the roadway worker in charge (*see* paragraph (e)(1)(ii)), or that side has an inter-track barrier between the occupied track and the closest adjacent track on that side (*see* paragraph (e)(1)(iii)).

Paragraph (a)(3) adds definitions of four new terms used exclusively in § 214.336 (''adjacent controlled track,'' ''inter-track barrier,'' ''minor correction,'' and ''occupied track''). This paragraph also adds a definition of the term ''adjacent track'' to this section that in a sense is substantively the same as an existing term (''adjacent tracks'') that is defined in § 214.7, but which has been made singular and reworded so as

to parallel the construction of the definition of the new term ''adjacent controlled track'' in this section and moreover is an application of the general definition of a track *adjacent* to *the occupied* track (not simply adjacent to another track).

For purposes of this section, ''adjacent controlled track'' means ''a controlled track whose track center is spaced 19 feet or less from the track center of the occupied track.'' [10] In contrast, the definition of ''adjacent tracks'' (in § 214.7) includes any tracks, controlled *or non-controlled* (though this is implied, rather than explicitly stated), whose track centers are spaced *less than 25 feet apart.* The new definition of ''adjacent track'' in this section (''a controlled or non-controlled track whose track center is spaced less than 25 feet from the track center of the occupied track'') describes the track with respect to its relationship to the occupied track, and also explicitly states that the term could be applied to either a controlled or a non-controlled track. This helps ensure that the reader is aware of the distinctions between that term and the similar term ''adjacent controlled track.'' Additionally, as noted above in the discussion of the amendments to § 214.7, the definition of ''adjacent tracks'' still applies to any other sections in part 214 that reference the term, either in its plural or singular form, unless otherwise provided. To ensure that the terms do not conflict in any way, FRA has added qualifying language to the beginning of the general definitions section (§ 214.7).

FRA has adopted this narrower definition of ''adjacent controlled track'' and used the term as part of the triggering language for the requirements of this section based on the roadway worker fatality data discussed above in ''IV. Recent Roadway Worker Accidents (1997–2010),'' which show that the adjacent tracks on which the roadway worker fatalities occurred were all controlled tracks and that the track centers of these controlled tracks were within 15 feet of the track centers of the occupied track. In light of these data, the Working Group agreed that 19 feet would be a reasonable and safe threshold at which to trigger the requirement to establish on-track safety on an adjacent track and that it would be reasonable to cover controlled tracks within that 19-foot zone but to exclude non-controlled tracks. FRA also agrees that it is wise to adopt a 19-foot threshold, rather than a 15-foot threshold, to have an additional safety factor built in to prevent fatalities as well as injuries that could occur as a result of a shifted load/lading or debris, stones, or track construction/maintenance materials becoming airborne while trains pass roadway workers. FRA notes that the lack of fatalities on non-controlled adjacent tracks may be attributable to the reduced operating speeds on non-controlled tracks, where railroad operating rules generally require that movements must stop short of obstructions within half the range of vision. The Working Group discussed, and the full RSAC recommended for inclusion in § 214.335(c), that on-track safety be required for ''adjacent controlled track within 19 feet of the centerline of the occupied track'' for certain work activities. FRA agrees with this analysis, absent special circumstances (*see* discussion of § 214.336(a)(2), above), and has reflected it in the proposed definition of ''adjacent controlled track.'' Note, however, that this section also uses the broader term ''adjacent track'' or ''adjacent tracks'' in paragraphs (a)(2), (a)(3) (*see* definition of ''inter-track barrier''), (d), and (e)(1)(i) through (iii), as further discussed, below.

The third definition in § 214.336(a)(3) is of the term ''inter-track barrier,'' which means ''a continuous barrier of a permanent or semi-permanent nature that spans the entire work area, that is at least four feet in height, and that is of sufficient strength to prevent a roadway worker from fouling the adjacent track.'' As discussed in Section VI.D.4, regarding the comment requesting establishment of an exception for a ''continuous barrier,'' this term was added to clarify that only sturdy and continuous barriers that are at least four feet high are permissible for purposes of qualifying for this exception. *See* § 214.336(e)(1)(iii) of the final rule.

The fourth definition is of the term ''minor correction,'' which means ''one or more repairs of a minor nature, including but not limited to, spiking, anchoring, hand tamping, and joint bolt replacement that is accomplished with hand tools or handheld pneumatic tools only.'' The term does not include welding, machine spiking, machine tamping, or any similar type of repair. This term was added to provide guidance as to what type of work a roadway work group may perform under the exceptions for hi-rail vehicles and automated inspection cars being used for ''inspection or minor correction purposes'' (*see* paragraphs (e)(3)(i) and (ii)). The definition itself is based, in part, on the language in subpart B of part 214 describing ''repairs or inspections of a minor nature'' for purposes of an exception to the fall protection requirements for bridge workers. *See* § 214.103(d). FRA recognizes that the language in the bridge worker rule also contained the condition that the work be ''completed by working exclusively between the outside rails [of the occupied track].'' *See id.* As FRA has decided not to impose that same limitation here, the language has been tailored to ensure that the hi-rail vehicles or automated inspection cars are not being used in such a manner so as to create similar levels of noise and dust generated by the operation of on-track, self-propelled equipment performing machine tamping or machine surfacing, for example.

The fifth definition to be used for purposes of § 214.336 is ''occupied track.'' FRA has defined the term ''occupied track'' to mean a track on which on-track, self-propelled equipment or coupled equipment is authorized or permitted to be located while engaged in a common task with a roadway work group with at least one of the roadway workers on the ground. FRA had originally proposed to replace the consensus language of ''on-track, self-propelled or coupled equipment'' with ''on-track roadway maintenance machine or coupled equipment'' so as to use a term that was already defined in part 214. While FRA recognized that the term ''on-track roadway maintenance machine'' excludes hi-rail vehicles, FRA did not anticipate any issues with the triggering language, as FRA had proposed that there be an exception for all hi-rail vehicles that were not coupled to one or more railroad cars or not operating on the same occupied track and within the working limits of a roadway work group as described in the NPRM-proposed paragraph (a) (*e.g.,* a roadway work group that had triggered the applicability of this section due to being engaged in a common task with a hi-rail vehicle and at least one other piece of equipment that did in fact meet the definition of an on-track roadway maintenance machine). However, now that FRA has decided to limit the hi-rail vehicle exception in what is now paragraph (e)(3)(i) to those hi-rail vehicles being used for inspection or minor correction purposes, the broader consensus language needs to be reinstated in order to capture those hi-rail vehicles that are being used for

[10] The definition continues as follows: ''Note, however, that under the special circumstances specified in paragraph (a)(2)(ii) of this section, a non-controlled track whose track center is spaced 19 feet or less from the track center of the occupied track must be treated as an adjacent controlled track for purposes of this section.''

purposes other than inspection or minor correction.

FRA has also added the words ''authorized or permitted to be'' in front of ''located'' to make clear that if a roadway work group and an on-track roadway maintenance machine, for example, were to be physically located on a track without authorization or permission (and would be occupying the track in the physical sense), FRA would not consider the track to be an ''occupied track'' for purposes of enforcing this section. Instead, FRA would enforce other sections of the rule that would prohibit an operator of such a machine from fouling a track without appropriate on-track safety on that track (*see, e.g.,* §§ 214.313(c) and 214.335(a)), as the roadway workers in this scenario would be subject to a much greater danger than those that had established appropriate on-track safety for the track on which they were located but had failed to establish on-track safety on an adjacent controlled track.

Another change from the NPRM-proposed language was to add the phrase ''with at least one of the roadway workers on the ground'' following ''a roadway work group'' at the end of the sentence. This change was made in response to a concern raised by BMWED and BRS in their joint comments that it was unclear that one roadway worker on the ground would trigger the requirements of this section. Their comments noted that clarification was necessary because roadway worker fatalities have occurred while only one roadway worker was on the ground. FRA notes that while the definition as proposed in the NPRM did not affect the triggering language in paragraph (a)(1), FRA decided to make the definition consistent with such language for additional clarity.

Paragraphs (b), Procedures for Adjacent-Controlled-Track Movements Over 25 mph; and (c), Procedures for Adjacent-Controlled-Track Movements 25 mph or Less

Paragraphs (b) and (c) list the specific procedures to follow depending on the authorized or permitted speed of one or more train or other on-track equipment movements on an adjacent controlled track (''adjacent-controlled-track movements''). FRA believes that revising and reorganizing the consensus language from paragraphs (c)(1) and (c)(3) into paragraphs (b) and (c) and contrasting the procedures with headings based on higher-speed (*i.e.,* over 25 mph) versus low-speed (*i.e.,* 25 mph or less) movements makes the section easier to understand.

Paragraph (b), Procedures for Adjacent-Controlled-Track Movements Over 25 mph

Paragraph (b) lists the procedures to follow for one or more adjacent-controlled-track movements over 25 mph (*i.e.,* if a train or other on-track equipment is authorized by the dispatcher or by the applicable timetable or permitted by the roadway worker in charge to move on an adjacent controlled track at a speed greater than 25 mph). Paragraph (c) lists the procedures to follow when one or more adjacent-controlled-track movements are authorized or permitted at a speed of 25 mph or less.[11] As noted above in the discussion of paragraph (a)(2)(i), if an occupied track has two adjacent controlled tracks, and one of these adjacent controlled tracks has one or more movements authorized or permitted at 25 mph or less, and the other adjacent controlled track has one or more concurrent movements authorized or permitted at over 25 mph, the more restrictive procedures in paragraph (b) would apply. Note that the word ''permitted'' has been added to this section for consistency with its use in § 214.321(a)(2) and to ensure that there is no confusion caused by the use of the word ''authorized,'' which may be understood by some members of the regulated community to denote authorized by a train dispatcher or by a timetable (*e.g.,* maximum authorized speed).

The first clause of the introductory language in paragraph (b) has been slightly modified from what was proposed in the NPRM. The cross-reference to the exceptions in paragraph (e) has been revised to be more descriptive (''[e]xcept for the work activities as described in paragraph (e)'' instead of ''except as provided in paragraph (e)'') and moved to paragraph (b)(1) to ensure that it is read in conjunction with the requirements listed in that paragraph.

The introductory language in paragraph (b) has also been modified by limiting the applicability of the procedures (which include the requirement to cease work) to only those roadway workers that would be ''affected by'' the adjacent-controlled-track movement(s). This narrowing of the requirement is necessary because, in some situations, a roadway worker in charge may have authority limits that span a greater distance than the working limits (the specifically designated area in which roadway workers have been given permission to work by the roadway worker in charge) of the roadway work group, and he or she may want to permit a train into the limits of the authority on an adjacent controlled track, but hold the train short of the working limits (work area) of the roadway work group on the occupied track. In such situations, the rule does not require any work within the working limits (work area) of the roadway work group to cease because the roadway workers would not be affected by the movement (*i.e.,* the train would not be passing by the work area).

The addition of the word ''affected'' to this section is consistent with how the existing notification procedures regarding a change in the on-track safety procedures have been written and applied (*see* § 214.315(d), which states in part, ''[s]uch information shall be given to all roadway workers affected before the change is effective, except in cases of emergency''). If no notification is necessary for certain roadway workers because the change in on-track safety does not affect them, then it follows that those roadway workers would not need to cease work. Thus, this issue is not unique to the adjacent-controlled-track context. For example, if a roadway worker in charge had ''track and time'' (a form of exclusive track occupancy, which is one method of establishing working limits) on a single main track from milepost (MP) 10 to MP 20, but explained in the on-track safety job briefing that the roadway work group's working limits were only from MP 15 to MP 20, then the roadway worker in charge would be permitted to allow a train to come into the larger authority limits up to a designated point (*i.e.,* between MP 10 and MP 15) short of the smaller working limits (*i.e.,* between MP 15 and MP 20) given to the roadway workers, without first having to notify those roadway workers of the pending movement because they would not be ''affected'' by this movement.

In other cases, the limits of the track authority and the working limits for the roadway work group start off the same, but as the work is completed along the track, the roadway worker in charge may decide that it is best to ''roll up,''

[11] If a roadway worker in charge, in his or her discretion, permits a train through the working limits on an adjacent controlled track at 30 mph, but the train is actually traveling at a speed of only 20 mph, the procedures in new paragraph (b), regarding adjacent-controlled-track movements over 25 mph, would still apply. Where exclusive track occupancy is the method of on-track safety established on the adjacent controlled track, FRA notes that existing § 214.321(d) provides that movements of trains and roadway maintenance machines within working limits shall be made only under the direction of the roadway worker having control over the working limits, and further notes that such movements shall be at restricted speed unless a higher speed has been specifically authorized by the roadway worker in charge of the working limits.

or shorten, the working limits of the group (and may even formally relinquish a portion of the authority limits to the dispatcher). In such cases, the roadway worker in charge must inform each affected roadway worker in the roadway work group of the new working limits through an updated on-track safety job briefing. *See* § 214.315(d). FRA believes that it is safe to apply the same principles that have been applied outside of the adjacent-controlled-track context (*e.g.,* to single-main-track territory), regarding each ''affected'' roadway worker, to the adjacent-controlled-track context, especially since the train (or other on-track equipment movement) would be traveling on the adjacent controlled track rather than the occupied track, where an accidental incursion into the working limits of the roadway work group would likely be more dangerous.

Paragraph (b)(1), Ceasing Work and Occupying a Predetermined Place of Safety

Paragraph (b)(1) generally requires that, upon receiving a watchman/lookout warning or notification of one or more pending movements on an adjacent controlled track (as applicable), each roadway worker in the roadway work group shall, as described in Table 1 of this section, cease all on-ground work and equipment movement that is being performed on or between the rails of the occupied track or on one or both sides of the occupied track, and occupy a predetermined place of safety. FRA has added the language ''as described in Table 1 of this section'' to the rule text to ensure that the reader is aware that Table 1 indicates the areas where the work must cease and, in addition to providing clarifications of the rule text, expands upon the requirements.

When Work Must Cease

When the work must cease depends upon which method of on-track safety is being used. If on-track safety is established on the adjacent controlled track through train approach warning in accordance with § 214.329 (either as the sole method of on-track safety or in addition to working limits), all work must cease upon receiving a watchman/lookout warning. *See* § 214.336(b)(1)(ii). On the other hand, if working limits are established on the adjacent controlled track and the roadway work group has not been assigned a watchman/lookout, all work must cease upon receiving a notification that the roadway worker in charge intends to permit one or more train movements or other on-track equipment movements within the working limits on the adjacent controlled track. *See* § 214.336(b)(1)(i). This notification must occur before the roadway worker in charge releases the working limits (or a portion thereof that would affect one or more of the roadway workers in the roadway work group), in order to comply with existing § 214.319(c). *See also,* Table 1 of § 214.336, note 1. It should be noted that FRA has changed the word ''through'' to ''within'' so that there would be no doubt that the ''cease work'' procedures would also be triggered if, for example, a roadway worker in charge decided to permit a train ''within'' the limits, but not all the way ''through'' such limits. This same change has been made to paragraphs (e)(1)(ii) and (f) for consistency throughout this section and with existing § 214.321(d), which states in part that movements of trains and roadway maintenance machines ''within'' working limits shall be made only under the direction of the roadway worker in charge.

Where Work Must Cease

Where the work must cease would depend upon various factors, including the speed of the movement on the adjacent-controlled track, the method(s) of on-track safety being used on one or both sides of the occupied track, and whether the work that is being performed meets one of the exceptions in paragraph (e). In order to help roadway workers and the regulated community at large better understand how these factors determine which procedures they are to follow, FRA has created a table (Table 1) that summarizes how the procedures apply to different factual scenarios. The accompanying diagrams (Figure 1), which were created to correspond to the same example numbers in Table 1, help the reader visualize the factual scenarios. While FRA refers to the tracks in Table 1 and in the diagrams in Figure 1 with specific track numbers, both Table 1 and the diagrams are intended to apply to similarly-situated tracks, regardless of the actual number or letter of the track.

As noted above, Table 1 is part of the rule text of § 214.336 and provides examples of the application of the rest of the rule text, but Table 1 also expands upon the requirements set forth in the paragraphs of § 214.336. One such expansion, which represents a change from the NPRM, is the way in which FRA is interpreting the word ''side.'' The NPRM proposed to require that (upon receiving a notification or a watchman/lookout warning, as applicable) work must cease ''in the fouling space of the occupied track and the adjacent controlled track.'' This language would have created a potential loophole, in which a roadway worker would technically not have been required to cease work in the small area (if any, depending on how closely spaced the track centers are) between the fouling space of the adjacent controlled track (*e.g.,* Track 1 on Side A) and the fouling space of the occupied track (*e.g.,* Track 2) on Side A.

While FRA does not believe that any member of the Working Group intended that work be permitted in any area between the fouling spaces on Side A during a movement on Side A, FRA believes that it would have been reasonable for some members to interpret this language as permitting work to continue *beyond the fouling space* of the occupied track on the *opposite* side of the occupied track (*e.g.,* Side B), since work beyond the fouling space of the occupied track on that side (*e.g.,* Side B) was not specifically addressed by the rule text, and since roadway workers that are fouling any adjacent track on that side would already be required to have on-track safety for that track. However, this interpretation would have presented a potential conflict with the spirit of the proposed language in the NPRM that would have permitted work to occur on a side that ''has an adjacent track or tracks on that side if working limits had been established in accordance with this subpart on the closest adjacent track on that side and there were no movements authorized through the working limits by the roadway worker in charge on that adjacent track.'' [12]

FRA has decided to resolve both the potential loophole and the potential conflict by describing a ''side'' with an adjacent controlled track (including an adjacent track that is being treated as an adjacent controlled track, per § 214.336(a)(2)(ii)), broadly in Table 1 as

[12] 74 FR 61653. FRA noted in the NPRM that, in applying the exception in proposed paragraph (e)(1), this language would have the effect of requiring that working limits be established on an adjacent track (on the side where the on-ground roadway workers are exclusively positioned) that is non-controlled and whose centerline is 25 feet from the centerline of the occupied track, while no form of on-track safety (*i.e.,* working limits or train approach warning) would be required on the adjacent controlled track that is located on the other side of the occupied track and whose centerline is within 12 feet of the occupied track. *See id.* at 61640–61641. FRA sought comment as to the frequency with which these, or similar, circumstances would occur, and whether this language imposed an unreasonable burden. *See id.* at 61641. BMWED and BRS commented that the language proposed in paragraph (e)(1) was overly broad and would impose an unreasonable safety burden on roadway workers, but did not comment as to the frequency of these, or similar, circumstances. FRA received no comments from AAR on this issue, thus it is FRA's understanding that such circumstances are rare.

''the side from the vertical plane of the near running rail of the occupied track extending outward through to the fouling space of the adjacent controlled track.'' FRA does not expect this interpretation of a ''side'' to have a significant cost impact on a railroad because it is FRA's understanding that the railroad would primarily be working on the occupied track (*e.g.,* Track 2) and would not be likely to take Track 3 out of service (*e.g.,* by establishing working limits, if Tracks 1 and 2 are already out of service) unless the work was of such a nature to require that, rather than establishing train approach warning. In such cases, the working limits would already need to be established on that track due to the nature of the work being performed on that track, rather than as a result of this rule. As Track 3 in this scenario would essentially become an extension of the occupied track (where work amongst components of a roadway work group on two tracks is coordinated in much the same way as work amongst components of a roadway work group on the same track), work would be permitted to continue in the fouling space of that track (and the rest of Side B), so long as there are no movements permitted within the working limits on that track (other than movements of the roadway work group that is occupying Tracks 2 and 3). FRA makes clear that it is concerned with ''outside'' movements, as all of the fatalities occurred on an adjacent track with equipment that was not being operated by a roadway worker that was a member of the same roadway work group as the employee that was fatally injured.

Table 1 also illustrates the interrelation of various sections of the rule. For example, note 2 (which is referenced in the center column of examples 1–4, and 6) reminds the reader that, per § 214.336(a)(2)(i), work would no longer be permitted to continue on or between the rails of the occupied track during movement(s) on an adjacent controlled track at 25 mph or less if there is a simultaneous movement on the other adjacent controlled track at more than 25 mph.

Note 2 of Table 1 further provides that on-ground work is prohibited in the areas 25′ in front of and 25′ behind equipment (on the occupied track during a low-speed movement on an adjacent controlled track), and must not break the plane of a rail on the occupied track (Track 2) towards a side of the occupied track unless work is permitted on that side. Without this clarifying note, a roadway worker performing on-ground work exclusively between the rails of the occupied track would not technically have been permitted to break the plane of the rail closest to a side of the occupied track (*e.g.,* Side B) on which work was permitted during a low-speed (25 mph or less) movement on an adjacent controlled track. Similarly, in note 3, FRA clarifies that breaking the plane of the rail while working on a side of the occupied track is permitted: 1) During the times that work is permitted on or between the rails of the occupied track in accordance with § 214.336(c) (Procedures for adjacent-controlled-track movements 25 mph or less); or 2) if such work is performed alongside a roadway maintenance machine or coupled equipment in accordance with § 214.336(e)(2).

Another clarifying point in the table worth noting is that, while the rule permits train approach warning to be used as a method for providing on-track safety for an adjacent controlled track, work that is being performed under train approach warning on both sides of an occupied track (assuming there is an adjacent controlled track on each side of the occupied track) must cease on both sides of the occupied track upon receiving a watchman/lookout warning for a train or other on-track equipment movement (at any speed) on the adjacent controlled track on either side. *See* Table 1, Ex. 4. This is the practical effect of not meeting the conditions for permitting work to continue on a side of the occupied track under the exception in paragraph (e)(1)(ii), which permits work on a side with one or more adjacent tracks if the closest adjacent track has working limits on it and no movements permitted within such working limits. The cessation of work on both sides of the occupied track is necessary to ensure that a roadway worker will not mistake a watchman/lookout's warning regarding a train on Track 1, for example, for a warning regarding a train on Track 3, and vice versa.

Additionally, FRA makes clear that upon receiving the warning for a train on Track 1 in the above scenario, it would not be safe for a roadway worker to occupy Track 3 as a predetermined place of safety, as a train could arrive on that track at any time during the movement on Track 1. Rather, the predetermined place of safety must be clear of all tracks that do not have working limits established on them (with no outside movements within such limits), and may be the space between the rails of the occupied track under such circumstances. *See* Table 1, note 1; *see also* Section VI.D.6 of this preamble (regarding the response to comments concerning a predetermined place of safety).

Paragraph (b)(2), Resuming Work

Regarding when the work required to cease in paragraph (b)(1) is permitted to resume, paragraph (b)(2) provides that an affected roadway worker may resume on-ground work and equipment movement (on or between the rails of the occupied track or on one or both sides of the occupied track as described in Table 1 of this section) only after the trailing-end of all trains or other on-track equipment moving on the adjacent controlled track (for which a warning or notification has been received in accordance with paragraph (b)(1) of this section) has passed and remains ahead of that roadway worker. As discussed in Section VI.D.5 of this preamble, FRA received comments from AAR indicating that work performed exclusively between the rails of the occupied track or on the side of the occupied track furthest from the movement should be permitted to resume when the leading end of the equipment has passed.

FRA has decided in this final rule that each affected roadway worker whose work is not subject to an exception shall not be permitted to resume such work until after the entire movement (the trailing-end of the movement) has passed by the location of the roadway worker, due to the concerns raised by BMWED and BRS on this issue. Those concerns include hazards presented to roadway workers by abnormal consist conditions (*e.g.,* ''shifted loads/shifted ladings, loose banding, dragging chains/binders, loose brake piping, loose/swinging boxcar doors, [and] fragmented brake shoes'') and by ''dust, rust, debris, stone, and track construction/maintenance materials,'' which may become airborne while trains pass roadway workers. For the reasons set forth in the NPRM and above, FRA has adopted the above language in this final rule, with modifications for consistency with other modified sections. For example, ''a component of a roadway work group'' was changed to ''an affected roadway worker,'' and the descriptions of the equipment and where the work needed to cease was revised to parallel the language for ceasing work in new paragraph (b)(1).

If the train or other on-track equipment stops before its trailing-end has passed all of the affected roadway workers in the roadway work group, the work to be performed (on or between the rails of the occupied track or on one or both sides of the occupied track as described in Table 1 of this section) ahead of the trailing-end of the train or other on-track equipment on the

adjacent controlled track may resume only under two circumstances. First, this work may resume if on-track safety through train approach warning (§ 214.329) has been established on the adjacent controlled track.[13] *See* § 214.336(b)(2)(ii)(A). Second, this work may resume if the roadway worker in charge has communicated with a member of the train crew or on-track equipment operator and established that further movements of such train or other on-track equipment shall be made only as permitted by the roadway worker in charge. *See* § 214.336(b)(2)(ii)(B).

FRA received no comments on the proposed language in paragraph (b)(2)(ii) of the NPRM. For the reasons stated in the NPRM, FRA has adopted the proposed language with two minor modifications, namely, revising the description of where the work would need to cease to parallel the language for the requirement to cease work in new paragraph (b)(1), and changing ''the train engineer or equipment operator'' to ''a member of the train crew or the on-track equipment operator'' to be more consistent with § 214.325(b) (regarding train coordination).

Paragraph (c), Procedures for Adjacent-Controlled-Track Movements 25 mph or Less

The procedures for adjacent-controlled-track movements at a speed of 25 mph or less are the same as those procedures for adjacent-controlled-track movements at a speed greater than 25 mph, except that certain work would be permitted to continue, due to the low speed of the movements. In paragraph (a)(2), FRA makes clear that if an occupied track has two adjacent controlled tracks, and one of the tracks has one or more adjacent-controlled-track movements authorized at a speed of 25 mph or less, and the other has one or more concurrent adjacent-controlled-track movements authorized at a speed greater than 25 mph, the more restrictive procedures in paragraph (b) apply.

Paragraph (c) provides that ''equipment movement on the rails of the occupied track and on-ground work performed exclusively between the rails (*i.e.,* not breaking the plane of the rails) of the occupied track may continue'' during low-speed movements on adjacent controlled tracks, ''provided that no on-ground work is performed within the areas 25 feet in front of and 25 feet behind any on-track, self-propelled equipment or coupled equipment that is moving or permitted to move on the occupied track.'' Thus, unless the work falls under one of the exceptions in paragraph (e), an affected roadway worker (after receiving a warning or notification of an adjacent-controlled-track movement at any speed [14]) would be required to cease all on-ground work within the areas 25 feet in front of and 25 feet behind any on-track, self-propelled equipment or coupled equipment that is moving or permitted to move on the occupied track. The words ''that is moving or permitted to move'' were added to this condition to permit some (very limited) flexibility where preventative measures are in place to ensure that the equipment would not move and pose a danger or distraction to the on-ground roadway workers in its immediate vicinity. FRA makes clear, however, that stationary on-track, self-propelled equipment or coupled equipment located on the occupied track is considered to be ''permitted to move'' for purposes of this section unless it is expressly prohibited from moving by the roadway worker in charge (and discussed in an on-track safety job briefing) or an operating rule of the railroad that prohibits all such equipment movement on the occupied track during a low-speed movement on an adjacent controlled track.

For the reasons set forth in the NPRM, FRA has decided to adopt the Working Group's recommendation of a 25-foot buffer zone as a condition for permitting work to continue as described in paragraph (c). FRA has modified the language proposed in the NPRM for consistency with other changes to the rule text in this final rule, such as adding the concept of the ''affected'' roadway worker, and also to add clarity. For example, the NPRM language phrased the 25-foot buffer zone condition in part as, ''provided that any on-ground work is performed more than 25 feet in front of or behind any roadway maintenance machine;'' however, this language may have been interpreted by some as prohibiting work alongside equipment (to verify the quality of the work being performed by that equipment, for example) on a side of the occupied track meeting specified condition(s) (*see* § 214.336(e)(1)), which FRA intended to permit. *See* 74 FR 61647. FRA has also revised the applicability of the prohibition to the 25-foot areas in front of and behind any ''on-track, self-propelled equipment or coupled equipment,'' rather than ''roadway maintenance machines,'' because the need to maintain a safe distance between on-ground roadway workers and such equipment is the same as the need to maintain a safe distance between on-ground roadway workers and roadway maintenance machines on the occupied track. Additionally, FRA does not believe that the Working Group intended to recommend requiring a distance between on-ground roadway workers and smaller roadway maintenance machines that are not rail-mounted (*i.e.,* that are not designed to operate on the rails of a track) and self-propelled, such as pneumatic hand tampers, as it is FRA's understanding that the machine-spacing requirements already in existence (per § 214.341(a)(5)) do not apply to these types of roadway maintenance machines.

Paragraph (c) has also been revised from that proposed in the NPRM to permit the continuation of on-ground work that is performed ''exclusively between the rails (*i.e.,* not breaking the plane of the rails) of the occupied track,'' rather than ''exclusively while positioned on or between the rails of the occupied track,'' provided that the on-ground work is not performed within the 25-foot areas discussed above. This revision provides a clear, ''bright line'' approach to make it easier both for roadway workers and the regulated community at large to follow and for FRA to enforce. As a result, on-ground roadway workers must be mindful not to break the plane of the rail with his or her person or tools towards a side of the occupied track on which work is prohibited during a low-speed movement on an adjacent controlled track. *See* Table 1, note 2. If, however, work is permitted on one side of the occupied track during the low-speed movement, then the roadway worker is permitted to break the plane of the rail on that side only. *See id.*

The NPRM had also proposed a second set of circumstances in paragraph (c) for permitting work to continue during a low-speed movement

[13] It should be noted that the train approach warning option provided in new § 214.336(b)(2)(ii)(A) would not be permitted alongside the train on the adjacent controlled track (or for a certain distance on the occupied track ahead of the location of the train on the adjacent controlled track), since the train, if it were traveling at the ''maximum speed authorized on that track'' would already be at the roadway worker's location (or, at certain distances, would be able to reach the roadway worker's location sooner than 15 seconds) and would not permit the watchman/lookout to give the roadway worker any (or sufficient) time to clear. Under such circumstances, work would not be permitted to resume until the conditions in § 214.336(b)(2)(ii)(B) have been met, or until the train resumes its movement and its trailing-end passes the affected roadway worker's location, whichever comes first.

[14] If the movement were authorized or permitted at a speed greater than 25 mph, on-ground work not subject to an exception would need to cease between the rails of the occupied track regardless of whether the work is being performed more than 25 feet from on-track, self-propelled equipment or coupled equipment on the occupied track.

on an adjacent controlled track, which was when the work is performed to the ''clear side'' of the occupied track, provided that it is performed outside of the 25-foot areas described above. However, this set of circumstances was for the most part repetitive of what was proposed in the exceptions in paragraph (e) and was really provided as more of a cross-reference so that the reader would be able to understand the range of work that was permissible during a low-speed movement on an adjacent controlled track. Given that the proposed term ''clear side'' has not been adopted in this final rule and that FRA has created a table and diagrams that provide a more comprehensive overview of how the exceptions fit in with the general rules and procedures of this section (*see, e.g.,* Table 1, note 3; Figure 1, Ex. 2), FRA has decided that replacing the term ''clear side'' with a cross-reference to the language in paragraph (e) is not necessary.

It should also be noted that paragraph (c) only directly addresses the types of work that a roadway worker in the roadway work group affected by the movement on the adjacent controlled track may continue performing. Paragraph (c) does not directly address when all other work (*i.e.,* work that paragraph (c) does *not* cover) may resume. Thus, roadway workers who are assigned to perform work not covered by paragraph (c) must follow the procedures in paragraph (b)(2). For example, since on-ground work that would need to be performed between the rails *and* near a roadway maintenance machine (*i.e.,* in the 25-foot areas in front of or behind the specified equipment that is on the occupied track) is not covered by paragraph (c), such work must cease upon receiving a warning or notification (as applicable) and is not permitted to resume until the conditions in paragraph (b)(2) have been fulfilled. That is to say, such work (as well as all other work that an affected roadway worker must cease, as noted in paragraph (b)(1), that is not permitted to continue by paragraph (c) and not subject to one of the exceptions in paragraph (e)) is permitted to resume only after the trailing-end of all movements (for which a warning or notification (as applicable) has been received in accordance with paragraph (b)(1) of this section) has passed by (and remains ahead of) the affected roadway worker (including any equipment or tools that he or she is using).

Paragraph (d), Discretion of Roadway Worker in Charge

This paragraph emphasizes that the on-track safety procedures of this section are minimum requirements, and that a roadway worker in charge is free to establish on-track safety on one or more adjacent tracks as he or she deems necessary consistent with both the purpose and requirements of this subpart. This paragraph was proposed in the NPRM as paragraph (f), but has been switched with what was proposed as paragraph (d) (''Procedures for a roadway maintenance machine or coupled equipment fouling an adjacent controlled track'') in order to accommodate a potential future deletion of that paragraph as discussed in the analysis of paragraph (f), below.

Paragraph (d) is based on the language recommended by the Working Group in consensus paragraphs (e)(1) and (3) for the reasons described in the preamble of the NPRM. No comments on paragraph (f) as proposed in the NPRM have been received, and proposed paragraph (f) has been adopted verbatim in this final rule as paragraph (d).

Paragraph (e), Exceptions to the Requirements in Paragraphs (a), (b), and (c) for Adjacent-Controlled-Track On-Track Safety

The Working Group also discussed, and the RSAC recommended, that there be three exceptions when adjacent-controlled-track on-track safety would not have to be established at all. *See* consensus paragraphs (e)(1) through (3). In this final rule, FRA has adopted all three exceptions proposed in the NPRM, with modifications for clarity, and has also adopted two additional exceptions on which FRA sought comment. *See* § 214.336(e); 74 FR 61641–42.

In this final rule, the introductory language and heading in paragraph (e) clarify that this paragraph is not meant to exempt roadway workers from having to establish on-track safety in accordance with paragraphs (d) (Discretion of roadway worker in charge) or (f) (Procedures for components of roadway maintenance machines fouling an adjacent controlled track). Rather, paragraph (e) is meant to exempt roadway workers from the requirements in paragraphs (a), (b), and (c) for adjacent-controlled-track on-track safety during the times that the roadway work group is exclusively performing one or more of the work activities listed in paragraphs (e)(1) through (3).

Paragraph (e)(1), On-Ground Work Performed on a Side of the Occupied Track Meeting Specified Conditions(s)

The first exception to the requirement for adjacent-controlled-track on-track safety is for on-ground work performed on a side of the occupied track meeting specified condition(s) that would ensure that those performing the work would essentially not be exposed to danger caused by a train movement on any adjacent track on that side. FRA believes that there are three types of sides meeting a condition (or sets of conditions) that make it safe for on-ground work to be performed on that side of an occupied track while there is no on-track safety (or the on-track safety, such as a Form B (a form of exclusive track occupancy) has been temporarily nullified to permit a train within or through the working limits) on the opposite side of the occupied track.

The first type of side of the occupied track is a side with no adjacent track. *See* § 214.336(e)(1)(i). This means that either that side has no track whatsoever, or else that the closest track on that side is at least 25 feet away from the occupied track (as measured from track center to track center). In the latter situation, there is sufficient distance to prevent inadvertent fouling of an adjacent track, as supported by the accident data as well as by current (through the effective date of this rule) § 214.335(c), which does not require on-track safety on tracks that are at least 25 feet away even if the work is considered ''large-scale maintenance or construction.''

If, on the other hand, a side of the occupied track has one or more adjacent tracks (*i.e.,* one or more tracks within 25 feet), then work is permitted on that side by this final rule only if either (1) the closest adjacent track on that side has working limits on it and no movements permitted within such working limits by the roadway worker in charge, or (2) there is an inter-track barrier (meeting specified criteria) between the occupied track and the closest adjacent track on that side. *See* §§ 214.336(e)(1)(ii) and (iii) and 214.336(a)(3) (definition of ''inter-track barrier'').

In this final rule, FRA has considered the additional comments raised by BMWED and BRS on this section, particularly on the use of the term ''clear side,'' and has removed the term to eliminate any confusion. However, FRA still believes that it is safe to work on the side of an occupied track with working limits on the closest adjacent track on that side and no movements permitted within such limits on that

side, and that establishing the near running rail as a demarcation point is a bright line approach that will make it easier both for the roadway workers and the regulated community at large to follow and for FRA to enforce. In addition, as discussed in the comments addressing the inter-track barrier in Section VI.D.4, above, FRA also believes that it is safe to work on a side of the track that has an inter-track barrier (''a continuous barrier of a permanent or semi-permanent nature that spans the entire work area, that is at least four feet in height, and that is of sufficient strength to prevent a roadway worker from fouling the adjacent track'') between the occupied track and the closest adjacent track on that side. *See* §§ 214.336(a)(3) (''inter-track barrier'') and 214.336(e)(1)(iii).

Paragraph (e)(2), Maintenance or Repairs Performed Alongside Machines or Equipment on the Occupied Track

The second exception to the requirements for adjacent-controlled-track on-track safety is for maintenance or repairs performed alongside roadway maintenance machines or coupled equipment (located on the occupied track), provided that such machine or equipment would effectively prevent the worker from fouling the adjacent controlled track on the other side of such equipment, and that such maintenance or repairs are performed while positioned on a side of the occupied track where there should essentially be no danger posed by any other adjacent track (*i.e.,* a side of the occupied track as described in paragraph (e)(1)(i), (ii), or (iii) and Table 1 of this section). This new exception is really an outgrowth of the first exception which, as proposed in the NPRM, would have permitted this type of work to be performed during a train or other on-track equipment movement on the opposite side of the occupied track. However, the joint comments of BMWED and BRS expressed concern that work should not be permitted in the foul of the occupied track (even if mostly positioned on the side opposite from the movement) unless the machine acted as a physical barrier between the roadway worker and the adjacent controlled track on which the movement was occurring.

As this final rule adopts a bright line approach that would generally not permit a roadway worker to break the plane of a rail (into the gage of the occupied track towards an adjacent controlled track on which a movement is occurring), and since, in order to change out a grinding stone (one of the examples the Working Group sought to address), the bright line of the rail must necessarily be crossed, FRA has decided to adopt this physical barrier concept for any work that would need to cross the plane of the rail into the gage of the occupied track. Thus, this final rule permits one or more roadway workers to perform maintenance or repairs alongside a roadway maintenance machine or coupled equipment, provided that (1) such machine or equipment would effectively prevent the worker from fouling the adjacent controlled track on the other side of such equipment, and (2) that such maintenance or repairs are performed while positioned on a side of the occupied track as described in paragraph (e)(1)(i), (ii), or (iii) and Table 1 of this section. FRA specifically refrained from using the word ''barrier'' to describe this first condition in the rule text, so that it would not be confused with the exception involving an ''inter-track barrier.'' The second condition ensures that the roadway worker will remain out of harm's way because he or she will need to be positioned (standing, kneeling, sitting, squatting, or lying with both feet outside of the gage of the track) for the most part on a side meeting specified condition(s) (as described in paragraph (e)(1) and Table 1) while performing such maintenance or repairs. For example, paragraph (e)(2) permits a roadway worker to refuel a roadway maintenance machine, if the machine would effectively prevent the worker from fouling the adjacent controlled track on the other side of such equipment and he or she is able to do so while positioned (for the most part) on a side meeting the specified condition(s).

Paragraph (e)(3), Work Activities Involving Certain Equipment and Purposes

The third exception to the requirements for adjacent-controlled-track on-track safety is for work activities involving certain types of equipment used for certain purposes. Specifically, this exception applies to one or more on-ground roadway workers engaged in a common task on an occupied track with on-track, self-propelled equipment or coupled equipment consisting exclusively of one or more of three types of equipment: hi-rail vehicles; automated inspection cars; and catenary maintenance tower cars. This language mimicking the triggering language in paragraph (a)(1) was moved to the introductory text in paragraph (e)(3), rather than having to repeat it multiple times in the paragraphs that follow paragraph (e)(3) (that is, paragraphs (e)(3)(i), (ii), and (iii)).

The exception for the first type of equipment (hi-rail vehicles) was proposed in the NPRM as paragraph (e)(2) of this section, but has been modified in this final rule for clarity and in response to comments. *See* § 214.336(e)(3)(i) of this final rule. A hi-rail vehicle is defined by § 214.7 as ''a roadway maintenance machine that is manufactured to meet Federal Motor Vehicle Safety Standards and is equipped with retractable flanged wheels so that the vehicle may travel over the highway or on railroad tracks.'' As discussed in Section IV of this preamble, there has been only one adjacent-track fatality where a roadway work group had been engaged in a common task with a hi-rail vehicle as defined in § 214.7, and the roadway workers in that case were under the impression that adjacent-track on-track safety was in effect when, due to a miscommunication, it was not. Given the circumstances of the one fatality and because the duties normally performed by an employee operating a hi-rail vehicle tend to be less distracting to on-ground roadway workers and produce less dust and noise than a typical on-track roadway maintenance machine, FRA proposed in the NPRM that adjacent-track on-track safety not be required for roadway work groups engaged in a common task with a hi-rail vehicle. Additionally, FRA proposed that, in accordance with § 214.315(a)(3), where multiple hi-rail vehicles are engaged in a common task, the on-track safety briefing shall include discussion of the nature of the work to be performed to determine if adjacent-controlled-track on-track safety is necessary.

The final rule adopts this proposed exception, but limits it to those hi-rail vehicles being used only for inspection or minor correction purposes. This new limitation is imposed in response to comments from BMWED and BRS that this restriction intended by the consensus language, and that failing to impose this limitation would permit work to be performed by hi-rail vehicles that is equally as distracting (such as a thermite welding crew working out of the back of a large hi-rail vehicle work platform) as that performed by other types of on-track, self-propelled equipment or coupled equipment subject to the requirements of this section. FRA has added a definition of the term ''minor correction purposes'' to paragraph (a)(3) of this section for additional clarity. Additionally, paragraph (e)(3)(i) has been revised for clarity by adding the parenthetical ''(other than a catenary maintenance

tower vehicle)'' after the words ''a hi-rail vehicle'' because some catenary maintenance tower vehicles are also hi-rail vehicles, and FRA intends that roadway workers engaged in a common task with this subset of hi-rail vehicles are instead subject to the different conditions imposed in paragraph (e)(3)(iii).

Finally, as discussed above in Section VI.D.2 of this preamble, in response to the concern raised by AAR (and a similar concern raised by APTA) that a hi-rail vehicle that is operated within the same working limits but a considerable distance away from the distractions of the roadway work group would not qualify for the exception, FRA has modified the language in proposed paragraph (e)(2) of the NPRM (now in paragraph (e)(3)), so as to permit the exception to still apply if certain conditions are met. In this situation, this final rule requires that the groups conduct an on-track safety job briefing to determine if adjacent-controlled-track on-track safety is necessary for the excepted group. The determination as to whether on-track safety is necessary for the excepted group shall be made by the roadway worker in charge of the working limits, rather than by the roadway worker in charge of the entering group. The roadway worker in charge of the working limits has the discretion to require on-track safety for the excepted group; however, if the two groups are in such proximity where the ability of the roadway workers in the excepted group to hear or see approaching trains and other on-track equipment is impaired by background noise, lights, sight obstructions or any other physical conditions caused by the equipment, then this exception does not apply, regardless of the roadway worker in charge's initial determination, and adjacent-controlled-track on-track safety must be provided to both groups.

The second type of equipment (''automated inspection cars'') is a new exception on which FRA had sought comment in the NPRM. *See* § 214.336(e)(3)(ii); 74 FR 61641, 61648. As discussed in Section VI.D.3, above, AAR had requested in its comments on the first (July 17, 2008) NPRM that the exception for hi-rail vehicles be expanded to include rail-bound geometry and detection equipment, since the level of distraction posed by this equipment is similar to that of hi-rail vehicles. AAR suggested that FRA expand the hi-rail vehicle exception by adding ''or self-propelled track geometry or detector car'' after ''a hi-rail vehicle.'' In seeking comments on AAR's request in the November 25, 2009 NPRM, FRA noted that ''it seems that the level of distraction is similar for a roadway worker on the ground who is field-verifying a measurement behind a geometry car and a roadway worker on the ground who is replacing a bolt behind a hi-rail.'' 74 FR 61641.

BMWED and BRS commented that they believed that the distractions are dissimilar, in that the detector cars are larger (reducing visibility) and much louder than a hi-rail pickup, and could therefore affect a person's ability to detect the approach of a train. Additionally, they note that there are other operators of roadway maintenance machines performing a common task with such detection equipment who will also be at risk. APTA expressed support for expanding the ''hi-rail vehicle'' exception to self-propelled detector (and ''inspection-type'') cars, noting its belief that self-propelled detector cars are under the same circumstances as hi-rail vehicles, and thus, should be granted the same exemption.

FRA has decided to adopt an exception in new paragraph (e)(3)(ii) for ''an automated inspection car being used for inspection or minor correction purposes'' because the level of distraction posed by the task of inspecting or performing minor correction is the same, and if there are other roadway maintenance machines (presumably on-track, self-propelled equipment or coupled equipment not meeting the exception) performing a common task with such equipment, then the roadway work group would be subject to the requirements of this section by virtue of the presence of the other equipment. An automated inspection car includes rail-mounted, non-highway, self-propelled or coupled equipment whose primary purpose is to take measurements or collect data concerning the railroad right of way, such as rail-bound track geometry cars, gage restraint measurement system cars, and rail flaw detector cars. It does not generally include a locomotive equipped with vehicle-track interaction because the primary purpose of that locomotive is to haul freight or passenger cars, rather than to take measurements or collect data concerning the railroad right of way. If, however, such locomotive is hauling only a rail-bound geometry car that is taking measurements and collecting data along the railroad right-of-way, then this coupled equipment would be considered an automated inspection car for purposes of this section. Additionally, FRA considered that inspection or minor correction work performed by a roadway work group with this type of equipment would clearly not have triggered the requirement for adjacent-track on-track safety under the former § 214.335(c) (as this would not have been considered ''large scale maintenance or construction'').

The third type of equipment (catenary maintenance tower cars or vehicles) was proposed in the NPRM as paragraph (e)(3) of this section, and has been modified in this final rule for clarity and consistency. *See* § 214.336(e)(3)(iii) of the final rule. FRA had proposed in the NPRM that an exception be adopted for a catenary maintenance tower car with one or more roadway workers positioned on the ground within the gage of the occupied track for the sole purpose of applying or removing grounds. As discussed in Section IV of this preamble and in the NPRM, there have been no adjacent-track fatalities where a roadway work group had been engaged in a common task with a catenary maintenance tower car on the occupied track, and the duties normally performed by an employee operating a catenary maintenance tower car tend to be less distracting to on-ground roadway workers and produce less dust and noise than a typical on-track roadway maintenance machine.

No comments were received on this exception, and FRA has adopted the proposed exception with two modifications for clarity, along with other changes for consistency with the hi-rail vehicle exception (including moving similar language from the proposal for hi-rail vehicles and the proposal for catenary maintenance tower cars into introductory paragraph (e)(3)). First, the words ''or vehicle'' have been added to the end of ''catenary maintenance tower car'' to clarify that some of these maintenance machines are railroad cars and others are vehicles, but both are subject to the conditions of this exception. Second, FRA is requiring that all of the on-ground workers engaged in the common task (other than those performing work in accordance with another exception in paragraph (e) of this section), rather than ''one or more roadway workers,'' be positioned within the gage of the occupied track for the sole purpose of applying or removing grounds. This language is necessary because otherwise, one could interpret that as long as one of the roadway workers was positioned in the gage of the occupied track, the rest were permitted to be outside of the gage. Note that these roadway workers are permitted to break the vertical plane of the rail of the occupied track in order to apply or remove a ground (as it is not always possible to do so without

breaking the plane of the rail) as long as they would still be positioned for the most part within the gage of the occupied track (*i.e.,* standing, kneeling, sitting, or squatting with both feet between the rails of the occupied track).

Paragraph (f), Procedures for Components of Roadway Maintenance Machines Fouling an Adjacent Controlled Track

Regarding the prohibition in consensus paragraph (d) against ''equipment'' fouling an adjacent controlled track unless protected by working limits, FRA had changed the term to ''roadway maintenance machines'' in the language proposed in the NPRM to clarify that this prohibition is meant to be broad and includes hi-rail vehicles that would otherwise come under the exception in paragraph (e)(2)(ii). Further, FRA clarified in the NPRM that the prohibition is not meant to be so broad as to forbid a roadway worker from using readily portable tools or equipment similar to a jackhammer, such as a pneumatic tamping gun or a spike driver, on an adjacent controlled track while afforded on-track safety through train approach warning. FRA urged that employers and employees use common sense in determining which tools or equipment they would permit to be used or use under train approach warning. If there is any doubt as to whether the tools or equipment could be readily removed, the employee must not foul the track with those tools or equipment under train approach warning provided by watchmen/lookouts (§ 214.329). Because the issue of fouling a track with heavier tools or equipment is not unique to the adjacent-controlled-track context, FRA has decided to address the issue in the larger RWP rulemaking in the section concerning the appropriate use of train approach warning (§ 214.329). In the event that FRA is able to address the issue broadly in that section, FRA has moved the language proposed in paragraph (d) to paragraph (f), and vice versa, so that this paragraph would be able to be deleted without leaving a gap in the rule text paragraphs.

Additionally, in order to avoid a potential conflict with an existing section in part 214, and to make the final rule consistent with that language, FRA has added the introductory phrase ''[e]xcept as provided for in § 214.341(c),'' and the modifying language ''a component of'' ahead of the remainder of the requirement in this final rule that ''a roadway maintenance machine shall not foul an adjacent controlled track unless working limits have been established on the adjacent controlled track and there are no movements permitted within the working limits by the roadway worker in charge that would affect any of the roadway workers engaged in a common task with such machine.'' This language has also been modified from that proposed in the NPRM by (1) making ''roadway maintenance machines'' singular to ensure that the prohibition is applied to each machine; (2) substituting ''within the working limits'' for ''through the working limits'' to ensure that a movement that is permitted within the working limits, but not all the way ''through'' would still trigger the prohibition against fouling in this paragraph; and (3) adding ''that would affect any of the roadway workers engaged in a common task with such machine'' at the end of the sentence so that a movement permitted within the limits of the authority, but short of the group's working limits (that would therefore not affect the roadway workers) would not trigger this prohibition.

VIII. Regulatory Impact and Notices

A. Executive Orders 12866 and 13563 and DOT Regulatory Policies and Procedures

This final rule has been evaluated in accordance with existing policies and procedures in Executive Orders 12866 and 13563 and DOT policies and procedures, and determined to be significant under both Executive Order 12866 and DOT policies and procedures. *See* 44 FR 11034, Feb. 26, 1979. FRA has prepared and placed in the docket a Regulatory Impact Analysis (RIA) addressing the economic impact of this final rule. Document inspection and copying facilities are available at the Federal Docket Management Facility, U.S. Department of Transportation, West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. Docket material is also available for inspection on the Internet at *http://www.regulations.gov.* Photocopies may also be obtained by submitting a written request to the FRA Docket Clerk at Office of Chief Counsel, Mail Stop 10, Federal Railroad Administration, 1200 New Jersey Avenue SE., Washington, DC 20590; please refer to Docket No. FRA–2008–0059, Notice No. 4.

Certain requirements contained in this rule reflect current industry practice, restate existing regulations, or both. As a result, in calculating the costs of this final rule, FRA has included neither the costs of those actions that would be performed voluntarily in the absence of a regulation, nor the costs of those actions that are required by an existing regulation. Similarly, in estimating the benefits of this final rule, FRA has included neither the benefits that result from those actions that would be performed voluntarily in the absence of a regulation, nor the benefits that result from those actions that are required by an existing regulation.

This analysis includes quantitative measurements and qualitative discussions of implementation costs for this final rule. The costs will primarily be imposed by a small increase in job briefing time and additional resources spent to provide on-track safety for the safe conduct of other than large-scale maintenance and construction of track located adjacent to (and within a certain distance of) one or more controlled tracks on which train movements may be occurring. Training costs will also accrue. The benefits will primarily accrue from a reduction in roadway worker casualties (fatalities and injuries). Business benefits stemming from avoided train delays and property damages will also accrue, as well as benefits from reduced safety stand downs.

At the NPRM stage, FRA found that the accident-reduction benefits expected to accrue over the first 20 years of the rule would exceed and justify the costs imposed. Cost estimates were based on an uncertain level of existing compliance with proposed requirements resulting from a strong safety culture. Although FRA requested comments on the actual level of such compliance, FRA received no comments. However, FRA reviewed its methodology and found that some improvements could be made, making the analysis more robust.

First, FRA increased the data period on which it based its estimate of fatalities, from a four-year period to a ten-year period, 1999–2008. This reduced the expected number of fatalities avoidable (had new § 214.336 been in effect) from 1.0 per year to 0.6 per year. It should be noted that FRA also added a benefit in this final rule for the revised on-track safety job briefing requirements in § 214.315, as the revised requirements will affect roadway workers broadly, and not just those required to establish adjacent-track on-track safety. Then, FRA estimated the number of injuries avoidable directly from casualty data, instead of from a loose ratio of injuries to fatalities. This reduced the number of injuries avoidable per year from approximately 11 to 9.36. FRA then applied recently updated values for monetizing benefits from casualties avoided. This entailed increasing the value of a statistical life (VSL) from $6.0

million to $6.2 million, increasing the ratio of estimated costs per Abbreviated Injury Scale Level 3 injuries from 0.0595 times VSL to 0.105 times VSL, and using a range of VSL from 55 percent to 145 percent of the basic VSL value, $6.2 million, for sensitivity analysis.

For the 20-year period analyzed, the estimated quantified cost that will be imposed on industry totals $285.7 million, with a present value (PV) (7 percent) of $151.4 million, and a PV (3 percent) of $212.6 million. For the same 20-year period, the estimated quantified benefits total $286.2 million, with a PV (7 percent) of approximately $151.6 million and a PV (3 percent) of $212.9 million. Based on the annual fatality rate leading up to this rulemaking, this analysis estimates that there will be 10.3 fewer roadway worker fatalities over the next 20 years. In addition, it estimates that this final rule will reduce roadway worker injuries by 182 over the next 20 years.

This analysis has been conducted using an implicit assumption that railroads continue existing maintenance and scheduling practices. In the past, when FRA has promulgated a new regulation, railroads have adapted their operations over time to reduce the adverse impact of the regulation. FRA is not in a position to predict how railroads may adapt their operations, but, clearly, the railroads have an incentive to reduce the adverse impact of such events as slowing a train as it passes a work site. Hence, FRA believes that the railroads also have the ability to reduce such impacts. Therefore, this analysis has been conservative in using current operating and maintenance practices when calculating the burdens from this final rule.

The following table presents the estimated quantified costs broken down by section of the RIA and by section of the rule:

Estimated cost of final rule	PV rate, 3%*	PV rate, 7%*
9.2 Job Briefings—§ 214.315	$1.94	$1.38
9.4 On-Track Safety—§ 214.336	207.60	147.83
9.4 Other (Signalmen, Lone Workers)—§§ 214.315/336	2.76	1.97
9.4 Training—§ 214.336	0.25	0.18
Total	212.55	151.36

* Dollars are in millions and are discounted over a 20-year period.

FRA believes that introduction of wireless technologies, such as Positive Train Control, may offer opportunities to reduce costs in the years to come. For instance, such wireless technologies may reduce the necessity to post watchmen/lookouts because automatic notification of crews may be possible. FRA is aware of at least two railroads that currently use or have successfully tested an advanced automatic warning system for roadway workers.

The table below presents the estimated benefits associated with this final rule by section of the RIA and by benefit category:

Estimated benefits of final rule	PV rate, 3%*	PV rate, 7%*
10.1 Casualty Mitigation (§ 214.336)—Fatality (Struck by Train)	$43.72	$31.13
10.2 Casualty Mitigation (§ 214.336)—Injury (Struck by Train)	71.62	51.00
10.3 Casualty Mitigation (§ 214.336)—Injury (Struck by Object Other Than Train)	15.30	10.90
10.4 Adjacent Track Revision	9.79	6.97
10.5 Damage Reduction	0.89	0.64
10.6 Reporting/Recordkeeping—Cost Savings	0.02	0.01
10.7 Business Industry Benefit	46.71	33.26
10.8 Reduction in Safety Stand Downs	19.98	14.23
10.9 Job Briefing Fatality Prevention (§ 214.315)	3.69	2.63
10.9 Job Briefing Injury Prevention (§ 214.315)	1.16	0.83
Total	212.88	151.59

* Dollars are in millions and are discounted over a 20-year period.

In accordance with guidance from DOT, the RIA casualty prevention benefits are based on the value of a statistical life being $6.2 million. Office of Management and Budget (OMB) Circular A–4 states that the majority of studies on the value of a statistical life use values that range from approximately $1 million to $10 million. Use of a higher or lower value of a statistical life could significantly affect potential safety benefits and, ultimately, the relative ratio of costs to benefits for this rulemaking. In recognition of this potential impact and the imprecision of assumptions regarding the value of a statistical life, FRA also analyzed the sensitivity of its findings by evaluating safety benefits using the values of $3.41 million and $8.99 million (*i.e.,* the DOT value of a statistical life ($6.2 million) plus or minus 45 percent).

Applying $6.2 million for the value of a statistical life produces a total benefit of $286.2 million, with a discounted value of $151.6 million (PV, 7 percent) or $212.9 million (PV, 3 percent). If $3.41 million is used for the value of a statistical life, then the total benefit would be $204.2 million with a discounted value of $108.2 million (PV, 7 percent) or $151.9 million (PV, 3 percent). If $8.99 million is used for the value of a statistical life, then the total benefit would be $368.1 million with a discounted value of $195.0 million (PV, 7 percent) or $273.8 million (PV, 3 percent). The following table represents the range of benefits according to discount rate:

Benefit range analysis	3% Discount rate	7% Discount rate
$3.41 Million Value of Statistical Life	$151,906,156	$108,169,968
$8.99 Million Value of Statistical Life	273,849,809	195,004,112

FRA finds that the estimated quantified benefits will exceed the estimated quantified costs. Quantitative methodologies such as this benefit-cost analysis are a useful way of organizing and comparing the favorable and unfavorable effects of regulations like this one. A benefit-cost analysis does not provide a policy answer, but rather defines and displays a useful framework for debate and review.[15]

B. Regulatory Flexibility Act and Executive Order 13272

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) and Executive Order 13272 (67 FR 53461, Aug. 16, 2002) require agency review of proposed and final rules to assess their impact on small entities. FRA has prepared and placed in the docket a Certification Statement indicating that this final rule is not expected to have a significant economic impact on a substantial number of small entities. Document inspection and copying facilities are available at the Docket Management Facility, U.S. Department of Transportation, West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. Docket material is also available for inspection on the Internet at *http://www.regulations.gov.* Photocopies may also be obtained by submitting a written request to the FRA Docket Clerk at Office of Chief Counsel, Mail Stop 10, Federal Railroad Administration, 1200 New Jersey Avenue SE., Washington, DC 20590; please refer to Docket No. FRA–2008–0059, Notice No. 4.

In order to determine the significance of the economic impact for the final rule's Regulatory Flexibility Act requirements, FRA invited comments from all interested parties concerning data and information regarding the potential economic impact caused by the proposed rule, during the comment period. No comments were received pertaining to the potential impact on small entities.

''Small entity'' is defined in 5 U.S.C. 601 as including a small business concern that is independently owned and operated, and is not dominant in its field of operation. The U.S. Small Business Administration (SBA) has authority to regulate issues related to small businesses, and stipulates in its size standards that a ''small entity'' in the railroad industry is a for profit ''line-haul railroad'' that has fewer than 1,500 employees, a ''short line railroad'' with fewer than 500 employees, or a ''commuter rail system'' with annual receipts of less than seven million dollars. *See* ''Size Eligibility Provisions and Standards,'' 13 CFR part 121, subpart A. Additionally, 5 U.S.C. 601(5) defines as ''small entities'' governments of cities, counties, towns, townships, villages, school districts, or special districts with populations less than 50,000. Federal agencies may use a different standard for small entities, in consultation with SBA and in conjunction with public comment. SBA's ''size standards'' may be altered by Federal agencies upon consultation with SBA and in conjunction with public comment. Pursuant to that authority to alter the ''size standards,'' FRA has published a final statement of agency policy that formally establishes ''small entities'' or ''small businesses'' as being railroads, contractors, and hazardous materials shippers that meet the revenue requirements of a Class III railroad as set forth in 49 CFR 1201.1–1, which is $20 million or less in inflation-adjusted annual revenues, and commuter railroads or small governmental jurisdictions that serve populations of 50,000 or less. *See* 68 FR 24891, May 9, 2003, codified at appendix C to 49 CFR part 209. The $20-million limit is based on the Surface Transportation Board's revenue threshold for a Class III railroad carrier. Railroad revenue is adjusted for inflation by applying a revenue deflator formula in accordance with 49 CFR 1201.1–1. FRA is using this definition of ''small entity'' for regulatory flexibility purposes in this rulemaking.

There are approximately 668 small railroads.[16] Potentially all small railroads could be impacted by this proposed regulation. However, because of certain characteristics that these railroads typically have, there should not be any impact on the majority of them. Most small railroads have only single-track operations. Some small railroads, such as the tourist and historic railroads, operate across the lines of other railroads that would bear the burden or impact of the final rule's requirements. Finally, other small railroads, if they do have more than a single track, typically have operations that are light enough such that the railroads have generally always performed the pertinent trackside work with the track and right-of-way taken out of service, or conducted the work during hours that the track is not used.

In addition, FRA is not aware of any commuter railroads that qualify as small entities. This is likely because commuter railroad operations in the United States are part of larger governmental entities whose jurisdictions exceed 50,000 in population. *See* 49 CFR part 209, appendix C.

FRA is uncertain as to the number of contractors that will be affected by this final rule. FRA is aware that some railroads hire contractors to conduct some of the functions of roadway workers on their railroads. However, most of the costs associated with the burdens from this final rule will ultimately get passed on to the pertinent railroad. Most likely, the contracts will be written to reflect that, and the contractor will bear no additional burden for the final requirements. In addition, at the proposed rule stage, FRA requested information related to contractors and the burdens that might impact them as a result of the proposed rule and received none. Hence, FRA is confident that the final rule's requirements, which have not changed significantly from those proposed in the NPRM, will not have an impact on any contractors that will perform track work on a small railroad.

No other small businesses (non-railroads) are expected to be impacted by this final rule.

The impacts from this regulation are primarily a result of the requirements for roadway work groups to be provided on-track safety when working on a track within close proximity of an adjacent track that is controlled. Again, since small railroads either do not have any adjacent track or conduct track work on the occupied track with an adjacent track when the adjacent track is out of service, there is no impact for small railroads. Since contractors generally pass on costs to the railroads for which

[15] AEI-Brookings Joint Center for Regulatory Studies, *''Interests of Amici Curiae: American Trucking Associations, Inc. et al.,* v. *Carol Browner, Administrator of the Environmental Protection Agency, et al.,''* July 21, 2000, p. 8.

[16] Approximately 718 railroads—50 large freight, medium freight, passenger, and commuter railroads = 665 small railroads.

they perform work, there should be no impact on contractors.

Having made these determinations, FRA certifies that this final rule is not expected to have a significant economic impact on a substantial number of small entities under 5 U.S.C. 605(b).

C. Paperwork Reduction Act

The information collection requirements in this final rule are being submitted upon publication in the **Federal Register** for approval to OMB under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.* The sections that contain the new and current information collection requirements, and the estimated time to fulfill each requirement, are as follows:

CFR Section	Respondent universe	Total annual responses	Average time per response	Total annual burden hours
Form FRA F 6180.119—Part 214 Railroad Workplace Safety Violation Report.	350 Safety Inspectors	150 forms	4 hours	600
214.303—Railroad On-Track Safety Programs:				
—Amendments to Programs	60 Railroads	20 amend. + 584 amend	20 hours; 4 hrs	2,736
—Subsequent Years: New Programs	5 New Railroads	5 new programs	250	1,250
214.313—Good Faith Challenges to On-Track Safety Rules.	20 Railroads	80 challenges	4 hours per challenge	320
214.315/335—Supervision and Communication:				
—Job Briefings	50,000 Rdwy. Workers	16,350,000 briefings	2 minutes per briefing	545,000
—Adjacent-Track Safety Briefings (New Requirement).	24,500 Rdwy. Workers	2,403,450 briefings	30 seconds per briefing	20,029
214.321—Exclusive Track Occupancy—Working Limits.	8,583 Rdwy. Workers	700,739 written authorities	1 minute	11,679
214.325—Train Coordination:				
—Establishing Working Limits through Communication.	50,000 Rdwy. Workers	36,500 communications	15 seconds	152
214.327—Inaccessible Track:				
—Working Limits on Non-Controlled Track: Notifications.	718 Railroads	50,000 notifications	10 minutes	8,333
214.336—*Procedures for Adjacent-Controlled-Track Movements Over 25 mph* (New Requirements)				
—Notifications/Watchmen/Lookout Warnings.	100 Railroads	10,000 notifications	15 seconds	42
—Roadway Worker Communication with Train Engineers or Equipment Operators.	100 Railroads	3,000 communications	1 minute	50
—*Procedures for Adjacent-Controlled-Track Movements 25 mph or less:*				
—Notifications/Watchmen/Lookout Warnings.	100 Railroads	3,000 notifications	15 seconds	13
—Roadway Worker Communication with Train Engineers or Equipment Operators.	100 Railroads	1,500 communications	1 minute	25
—*Exceptions to the Requirements in Paragraphs (a), (b), and (c) for Adjacent-Controlled-Track On-Track Safety: Work Activities Involving Certain Equipment and Purposes:*				
—On-Track Job Safety Briefings	100 Railroads	1,030,050 briefings	15 seconds	4,292
214.337—On-Track Safety Procedures for Lone Workers: Statements by Lone Workers.	718 Railroads	2,080,000 statements	30 seconds	17,333
214.343/345/347/349/351/353/355—Training Requirements.	50,000 Rdwy. Workers	50,000 tr. Rdwy. Workers	4.5 hours	225,000
—Additional On-Track Safety Training (New Requirement).	35,000 Rdwy. Workers	35,000 tr. Rdwy. Workers	5 minutes	2,917
—Records of Training	50,000 Rdwy. Workers	50,000 records	2 minutes	1,667
214.503—Good Faith Challenges; Procedures for Notification and Resolution:				
—Notifications for Non-Compliant Roadway Maintenance Machines or Unsafe Condition.	50,000 Rdwy. Workers	125 notifications	10 minutes	21
—Development of Resolution Procedures.	644 Railroads	10 procedures	2 hours	20
214.505—Required Environmental Control and Protection Systems for New On-Track Roadway Maintenance Machines with Enclosed Cabs:	644 Railroads/200 Contractors.	500 lists	1 hour	500
—Designations/Additions to List	644 Railroads/200 Contractors.	150 additions/designations	5 minutes	13

CFR Section	Respondent universe	Total annual responses	Average time per response	Total annual burden hours
214.507—As-Built Light Weight on New On-Track Roadway Maintenance Machines.	644 Railroads	1,000 stickers	5 minutes	83
214.511—Required Audible Warning Devices for New On-Track Roadway Maintenance Machines.	644 Railroads	3,700 identified mechanisms.	5 minutes	308
214.513—Retrofitting of Existing On-Track Roadway Maintenance Machines:				
—Identification of Triggering Mechanism—Horns.	703 Railroads	200 mechanisms	5 minutes	17
214.515—Overhead Covers for Existing On-Track Roadway Maintenance Machines.	644 Railroads	500 requests + 500 responses.	10 minutes; 20 minutes	250
214.517—Retrofitting of Existing On-Track Roadway Maintenance Machines Manufactured on or after Jan. 1, 1991.	644 Railroads	500 stencils	5 minutes	42
214.518—Safe and Secure Position for Riders:				
—Positions Identified by Stencils/Markings/Notices.	644 Railroads	1,000 stencils	5 minutes	83
214.523—Hi-Rail Vehicles	644 Railroads	2,000 records	60 minutes	2,000
—Non-Complying Conditions	644 Railroads	500 tags + 500 reports	10 min.; 15 min	208
214.527—Inspection for Compliance; Repair Schedules.	644 Railroads	550 tags + 550 reports	5 min.; 15 min	184
214.533—Schedule of Repairs; Subject to Availability of Parts.	644 Railroads	250 records	15 minutes	63

All estimates include the time for reviewing instructions; searching existing data sources; gathering or maintaining the needed data; and reviewing the information. For information or a copy of the paperwork package submitted to OMB, contact Mr. Robert Brogan at (202) 493–6292 or Ms. Kimberly Toone at (202) 493–6132 or via email at the following addresses: *Robert.Brogan@dot.gov* and *Kimberly.Toone@dot.gov*.

Organizations and individuals desiring to submit comments on the collection of information requirements should direct them to the Office of Management and Budget, Office of Information and Regulatory Affairs, Washington, DC 20503, Attention: FRA Desk Officer. Comments may also be sent via email to OMB at the following address: *OIRA_Submission@omb.eop.gov*.

OMB is required to make a decision concerning the collection of information requirements contained in this final rule between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication.

FRA is not authorized to impose a penalty on persons for violating information collection requirements which do not display a current OMB control number, if required. FRA intends to obtain current OMB control numbers for any new information collection requirements resulting from this rulemaking action prior to the effective date of this final rule. The OMB control number, when assigned, will be announced by separate notice in the **Federal Register**.

D. Federalism Implications

FRA has analyzed this final rule in accordance with the principles and criteria contained in Executive Order 13132, issued on August 4, 1999, which directs Federal agencies to exercise great care in establishing policies that have federalism implications. *See* 64 FR 43255. This final rule will not have a substantial direct effect on the States, on the relationship between the National government and the States, or on the distribution of power and responsibilities among various levels of government.

One of the fundamental federalism principles, as stated in Section 2(a) of Executive Order 13132, is that ''Federalism is rooted in the belief that issues that are not national in scope or significance are most appropriately addressed by the level of government closest to the people.'' Congress expressed its intent that there be national uniformity of regulation concerning railroad safety matters when it enacted 49 U.S.C. 20106. As amended to date, that section provides that all regulations prescribed by the Secretary of Transportation with respect to railroad safety matters and the Secretary of Homeland Security with respect to railroad security matters preempt any State law, regulation, or order covering the same subject matter, except a provision necessary to eliminate or reduce an essentially local safety or security hazard that is not incompatible with a Federal law, regulation, or order and that does not unreasonably burden interstate commerce. Nothing in this final rule alters the preemptive effect of the RWP Rule so these provisions have the same preemptive effect as the 1996 RWP Rule in accordance with the statute.

FRA notes that the above factors have been considered throughout the development of this final rule both internally and through discussions within the RSAC forum, as described in Sections VI and VII of this preamble. The full RSAC, which, prior to the publication of this final rule, reached consensus on proposed rule text and recommended the proposal to FRA, has as permanent voting members two organizations representing State and local interests: AASHTO and ASRSM. As such, these State organizations concurred with the proposed requirements, which differ in only limited respects from the requirements contained in this final rule. The RSAC regularly provides recommendations to the FRA Administrator for solutions to regulatory issues that reflect significant input from its State members. To date, FRA has received no indication of concerns about the Federalism implications of this rulemaking from these representatives or from any other representative.

For the foregoing reasons, FRA believes that this final rule is in accordance with the principles and

criteria contained in Executive Order 13132.

E. Environmental Impact

FRA has evaluated this final rule in accordance with its ''Procedures for Considering Environmental Impacts'' (FRA's Procedures) (*see* 64 FR 28545, May 26, 1999) as required by the National Environmental Policy Act (*see* 42 U.S.C. 4321 *et seq.*), other environmental statutes, Executive Orders, and related regulatory requirements. FRA has determined that this final rule 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. *See* 64 FR 28547. 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 final rule is not a major Federal action significantly affecting the quality of the human environment.

F. 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 ''[b]efore 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 $100,000,000 or more (annually adjusted for inflation) in any 1 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. For the year 2010, this monetary amount of $100,000,000 has been adjusted to $140,800,000 to account for inflation. This final rule will not result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $140,800,000 or more in any one year, and thus preparation of such a statement is not required.

G. Energy Impact

Executive Order 13211 requires Federal agencies to prepare a Statement of Energy Effects for any ''significant energy action.'' *See* 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: (1)(i) That 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.

H. Trade Impact

The Trade Agreements Act of 1979 (Pub. L. 96–39, 19 U.S.C. 2501 *et seq.*) prohibits Federal agencies from engaging in any standards setting or related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

FRA has assessed the potential effect of this final rule on foreign commerce and believes that its requirements are consistent with the Trade Agreements Act of 1979. The requirements imposed are safety standards, which, as noted, are not considered unnecessary obstacles to trade.

I. Privacy Act

Anyone is able to search the electronic form of all comments received into any of FRA's 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*.

List of Subjects in 49 CFR Part 214

Occupational safety and health, Penalties, Railroad safety.

The Final Rule

In consideration of the foregoing, FRA amends part 214 of chapter II, subtitle B of title 49, Code of Federal Regulations, as follows:

PART 214—[AMENDED]

■ 1. The authority citation for part 214 is revised to read as follows:

Authority: 49 U.S.C. 20102–20103, 20107, 21301–21302, 21304; 28 U.S.C. 2461, note; and 49 CFR 1.49.

Subpart A—General

§ 214.4 [Removed]

■ 2. Section 214.4 is removed.

■ 3. Section 214.7 is amended by adding introductory text to read as follows:

§ 214.7 Definitions.

Unless otherwise provided, as used in this part—

* * * * *

Subpart C—Roadway Worker Protection

■ 4. Section 214.315 is amended by revising paragraph (a) to read as follows:

§ 214.315 Supervision and communication.

(a) When an employer assigns a duty to a roadway worker that calls for that employee to foul a track, the employer shall provide the employee with an on-track safety job briefing that, at a minimum, includes the following:

(1) Information on the means by which on-track safety is to be provided for each track identified to be fouled;

(2) Instruction on each on-track safety procedure to be followed;

(3) Information about any adjacent tracks, on-track safety for such tracks, if required by this subpart or deemed necessary by the roadway worker in charge, and identification of any roadway maintenance machines that will foul such tracks; and

(4) A discussion of the nature of the work to be performed and the characteristics of the work location to ensure compliance with this subpart.

* * * * *

■ 5. Section 214.335 is amended by removing paragraph (c) and revising the section heading to read as follows:

§ 214.335 On-track safety procedures for roadway work groups, general.

* * * * *

■ 6. Section 214.336 is added to read as follows:

§ 214.336 On-track safety procedures for certain roadway work groups and adjacent tracks.

(a) *Procedures; general.* (1) *General rule.* Except as provided in paragraph (e) of this section, on-track safety is required for each adjacent controlled track when a roadway work group with at least one of the roadway workers on the ground is engaged in a common task with on-track, self-propelled equipment or coupled equipment on an occupied track. The required on-track safety shall be established through § 214.319 (Working limits, generally) or § 214.329 (Train approach warning provided by watchmen/lookouts) and as more specifically described in this section.

(2) *Special circumstances arising in territories with at least three tracks, if an occupied track is between two adjacent tracks, at least one of which is an adjacent controlled track.* (i) If an occupied track has two adjacent controlled tracks, and one of these adjacent controlled tracks has one or more train or other on-track equipment movements authorized or permitted at a speed of 25 mph or less, and the other adjacent controlled track has one or more concurrent train or other on-track equipment movements authorized or permitted at a speed over 25 mph, the more restrictive procedures in paragraph (b) of this section apply.

(ii) If an occupied track has an adjacent controlled track on one side (Side X), and a non-controlled track whose track center is spaced 19 feet or less from the track center of the occupied track on the other side (Side Y), the affected roadway workers must treat the non-controlled track on Side Y as an adjacent controlled track for purposes of this section.

(3) *Definitions.* As used in this section—

Adjacent controlled track means a controlled track whose track center is spaced 19 feet or less from the track center of the occupied track. Note, however, that under the special circumstances specified in paragraph (a)(2)(ii) of this section, a non-controlled track whose track center is spaced 19 feet or less from the track center of the occupied track must be treated as an adjacent controlled track for purposes of this section.

Adjacent track means a controlled or non-controlled track whose track center is spaced less than 25 feet from the track center of the occupied track.

Inter-track barrier means a continuous barrier of a permanent or semi-permanent nature that spans the entire work area, that is at least four feet in height, and that is of sufficient strength to prevent a roadway worker from fouling the adjacent track.

Minor correction means one or more repairs of a minor nature, including but not limited to, spiking, anchoring, hand tamping, and joint bolt replacement that is accomplished with hand tools or handheld pneumatic tools only. The term does not include welding, machine spiking, machine tamping, or any similarly distracting repair.

Occupied track means a track on which on-track, self-propelled equipment or coupled equipment is authorized or permitted to be located while engaged in a common task with a roadway work group with at least one of the roadway workers on the ground.

(b) *Procedures for adjacent-controlled-track movements over 25 mph.* If a train or other on-track equipment is authorized to move on an adjacent controlled track at a speed greater than 25 mph, each roadway worker in the roadway work group that is affected by such movement must comply with the following procedures:

(1) *Ceasing work and occupying a predetermined place of safety.* Except for the work activities as described in paragraph (e) of this section, each affected roadway worker shall, as described in Table 1 of this section, cease all on-ground work and equipment movement that is being performed on or between the rails of the occupied track or on one or both sides of the occupied track, and occupy a predetermined place of safety upon receiving either a watchman/lookout warning or, alternatively, a notification that the roadway worker in charge intends to permit one or more train or other on-track equipment movements through the working limits on the adjacent controlled track.

(2) *Resuming work.* (i) An affected roadway worker may resume on-ground work and equipment movement (on or between the rails of the occupied track or on one or both sides of the occupied track as described in Table 1 of this section) only after the trailing-end of all trains or other on-track equipment moving on the adjacent controlled track (for which a warning or notification has been received in accordance with paragraph (b)(1) of this section) has passed and remains ahead of that roadway worker.

(ii) If the train or other on-track equipment stops before its trailing-end has passed all of the affected roadway workers in the roadway work group, the work to be performed (on or between the rails of the occupied track or on one or both sides of the occupied track as described in Table 1 of this section) ahead of the trailing-end of the train or other on-track equipment on the adjacent controlled track may resume only—

(A) If on-track safety through train approach warning (§ 214.329) has been established on the adjacent controlled track; or

(B) After the roadway worker in charge has communicated with a member of the train crew or the on-track equipment operator and established that further movements of such train or other on-track equipment shall be made only as permitted by the roadway worker in charge.

(c) *Procedures for adjacent-controlled-track movements 25 mph or less.* If a train or other on-track equipment is authorized or permitted to move on an adjacent controlled track at a speed of 25 mph or less, each roadway worker in the roadway work group that is affected by such movement must comply with the procedures listed in paragraph (b) of this section, except that equipment movement on the rails of the occupied track and on-ground work performed exclusively between the rails (*i.e.,* not breaking the plane of the rails) of the occupied track may continue, provided that no on-ground work is performed within the areas 25 feet in front of and 25 feet behind any on-track, self-propelled equipment or coupled equipment permitted to move on the occupied track.

(d) *Discretion of roadway worker in charge.* Nothing in this subpart prohibits the roadway worker in charge from establishing on-track safety on one or more adjacent tracks as he or she deems necessary consistent with both the purpose and requirements of this subpart.

(e) *Exceptions to certain requirements for adjacent-controlled-track on-track safety.* No on-track safety (other than that required by paragraph (f) of this section or provided under paragraph (d) of this section) is required by paragraphs (a) through (c) of this section for an adjacent controlled track during the times that the roadway work group is exclusively performing one or more of the following work activities:

(1) *On-ground work performed on a side of the occupied track meeting specified condition(s).* A roadway work group with all of its on-ground roadway workers (other than those performing work in accordance with another exception in paragraph (e) of this section) performing work while exclusively positioned on a side of the

occupied track as follows and as further specified in Table 1 of this section:

(i) The side with no adjacent track;

(ii) The side with one or more adjacent tracks, the closest of which has working limits on it and no movements permitted within such working limits by the roadway worker in charge; or

(iii) The side with one or more adjacent tracks, provided that that it has an inter-track barrier between the occupied track and the closest adjacent track on that side.

(2) *Maintenance or repairs performed alongside machines or equipment on the occupied track.* One or more roadway workers performing maintenance or repairs alongside a roadway maintenance machine or coupled equipment, provided that such machine or equipment would effectively prevent the worker from fouling the adjacent controlled track on the other side of such equipment, and that such maintenance or repairs are performed while positioned on a side of the occupied track as described in paragraph (e)(1)(i), (ii), or (iii) and Table 1 of this section.

(3) *Work activities involving certain equipment and purposes.* One or more on-ground roadway workers engaged in a common task on an occupied track with on-track, self-propelled equipment or coupled equipment consisting exclusively of one or more of the types of equipment described in paragraphs (e)(3)(i) through (iii) of this section. If such a roadway work group (''excepted group'') is authorized or permitted to operate on the same occupied track and within the working limits of a separate roadway work group performing work that is subject to the requirements of this section (''non-excepted group'') or vice versa (*i.e.,* a non-excepted group is authorized or permitted to operate on the same occupied track and within the working limits of an excepted group), the groups must conduct an on-track safety job briefing to determine if adjacent-controlled-track on-track safety is necessary for the excepted group. Such determination shall be made by the roadway worker in charge of the working limits; however, if the groups are in such proximity where the ability of the roadway workers in the excepted group to hear or see approaching trains and other on-track equipment is impaired by background noise, lights, sight obstructions or any other physical conditions caused by the equipment, then this exception does not apply, and adjacent-controlled-track on-track safety must be provided to both groups. This exception otherwise applies to work activities involving one or more of the following types of equipment:

(i) A hi-rail vehicle (other than a catenary maintenance tower vehicle) being used for inspection or minor correction purposes, provided that such hi-rail vehicle is not coupled to one or more railroad cars. In accordance with § 214.315(a), where multiple hi-rail vehicles being used for inspection or minor correction are engaged in a common task, the on-track safety job briefing shall include discussion of the nature of the work to be performed to determine if adjacent-controlled-track on-track safety is necessary.

(ii) An automated inspection car being used for inspection or minor correction purposes.

(iii) A catenary maintenance tower car or vehicle, provided that all of the on-ground workers engaged in the common task (other than those performing work in accordance with another exception in paragraph (e) of this section) are positioned within the gage of the occupied track for the sole purpose of applying or removing grounds.

(f) *Procedures for components of roadway maintenance machines fouling an adjacent controlled track.* Except as provided for in § 214.341(c), a component of a roadway maintenance machine shall not foul an adjacent controlled track unless working limits have been established on the adjacent-controlled-track and there are no movements permitted within the working limits by the roadway worker in charge that would affect any of the roadway workers engaged in a common task with such machine.

BILLING CODE 4910–06–P

TABLE 1–SUMMARY OF ON-TRACK SAFETY PROCEDURES FOR CERTAIN ROADWAY WORK GROUPS AND ADJACENT TRACKS

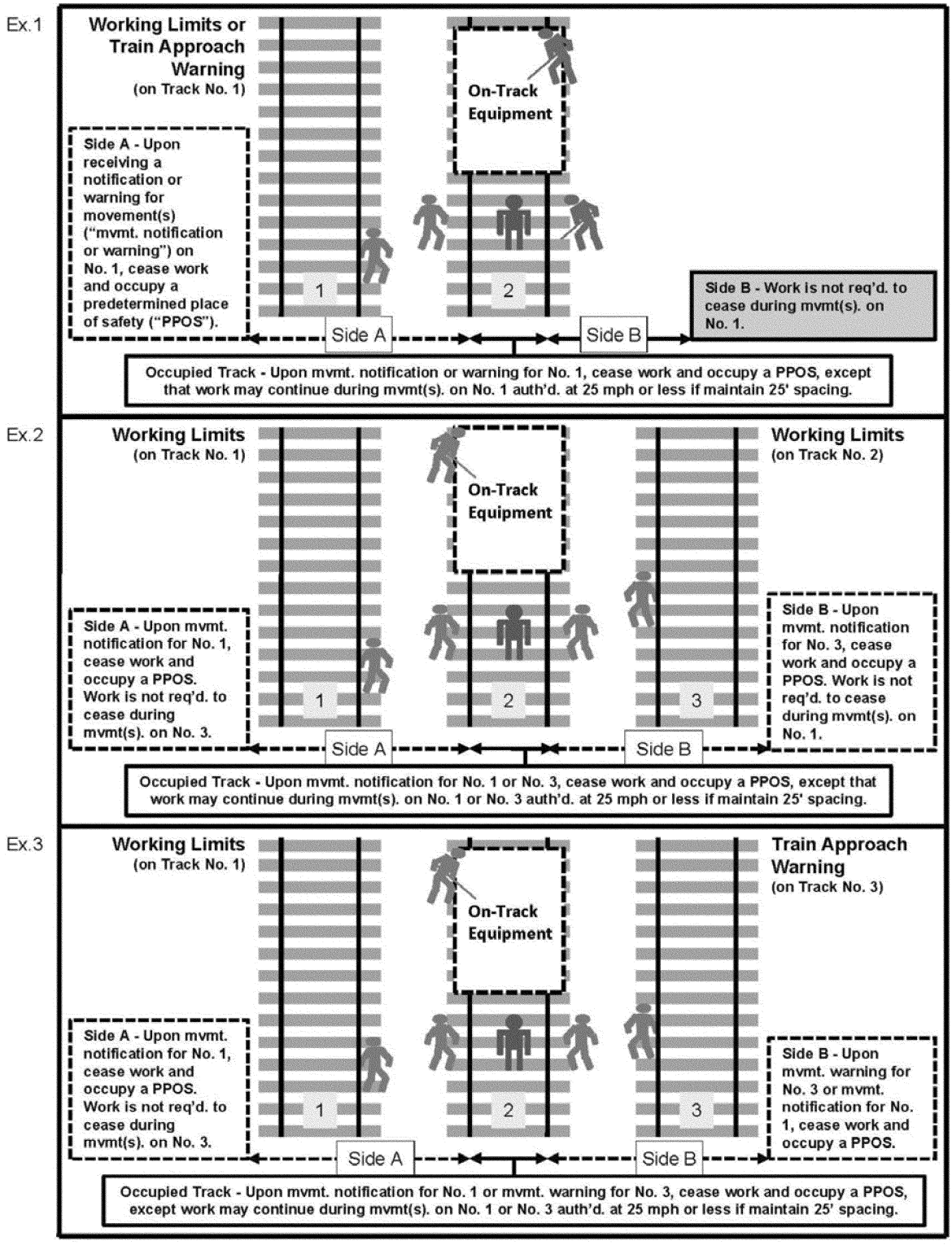
Example No./ Diagram No. (see Figure 1)	"Side A" of the Occupied Track—the side from the vertical plane of the near running rail of the occupied track extending outward through to the fouling space of the adjacent controlled track ("No. 1" Track)		On or Between the Rails of the Occupied Track ("No. 2" Track), where On-Track Safety Is Established through Working Limits	"Side B" of the Occupied Track—either (1) the side with no adjacent track or (2) the side from the vertical plane of the near running rail of the occupied track extending outward through to the fouling space of the adjacent controlled track ("No. 3" Track)	
	Method of On-Track Safety on Side A	Requirements	Requirements	Requirements	Method of On-Track Safety on Side B
1	Working limits or train approach warning	Upon receiving a notification or warning for movement(s) ("movement notification or warning") for No. 1, cease work and occupy a predetermined place of safety ("PPOS"). [1]	Upon movement notification or warning for No. 1, cease work and occupy a PPOS, except work may continue during movement(s) on No. 1 auth'd. at 25 mph or less if maintain 25' spacing.[2]	Work[3] is not required to cease during movement(s) on No. 1.	Not applicable (N/A), because there is no adjacent track
2	Working limits	Upon movement notification for No. 1, cease work and occupy a PPOS. Work[3] is not required to cease during movement(s) on No. 3.	Upon movement notification for No. 1 or No. 3, cease work and occupy a PPOS, except work may continue during movement(s) on No. 1 or No. 3 auth'd. at 25 mph or less if maintain 25' spacing.[2]	Upon movement notification for No. 3, cease work and occupy a PPOS. Work[3] is not required to cease during movement(s) on No. 1.	Working limits
3	Working limits	Upon movement notification for No. 1, cease work and occupy a PPOS. Work[3] is not required to cease during movement(s) on No. 3.	Upon movement notification for No. 1 or warning for No. 3, cease work and occupy a PPOS, except work may continue during movement(s) on No. 1 or No. 3 auth'd. at 25 mph or less if maintain 25' spacing.[2]	Upon movement warning for No. 3 or notification for No. 1, cease work and occupy a PPOS.	Train approach warning
4	Train approach warning	Upon movement warning for No. 1 or No. 3, cease work and occupy a PPOS.	Upon movement warning for No. 1 or No. 3, cease work and occupy a PPOS, except work may continue during movement(s) on No. 1 or No. 3 auth'd. at 25 mph or less if maintain 25' spacing.[2]	Upon movement warning for No. 3 or No. 1, cease work and occupy safety PPOS.	Train approach warning
5	None, but with inter-track barrier	Work is prohibited on No. 1 and up to barrier ("Side A1"). Work is not required to cease btwn. barrier and near running rail of occupied track ("Side A2") during movement(s) on No. 1.	Work is not required to cease during movement(s) on No. 1.	Work is not required to cease during movement(s) on No. 1.	N/A, because there is no adjacent track
6	None, but with inter-track barrier	Work is prohibited on Side A1. Work[3] is not required to cease on Side A2 during movement(s) on No. 1 or No. 3.	Work is not required to cease during movement(s) on No. 1. Upon movement notification or warning for No. 3, cease work and occupy a PPOS, except work may continue during movement(s) on No. 3 auth'd. at 25 mph or less if maintain 25' spacing.[2]	Upon movement notification or warning for No. 3, cease work and occupy a PPOS. Work[3] is not required to cease during movement(s) on No. 1.	Working limits or train approach warning

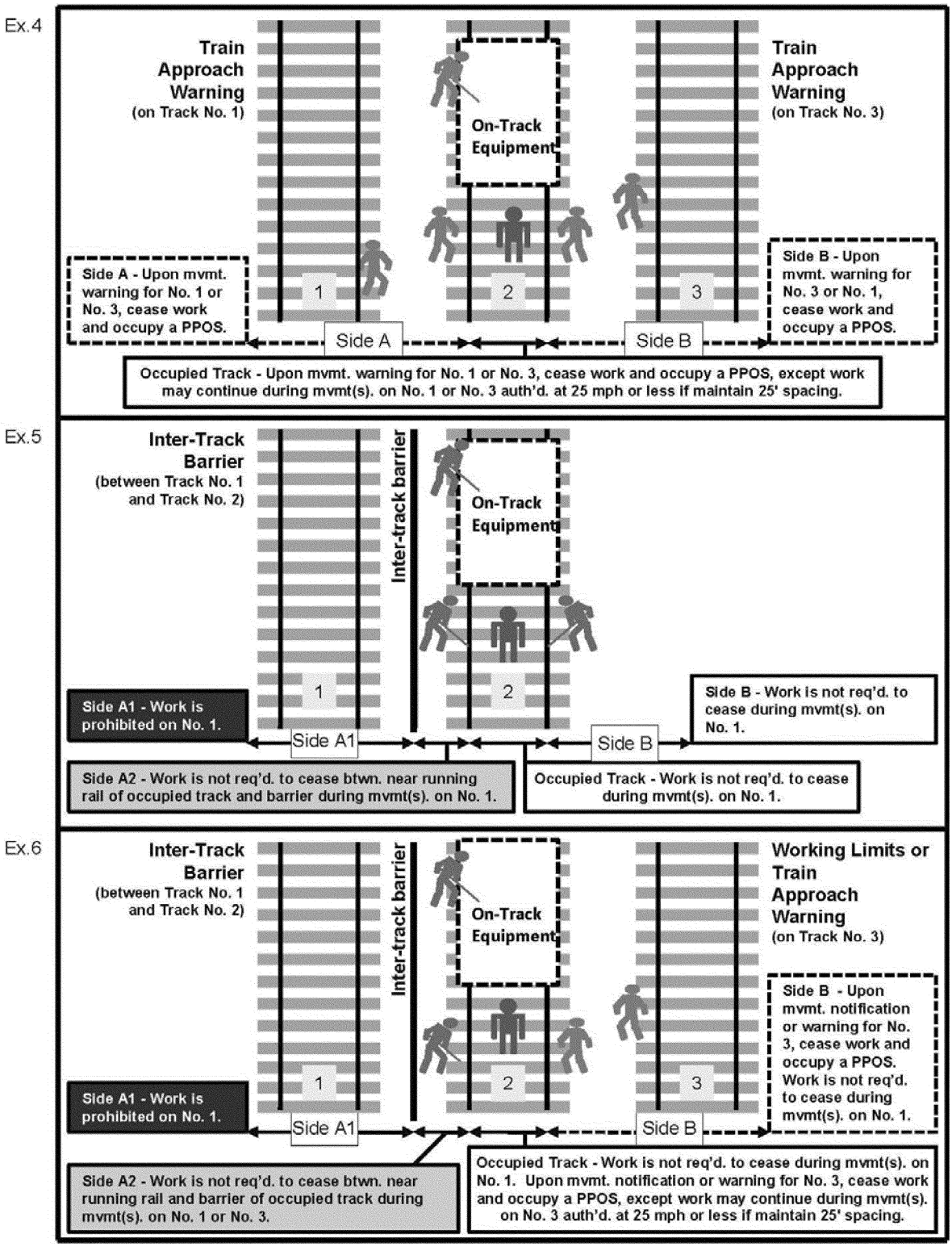
[1] As used in the above table, a "predetermined place of safety" (or "PPOS") means a specific location that an affected roadway worker must occupy upon receiving a watchman/lookout's warning of approaching movement(s) ("warning") or a roadway worker in charge's ("RWIC's") notification of pending movement(s) on an adjacent track ("notification"), as designated during the on-track safety job briefing required by § 214.315. The PPOS may not be on a track, unless the track has working limits on it and no movements permitted within such working limits by the RWIC. Thus, under these circumstances, the space between the rails of the occupied track (No. 2 in this table) may be designated as a place to remain in position or to otherwise occupy upon receiving a warning or notification. The RWIC must determine any change to a PPOS, and communicate such change to all affected roadway workers through an updated on-track safety job briefing.

[2] On-ground work is prohibited in the areas 25' in front of and 25' behind equipment on the occupied track (No. 2), and must not break the plane of a rail on No. 2 towards a side of No. 2 unless work is permitted on that side. Note, however, that per § 214.336(a)(2)(i), work would no longer be permitted to continue on or between the rails of the occupied track during movement(s) on an adjacent controlled track at 25 mph or less if there is a simultaneous movement on the other adjacent controlled track at more than 25 mph.

[3] Work that does not break the plane of the near running rail of the occupied track (No. 2) is not required to cease during such movements; work that breaks the plane of the near running rail of the occupied track may also continue: 1) during the times that work is permitted on or between the rails of the occupied track in accordance with § 214.336(c) (Procedures for adjacent-controlled-track movements 25 mph or less); or 2) if such work is performed alongside a roadway maintenance machine or coupled equipment in accordance with § 214.336(e)(2).

FIGURE 1 - EXAMPLES APPLYING § 214.336, ON-TRACK SAFETY PROCEDURES FOR CERTAIN ROADWAY WORK GROUPS AND ADJACENT TRACKS
(All tracks are controlled, with centerlines less than 19 feet apart.)





BILLING CODE 4910–06–C

■ 7. Appendix A to part 214 is amended by revising the entry under subpart C for § 214.315, by removing the entry under subpart C for § 214.335(c), by adding an entry under subpart C for § 214.336, and by revising footnote 1 and adding footnote 2 to read as follows:

APPENDIX A TO PART 214—SCHEDULE OF CIVIL PENALTIES [1]

Section [2]	Violation	Willful violation
* * * * * * *		*
Subpart C—Roadway Worker Protection Rule		
* * * * * * *		*
214.315 Supervision and communication:		
(a)(1) Complete failure of employer to provide on-track safety job briefing	5,000	10,000
(a)(2) Partial failure of employer to provide on-track safety job briefing	2,000	4,000
* * * * * * *		*
214.336 On-track safety procedures for certain roadway work groups and adjacent tracks:		
(a)(1) Failure to establish on-track safety for each adjacent controlled track as required under this section	5,000	10,000
(2)(i) Failure to implement the more restrictive procedures required by paragraph (b) during special circumstance of concurrent movement(s) on two adjacent controlled tracks where one movement is authorized or permitted at a speed over 25 mph	1,500	3,000
(ii) Failure to establish on-track safety on an adjacent track that is non-controlled and spaced 19 feet or less from the occupied track for special circumstance where there is a controlled track on the opposite side of an occupied track	2,000	4,000
(b)(1) Failure of roadway worker to cease work and occupy a predetermined place of safety upon receiving a warning or notification of train or other on-track equipment movement(s) on an adjacent controlled track	5,000	10,000
(2) Resumption of work before trailing-end of all applicable movements has passed the roadway worker	5,000	10,000
(c) Failure to maintain 25-foot spacing between on-track, self-propelled equipment or coupled equipment and roadway worker(s) on the occupied track during an adjacent-controlled-track movement at 25 mph or less	2,000	4,000
(d) Failure to implement on-track safety procedures on an adjacent track when deemed necessary by the roadway worker in charge of providing on-track safety for a roadway work group	2,000	4,000
(e)	(1)	(1)
(f) Roadway maintenance machine component fouling an adjacent controlled track without working limits or with movements permitted within working limits	5,000	10,000
* * * * * * *		*

[1] A penalty may be assessed against an individual only for a willful violation. The Administrator reserves the right to assess a penalty of up to $100,000 for any violation where circumstances warrant. See 49 CFR part 209, appendix A. Failure to observe any condition(s) of an exception set forth in paragraph (e) of § 214.336 will deprive the railroad or contractor of the benefit of the exception and make the railroad or contractor, and any responsible individuals, liable for penalty under the particular regulatory section(s) from which the exception would otherwise have granted relief.

[2] The penalty schedule uses section numbers from 49 CFR part 214. If more than one item is listed as a type of violation of a given section, each item is also designated by a ''penalty code,'' which is used to facilitate assessment of civil penalties, and which may or may not correspond to any subsection designation(s). For convenience, penalty citations will cite the CFR section and the penalty code, if any. FRA reserves the right, should litigation become necessary, to substitute in its complaint the CFR citation in place of the combined CFR and penalty code citation, should they differ.

Issued in Washington, DC, on November 17, 2011.

Joseph C. Szabo,

Administrator, Federal Railroad Administration.

[FR Doc. 2011–30250 Filed 11–29–11; 8:45 am]

BILLING CODE 4910–06–P

FEDERAL REGISTER

Vol. 76 Wednesday,
No. 230 November 30, 2011

Part IV

The President

Executive Order 13591—Continuance of Certain Federal Advisory Committees

Federal Register
Vol. 76, No. 230
Wednesday, November 30, 2011

Presidential Documents

Title 3—

The President

Executive Order 13591 of November 23, 2011

Continuance of Certain Federal Advisory Committees

By the authority vested in me as President by the Constitution and the laws of the United States of America, and consistent with the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), it is hereby ordered as follows:

Section 1. Each advisory committee listed below is continued until September 30, 2013.

(a) Presidential Commission for the Study of Bioethical Issues; Executive Order 13521 (Department of Health and Human Services).

(b) National Council on Federal Labor-Management Relations; Executive Order 13522 (Office of Personnel Management).

(c) President's Board of Advisors on Historically Black Colleges and Universities; Executive Order 13532 (Department of Education).

(d) President's Management Advisory Board; Executive Order 13538 (General Services Administration).

(e) President's Council of Advisors on Science and Technology; Executive Order 13539 (Office of Science and Technology Policy).

(f) Interagency Task Force on Veterans Small Business Development; Executive Order 13540 (Small Business Administration).

(g) State, Local, Tribal, and Private Sector (SLTPS) Policy Advisory Committee; Executive Order 13549, as amended (National Archives and Records Administration).

Sec. 2. The following advisory committee is continued until September 30, 2012: Advisory Group on Prevention, Health Promotion, and Integrative and Public Health; Executive Order 13544 (Department of Health and Human Services).

Sec. 3. Section 6 of Executive Order 13530 of January 29, 2010 (President's Advisory Council on Financial Capability), is amended to read as follows: ''Unless extended by the President, the Council shall terminate on January 29, 2013.''

Sec. 4. Notwithstanding the provisions of any other Executive Order, the functions of the President under the Federal Advisory Committee Act that are applicable to the committees listed in sections 1 and 2 of this order shall be performed by the head of the department or agency designated after each committee, in accordance with the guidelines and procedures established by the Administrator of General Services.

THE WHITE HOUSE,
November 23, 2011.

[FR Doc. 2011–30990
Filed 11–29–11; 11:15 am]
Billing code 3295–F2–P

Reader Aids

Federal Register

Vol. 76, No. 230

Wednesday, November 30, 2011

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations
General Information, indexes and other finding aids **202–741–6000**
Laws **741–6000**

Presidential Documents
Executive orders and proclamations **741–6000**
The United States Government Manual **741–6000**

Other Services
Electronic and on-line services (voice) **741–6020**
Privacy Act Compilation **741–6064**
Public Laws Update Service (numbers, dates, etc.) **741–6043**
TTY for the deaf-and-hard-of-hearing **741–6086**

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: **www.fdsys.gov.**

Federal Register information and research tools, including Public Inspection List, indexes, and links to GPO Access are located at: **www.ofr.gov.**

E-mail

FEDREGTOC-L (Federal Register Table of Contents LISTSERV) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to **http://listserv.access.gpo.gov** and select *Online mailing list archives, FEDREGTOC-L, Join or leave the list (or change settings);* then follow the instructions.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to **http://listserv.gsa.gov/archives/publaws-l.html** and select *Join or leave the list (or change settings);* then follow the instructions.

FEDREGTOC-L and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: **fedreg.info@nara.gov**

The Federal Register staff cannot interpret specific documents or regulations.

Reminders. Effective January 1, 2009, the Reminders, including Rules Going Into Effect and Comments Due Next Week, no longer appear in the Reader Aids section of the Federal Register. This information can be found online at **http://www.regulations.gov.**

CFR Checklist. Effective January 1, 2009, the CFR Checklist no longer appears in the Federal Register. This information can be found online at **http://bookstore.gpo.gov/.**

FEDERAL REGISTER PAGES AND DATE, NOVEMBER

67315–67580 1
67581–68056 2
68057–68296 3
68297–68624 4
68625–69082 7
69083–69600 8
69601–70036 9
70037–70320 10
70321–70634 14
70635–70864 15
70865–71240 16
71241–71448 17
71449–71864 18
71865–72080 21
72081–72300 22
72301–72612 23
72613–72820 25
72821–73474 28
73475–73992 29
73993–74624 30

CFR PARTS AFFECTED DURING NOVEMBER

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

2 CFR

Proposed Rules:
Ch. XX 70913

3 CFR

Proclamations:
8742 68273
8743 68611
8744 68613
8745 68615
8746 68617
8747 68619
8748 68621
8749 68623
8750 68625
8751 69081
8752 70633
8753 71447
8754 71863
8755 72079
8756 72603
8757 72605
8758 72607
8759 72821

Executive Orders:
13588 68295
13589 70863
13590 72609
13591 74623

Administrative Orders:
Memorandums:
Memorandums of October 28, 2011 68049
Notices:
Notice of November 1, 2011 68055
Notice of November 7, 2011 70035
Notice of November 9, 2011 70319
Presidential Determination No. 2012–02 of October 14, 2011 70635

5 CFR

530 68631
531 68631
532 70321
536 68631
731 69601
Ch. III 70037
Ch. XXXVII 70322

Proposed Rules:
300 73521
532 70365
2635 70667
Ch. XXIV 70913
Ch. XLVIII 70913

6 CFR

5 ..... 70637, 70638

Proposed Rules:
5 67621
31 70366

7 CFR

275 67315
301 72081
319 ..... 67581, 68057
958 67317
984 67320
1205 69083
1214 ..... 69094, 69110, 71241
2502 ..... 69114, 70639

Proposed Rules:
205 69141
319 67379
457 ..... 71271, 71276
759 70368
762 70368
930 69673
987 69678
1945 70368
2502 69146

8 CFR

103 ..... 69119, 73475
207 73475
208 73475
211 73475
212 73475
213a 73475
244 73475
245 73475
324 73475
335 73475

9 CFR

93 70037
94 70037
98 70037
381 68058

Proposed Rules:
319 69146
381 69146
416 72331
417 72331
430 72331

10 CFR

1 72082
9 72082
19 72082
20 72082
30 72082
35 72082
40 ..... 69120, 72082
50 72560
52 ..... 72082, 72560
55 72082
60 72082
61 72082
70 72082
72 70331

73.....72082
110.....72082
170.....72082
171.....72082
430 .....70548, 70865, 71836
431.....69122

Proposed Rules:
Ch. I.....70913
51.....70067
72.....70374
429 .....69870, 70918, 72332
430 .....69147, 69870, 70918, 72332
431.....70376
609.....67622
950.....67622

11 CFR

7.....70322
201.....70322

12 CFR

204.....68064
243.....67323
381.....67323
701.....67583, 73993
705.....67583
741.....67583
750.....73994
1278.....72823

Proposed Rules:
1.....73526
5.....73526
16.....73526
28.....73526
44.....68846
160.....73526
248.....68846
351.....68846
380.....72645
652.....71798
1290.....70069

13 CFR

Proposed Rules:
121 .....69154, 70667, 70680
124.....69154
125.....69154
126.....69154
127.....69154

14 CFR

23.....72087

25.....71865
39 .....67341, 67343, 67346, 67591, 67594, 68297, 68299, 68301, 68304, 68306, 68634, 68636, 69123, 70040, 70042, 70044, 70046, 70334, 70336, 71241, 71246, 72091, 73477, 73481, 73483, 73486, 73489, 73491, 73494, 73496
71 .....67596, 69608, 70051, 70865, 72093, 72836, 72837, 72838, 73501, 73502, 73503, 73504, 73505
73.....69125
95.....72094
97 .....70053, 70055, 72613, 72615

Proposed Rules:
39 .....67625, 67628, 67631, 67633, 68366, 68368, 68660, 68661, 68663, 68666, 68668, 68671, 69155, 69157, 69159, 69161, 69163, 69166, 69168, 69685, 70377, 70379, 70382, 71470, 71472, 72128, 72130, 72348, 72350, 72353, 72650, 72853, 72855, 72858, 72863, 74010, 74012
71 .....68674, 70919, 70920, 72867, 72868
73.....72869
183.....69171
382.....71914

15 CFR

738.....70337
740.....70337
744.....71867
748.....69609, 70337
902.....68310
922.....67348

Proposed Rules:
738.....68675
740.....68675
742.....68675
770.....68675
772.....68675
774.....68675

16 CFR

1107.....69586
1109.....69546

Proposed Rules:
301.....72132
303.....68690
305.....72872
Ch. II.....69596
1107.....69482

17 CFR

1.....69334, 71626
4.....71128
21.....69334
39.....69334
140.....69334
150.....71626
151.....71626
200 .....67597, 71449, 71872
201.....71872
202.....71872
210.....71872
229.....71872
230.....71872
232.....71872, 73506
239.....71872
240.....71872
243.....71872
249.....71872
250.....71872
251.....71872
256.....71872
257.....71872
259.....71872
260.....71872
270.....71872
274.....71872
275.....71128, 71872
279.....71128

Proposed Rules:
255.....68846

18 CFR

284.....72301

Proposed Rules:
Ch. I.....70913
11.....72134

19 CFR

4.....68066
10.....68067
24.....68067
162.....68067
163.....68067
178.....68067
210.....71248

Proposed Rules:
101.....69688

20 CFR

655.....73508, 73509

21 CFR

500.....72617
501.....71248
522.....72617
524.....72619
556.....72617

Proposed Rules:
866.....69034
1140.....71281
1300.....72355

22 CFR

42.....67361
123.....68311
126.....68313, 69612

Proposed Rules:
120.....72246
121.....68694
123.....72246
124.....72246
126.....72246
127.....72246
129.....72246

24 CFR

17.....69044
200.....72306

Proposed Rules:
100.....70921
905.....71287
1000.....71474

25 CFR

Proposed Rules:
162.....73784

26 CFR

1 .....71255, 71450, 71878
20.....69126
26.....70340
31.....67363
300.....72619
301 .....67363, 70057, 70340, 71259

Proposed Rules:
1 .....68119, 68370, 68373, 69172, 69188, 71919, 72362, 72367, 72652, 72875
20.....71491
31.....67384
301.....67384
602.....68119, 72367

27 CFR

9.....70866

Proposed Rules:
4.....68373
9.....69198

28 CFR

544.....72623

29 CFR

1980.....68084
4022.....70639

Proposed Rules:
101.....72368
102.....72368
103.....72368

30 CFR

Proposed Rules:
75.....70075
902.....67635
948.....67637

31 CFR

1.....70640

Proposed Rules:
1.....71293
149.....72645
Ch. X.....72878
1010.....69204
1030.....69204

32 CFR

174.....70878
706.....68097
1701.....67599

Proposed Rules:
165.....68376

33 CFR

100 .....68314, 69613, 69622, 70342, 70644, 73996
117 .....68098, 69131, 69632, 69633, 70342, 70345, 70346, 70348, 70349, 71260, 72308,72309, 72839, 73510, 73998
165 .....68098, 68101, 69131, 69613, 69622, 69634, 70342, 70350, 70647, 70649, 70882, 72839, 72842, 73511

Proposed Rules:
117.....70384
135.....67385
136.....67385
165.....72369
167.....67395
Ch. II.....70927

37 CFR

1.....70651, 72270
2.....69132
7.....69132
41.....72270

Proposed Rules:
3.....72372

38 CFR

3.....70883
59.....70885

Proposed Rules:
17.....71920
51.....70076

39 CFR

3055.....70653

Proposed Rules:
3050.....71498

40 CFR

9.....69134
26.....71880
52 .....67366, 67369, 67600, 68103, 68106, 68317, 68638, 69052, 69135, 69896, 69928, 70352, 70354, 70361, 70656,

70886, 70888, 71260, 71450, 71452, 71455, 71881, 71886, 72624, 72626, 72844, 74000
63.....70834, 72050
81.....70361, 71452, 71455, 72097, 74000
98.....73886
112.....72120
180.....69636, 69642, 69648, 69653, 69659, 69662, 70890, 70896, 71459
261.....72311
300.....70057
372.....69136, 70361
Proposed Rules:
52.....67396, 67640, 68378, 68381, 68385, 68698, 68699, 69214, 69217, 70078, 70091, 70929, 70940, 70952, 71922, 72142, 72374, 72377, 72885, 73956, 74014
63.....72508, 72770
81.....70078, 70091
158.....71294
161.....71294
180.....69680, 69692, 69693
280.....71708
281.....71708
300.....70105, 71500

41 CFR

101–26.....67370
102–39.....67371
302–3.....71888
302–9.....71888
303–70.....71890

42 CFR

Ch. IV.....67992
409.....68526
410.....73026, 74122
411.....74122
413.....70228
414.....70228, 73026
415.....73026
416.....74122
419.....74122
424.....68526
425.....67802
484.....68526
489.....74122
495.....73026, 74122
Ch. V.....67992

44 CFR

64.....67372, 70899
65.....68322, 68325
67.....68107, 69665, 72627
Proposed Rules:
67.....70386, 70397, 70403, 72661, 73534, 73537

45 CFR

5b.....72325
170.....72636
1307.....70010

46 CFR

160.....70062
180.....70062
199.....70062

47 CFR

0.....70902, 70904, 73830
1.....68641, 70904, 73830
2.....67604
15.....71892
20.....73830
27.....71909
36.....73830
43.....68641
51.....73830
54.....73830
61.....73830
64.....68116, 68328, 68642, 72124, 73830
69.....73830
73.....67375, 68117, 70660, 70904, 71267, 71909, 72849
74.....70660, 70904, 72849
79.....67366, 67377, 68117
80.....67604
90.....71909
Proposed Rules:
64.....74017
73.....67397, 68124, 69222, 72144, 72885
79.....67397

48 CFR

Ch. 1.....68014, 68044, 70037
1.....68015, 68017, 68043
2.....68015, 68026
3.....68017
4.....68027, 68028, 68043
8.....68032, 68043
12.....68017, 68032
16.....68032
19.....68026, 68032
22.....68015
25.....68027, 68028, 68037, 68039
31.....68040
38.....68032
52.....68015, 68026, 68027, 68028, 68032, 68039
Ch. 2.....71467
202.....71833
203.....71826
211.....71831
212.....71464
215.....71465
216.....71465
218.....71833
219.....71467
225.....71831
232.....71468
242.....71830
245.....71824
252.....71464, 71826
1809.....72327
1850.....72328
1852.....72328
3009.....70660
3052.....70660
Proposed Rules:
1.....73564
4.....73564
19.....73564
52.....73564
204.....70106, 71922
209.....71922
212.....71926
216.....71922
229.....71922
232.....71928
244.....71926
252.....70106, 71922, 71926, 71928

49 CFR

214.....74586
225.....72850
242.....69802
384.....68328
391.....70661
805.....71909
1011.....70664
Proposed Rules:
10.....71930
191.....73570
192.....70953, 72666, 73570
195.....73570
198.....73570
571.....72888
633.....67400

50 CFR

21.....71910
229.....73912
300.....67401, 68332, 70062, 71469, 73517
622.....67618, 68310, 68339, 69136
635.....69137, 69139, 70064, 74003
648.....68642, 68657, 70912, 72125, 74009
660.....68349, 68658, 70362, 73517
665.....72643
679.....68354, 68658, 70665, 71269, 71913, 73513
680.....68358
Proposed Rules:
17.....67401, 68393, 71300, 74018
21.....67650, 69223, 69225
92.....68264
216.....70695
218.....70695
223.....67652, 72891
224.....67652, 72891
226.....68710
622.....67656, 68711, 69230, 74038
635.....72382, 72383
679.....72384
697.....71501

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with ''P L U S'' (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal-register/laws*.

The text of laws is not published in the **Federal Register** but may be ordered in ''slip law'' (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO's Federal Digital System (FDsys) at *http://www.gpo.gov/fdsys*. Some laws may not yet be available.

H.R. 398/P.L. 112–58
To amend the Immigration and Nationality Act to toll, during active-duty service abroad in the Armed Forces, the periods of time to file a petition and appear for an interview to remove the conditional basis for permanent resident status, and for other purposes. (Nov. 23, 2011; 125 Stat. 747)

H.R. 2447/P.L. 112–59

To grant the congressional gold medal to the Montford Point Marines. (Nov. 23, 2011; 125 Stat. 749)

S. 1412/P.L. 112–60

To designate the facility of the United States Postal Service located at 462 Washington Street, Woburn, Massachusetts, as the ''Officer John Maguire Post Office''. (Nov. 23, 2011; 125 Stat. 752)

Last List November 25, 2011

Public Laws Electronic Notification Service (PENS)

PENS is a free electronic mail notification service of newly enacted public laws. To subscribe, go to *http://listserv.gsa.gov/archives/publaws-l.html*

Note: This service is strictly for E-mail notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.