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WHEN: Tuesday, December 11, 2012
9 a.m.–12:30 p.m.

WHERE: Office of the Federal Register
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Title 3—

The President

Proclamation 8903 of November 9, 2012

World Freedom Day, 2012

By the President of the United States of America

A Proclamation

There are times in the course of history when the actions of ordinary citizens spark movements for change because they speak to a longing for freedom that has been building up for years. So it was in Berlin on November 9, 1989, when the German people began tearing down a wall that divided them from their loved ones and symbolized a system that denied them universal human rights. In the face of tyranny, many individuals spoke with one voice. They insisted the world could change—and knowing that destiny is what human beings make of it, they courageously realized the change they sought.

Today, we commemorate the collapse of the Iron Curtain and celebrate the freedom that grew in its place. We also remember that for many, the walls of oppression still stand, and the human rights we honor today are still beyond reach. People around the world continue to demand fundamental liberties they are denied—freedom to express themselves, live their faith, assemble without fear, and choose their leaders freely and fairly. The United States was founded on the belief that people should govern themselves, and as keepers of that proud history, we must stand with those who are reaching for their rights, knowing their success will bring about a world that is more peaceful, more stable, and more just.

As we pursue those goals with renewed vigor, the lessons of the 20th century will continue to remind us what is possible in the 21st. Let us never forget what happened in Berlin 23 years ago, nor the sacrifices that made it possible. And together, let us keep the light of freedom burning bright for all who live in the shadow of oppression and dream of a better future for themselves and their children.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim November 9, 2012, as World Freedom Day. I call upon the people of the United States to observe this day with appropriate ceremonies and activities, reaffirming our dedication to freedom and democracy.

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

[FR Doc. 2012–27918
Filed 11–14–12; 8:45 am]
Billing code 3295–F3

Presidential Documents

Proclamation 8904 of November 9, 2012

American Education Week, 2012

By the President of the United States of America

A Proclamation

All children deserve access to a world-class education and the chance to pursue their dreams. Our schools are a gateway to those opportunities and the key to our Nation's economic prosperity and civic life. This week, we reaffirm our national mission of educating our students and training our workers better than any other country on earth.

My Administration is committed to enhancing American education by raising standards, making higher education more affordable, and preparing students for high-skill jobs and civic participation. We launched Race to the Top—the most meaningful reform for our public schools in a generation—to invest in innovative State plans that support and improve teacher effectiveness and student achievement. We reconfigured the student loan program to eliminate wasteful subsidies to banks and put students' needs first, increasing financial aid for millions of young people. We also invested in training programs that partner community colleges with high-growth industries—making it possible for young Americans to graduate into the workforce equipped for success.

Each of us has a role to play in helping our students thrive. Dedicated teachers, administrators, and other education professionals work tirelessly on behalf of America's young people. Outside of the classroom, parents, mentors, community leaders, local businesses, and public institutions help foster a love of learning in our students, sparking creativity, instilling a positive work ethic, and giving our children the tools needed to realize their full potential.

America is a country where no matter what you look like or where you come from, if you are willing to work hard, you can go as far as your talents will take you. During American Education Week, we recommit to keeping the promise of education alive for this generation and the next, because when we give our children the best chance to succeed, there is no telling what they might accomplish.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim November 11 to November 17, 2012, as American Education Week. I call upon all Americans to observe this week by supporting their local schools through appropriate activities, events, and programs designed to help create opportunities for every school and student in America.

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

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Rules and Regulations

Federal Register

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Thursday, November 15, 2012

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

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

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

12 CFR Part 46

[Docket No. OCC–2012–0016]

Policy Statement on the Principles for Development and Distribution of Annual Stress Test Scenarios

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Interim guidance with request for public comment.

SUMMARY: This interim guidance sets forth the general processes and factors to be used by the OCC in development and distributing the stress test scenarios for the annual stress test required by the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 as implemented by the Annual Stress Test final rule (Stress Test Rule) published on October 9, 2012. Under the Stress Test Rule national banks and Federal savings associations with total consolidated assets of more than $10 billion (covered institutions) are required to conduct annual stress tests using a minimum of three scenarios (baseline, adverse and severely adverse) provided by the OCC. The Stress Test Rule specified that the OCC will provide the required scenarios to the covered institutions by November 15th of each year.

DATES: This interim guidance is effective November 15, 2012. Comments must be submitted on or before January 14, 2013.

ADDRESSES: Because paper mail in the Washington, DC area and at the OCC is subject to delay, commenters are encouraged to submit comments by email if possible. Please use the title ''Policy Statement on Principles for Development and Distribution of Annual Stress Test Scenarios'' to facilitate the organization and distribution of the comments. You may submit comments by any of the following methods:

- *Email: regs.comments@occ.treas.gov.*
- *Mail:* Office of the Comptroller of the Currency, 250 E Street SW., Mail Stop 2–3, Washington, DC 20219.
- *Fax:* (202) 874–5274.
- *Hand Delivery/Courier:* 250 E Street SW., Mail Stop 2–3, Washington, DC 20219.
- *Instructions:* You must include ''OCC'' as the agency name and ''Docket Number OCC–2012–0016'' in your comment. In general, OCC will enter all comments received into the docket and publish them on the Regulations.gov Web site without change, including any business or personal information that you provide such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not enclose any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

You may review comments and other related materials that pertain to this notice by any of the following methods:

- *Viewing Comments Personally:* You may personally inspect and photocopy comments at the OCC, 250 E Street SW., Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 874–4700. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.
- *Docket:* You may also view or request available background documents and project summaries using the methods described above.

FOR FURTHER INFORMATION CONTACT: David Nebhut, Deputy Comptroller for Economic and Policy Analysis, Economic and Policy Analysis (202) 649–5472, Arthur McMahon, Director, International Analysis and Banking Conditions (202) 649–5475, Robert Scavotto, Lead International Expert, International Analysis and Banking Condition (202) 649–5477, Henry Barkhausen, Attorney, Legislative and Regulatory Activities Division (202) 874–5090, or Ron Shimabukuro, Senior Counsel, Legislative and Regulatory Activities Division (202) 874–5090, Office of the Comptroller of the Currency, 250 E Street SW., Washington, DC 20219.

SUPPLEMENTARY INFORMATION:

I. Background

Section 165(i)(2) of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 requires certain financial companies, including national banks and Federal savings associations with total consolidated assets of more than $10 billion (covered institutions), to conduct annual stress tests. The OCC published in the **Federal Register** on October 9, 2012, the final Annual Stress Test rule [1] implementing the requirements and setting out definitions and rules for scope of application, scenarios, reporting, and disclosure. Under the Stress Test Rule, covered institutions are required to conduct annual stress tests based on the annual stress test cycle set out in Table 1.

TABLE 1—PROCESS OVERVIEW OF ANNUAL STRESS TEST CYCLES FOR COVERED INSTITUTIONS

Key step	Over $50 billion	$10 to $50 billion
1. OCC distributes scenarios for annual stress tests.	By November 15	By November 15.

[1] 77 FR 61238 (October 9, 2012).

TABLE 1—PROCESS OVERVIEW OF ANNUAL STRESS TEST CYCLES FOR COVERED INSTITUTIONS—Continued

Key step	Over $50 billion	$10 to $50 billion
2. Covered institutions conduct annual stress test and submit Annual Stress Test Report to the OCC and the Board.	By January 5	By March 31.
3. Covered institutions make required public disclosures.	Between March 15 and March 31	Between June 15 and June 30.

A key component of the annual stress test is the stress test scenarios. Scenarios are sets of conditions that affect the U.S. economy or the financial condition of covered institutions. Each scenario includes the values of the variables specified for each quarter over the stress test horizon. The variables specified for each scenario generally address economic activity, asset prices, and other measures of financial market conditions for the United States and key foreign countries. The OCC annually will determine scenarios that are appropriate for use for each annual stress test. The timeline in Table 1 provides that the OCC will distribute stress test scenarios to covered institutions by November 15th of each year. This document articulates the principles that the OCC will apply to develop and distribute those scenarios for covered institutions.

II. Immediate Effective Date and Request for Comment

This interim guidance is effective November 15, 2012 and applicable, to the extent practicable, to the annual stress test cycle beginning this year. As explained in the preamble, the Stress Test Rule was effective immediately upon publication because the stress testing framework represents a critical tool for national bank supervision and is essential for the health of covered institutions and the overall financial stability of the economy.[2] For this reason, OCC believed that it was necessary for certain national banks and Federal savings associations with consolidated assets of $50 billion or more to conduct stress tests under the Stress Test Rule this year.

The stress tests conducted under the Stress Test Rule framework will provide important forward-looking information to supervisors to assist in the overall assessment of a covered institution's capital adequacy and will help determine whether additional analytical techniques and exercises are appropriate to identify, measure and monitor risk to the financial soundness of the covered institution. Moreover, the OCC believes that the stress tests will benefit the covered institutions by supporting their own forward-looking assessments of their risks and better equip them to address a range of adverse outcomes. Similarly, the OCC believes that it is necessary to make this interim guidance effective immediately. The OCC recognizes that because of timing issues many of the procedural aspects of this interim guidance will not be relevant for the development of the scenarios for this year, however, the OCC believes that it is important to give covered institutions a sense of the general processes and factors used for scenario development that the OCC expects to use going forward, as well as an opportunity to comment.

The agency solicits comment on all aspects of the interim guidance. Specifically, what challenges, if any, exist in applying this guidance generally or at particular banking organizations and why? Are there any terms described by the interim guidance that require further clarification and how should they be defined?

III. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3506; 5 CFR part 1320, Appendix A1, the OCC reviewed the interim guidance. The OCC may not conduct or sponsor, and an organization is not required to respond to, an information collection unless the information collection displays a currently valid OMB control number. The interim guidance contains no new collections of information under the PRA beyond those contained in OMB Control No. 1557–0311, the collection covering the Annual Stress Test rulemaking.

IV. Principles for Development and Distribution of Annual Stress Test Scenarios

The text of the proposed guidance is as follows.

PRINCIPLES FOR DEVELOPMENT AND DISTRIBUTION OF STRESS TEST SCENARIOS

I. INTRODUCTION

Section 165(i)(2) of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 requires certain financial companies, including national banks and Federal savings associations with total consolidated assets of more than $10 billion (covered institutions), to conduct annual stress tests. The Office of the Comptroller of the Currency (OCC) published in the **Federal Register** on October 9, 2012, a final rule (stress test rule) implementing the requirements and setting out definitions and rules for scope of application, scenarios, reporting, and disclosure.[1] Under the stress test rule, each year the OCC will distribute stress test scenarios to covered institutions. This document articulates the principles that the OCC will apply to develop and distribute those scenarios for covered institutions.

II. STRESS TESTS

As defined by the stress test rule, a stress test is ''a process to assess the potential impact of stressful scenarios on the consolidated earnings, losses, and capital of a covered institution over the planning horizon, taking into account the covered institution's current condition, risks, exposures, strategies, and activities.''[2]

Stress tests help covered institutions and the OCC determine whether those institutions have capital sufficient to absorb losses that could result from adverse economic conditions. The OCC views stress test results as one source of forward-looking information that can help identify downside risks and assess the potential impact of adverse outcomes on capital adequacy. Stress tests are not the only tool the OCC uses for these purposes; a complete assessment of a covered institution's capital position typically includes review of its capital planning processes, the governance concerning those processes, and the adequacy of capital under established regulatory capital measures. The OCC expects the board of directors and senior management of each covered institution to consider the results of the annual stress test when conducting capital planning, assessing capital adequacy, and evaluating risk management practices. The OCC also may use stress test results to determine whether additional analytical techniques and exercises are appropriate for a covered institution to employ in identifying, measuring, and monitoring risks to the financial soundness of the covered institution.

Under the final rule, each covered institution is required to conduct an annual stress test using its financial data as of September 30 of each year, unless the OCC requires a different ''as of'' date for any or all categories of financial data. The stress test

[2] See Id. at 61244.

[1] Annual Stress Test, 77 FR 61238 (October 9, 2012).

[2] 12 CFR 46.2 (Definition of Stress Test).

must assess the potential impact of specific scenarios on the regulatory capital of the covered institution and on certain related items over a forward-looking planning horizon, taking into account all relevant exposures and activities.[3] Under the final rule, the planning horizon is at least nine quarters, consisting of the fourth quarter of the current calendar year plus all four quarters of each of the two subsequent calendar years.

III. SCENARIOS

Scenarios are sets of conditions that affect the U.S. economy or the financial condition of covered institutions.[4] The OCC annually will determine scenarios that are appropriate for use under the stress test rule. In conducting the stress test under the stress test rule, each covered institution must use the scenarios provided by the OCC.

Each scenario includes the values of the variables specified for each quarter over the stress test horizon. The OCC expects that covered institutions may not need to use all of the variables provided and may need to estimate relationships to identify other variables, such as those reflecting local economic conditions, from the values the OCC provides. The OCC will review the appropriateness of estimation processes and resulting estimates, or other modifications of variables, through its ongoing supervisory processes.

The variables specified for each scenario generally address economic activity, asset prices, and other measures of financial market conditions for the United States and key foreign countries. Variables that describe economic activity likely will include, but not be limited to, the growth rate of gross domestic product, the unemployment rate, and the inflation rate. The OCC anticipates that the path (which reflects the level and rate of change) of the unemployment rate during the planning horizon in particular will be a key variable indicating the severity of economic stress, as this variable provides a simple and widely noted gauge of the state of the U.S. economy. This point is discussed further in this statement in connection with severely adverse scenarios.

Other variables may represent asset prices and financial market conditions, including interest rates. The OCC expects to specify scenarios using a fairly stable core set of variables, although variables may be added or deleted as the U.S. and global economic environment evolves. The OCC will attempt to minimize additions, redefinitions, or re-specifications from year to year, recognizing that the use of new or modified variables for stress tests may require potentially costly systems changes at covered institutions.

The scenarios provided by the OCC reflect at least three sets of economic and financial conditions, described in the rule as baseline, adverse, and severely adverse. The baseline broadly corresponds to the set of conditions expected to prevail over the term of the stress tests. The adverse and severely adverse scenarios introduce hypothetical stress conditions intended to test the safety and soundness of covered institutions as well as their capital planning processes. The aim is to assess the covered institutions' ability to identify and measure the risks it faces under adverse conditions, and to ensure that appropriate amounts of capital exist to support those risks. The OCC will evaluate both the adequacy of the projections and the processes used in the company-run stress test. The OCC expects covered institutions to be able to maintain ready access to funding, continue operations, meet obligations to creditors and counterparties, and continue to serve as credit intermediaries under conditions that are significantly more adverse than expected.

The *baseline* scenario establishes a benchmark set of conditions that incorporates the most current views on the macroeconomic outlook. These views are based on information obtained from government agencies, other public sector organizations, and private sector forecasters as close to the date of the annual stress test as possible. The baseline may be based on one or more of the ''consensus'' forecasts produced by various organizations, although the OCC may choose to depart from the consensus if necessary to provide a more appropriate baseline for the stress tests.

The *adverse* scenario is a hypothetical set of conditions designed to simulate a moderate level of stress that covered companies could experience, such as a mild-to-moderate U.S. recession. The adverse scenario may also be used to investigate other risks, perhaps including operational risks, that the OCC believes should be better understood or more closely monitored.

The *severely* adverse scenario is a set of quite challenging economic and financial conditions, such as those that might be experienced in a relatively severe recession. Three examples of severe recessions from recent U.S. experience may illustrate the anticipated depth of the severely adverse scenario as it relates to the unemployment rate:

- The 1973–75 recession, during which the unemployment rate increased 4.1 percentage points, from 4.9 percent in 1973Q3 to 9.0 percent in 1975Q2 (one quarter after the recession ended).
- The back-to-back recessions in 1980 and 1981–82, during which the unemployment rate increased 4.7 percentage points, from 6.1 percent in 1979Q4 to 10.8 percent in 1982Q4 (the last quarter of the recession).
- The 2007–09 recession, during which the unemployment rate increased 5.3 percentage points, from 4.7 percent in 2007Q3 to 10.0 percent in 2009Q4 (two quarters after the recession ended).

Other variables under the adverse and severely adverse scenarios would be expected to follow paths consistent with the depth and duration of previous recessions and with models of macroeconomic activity. The severely adverse scenario also may reflect other risks that are especially salient and that might not be captured by past recessions, including elevated levels of systemic risk.

The scenarios distributed by the OCC for the stress tests cover at least nine quarters. In addition, the OCC will generally publish scenarios that cover one year beyond the planning horizon of the stress test, to allow for the estimation of loan losses for the year following the stress planning horizon; this additional specification allows covered institutions to determine adequate levels of loan loss reserves.

The OCC believes that as a general matter all covered institutions should use the same set of scenarios and planning horizon so that the OCC can better compare results across institutions. To that end, the OCC intends to provide one set of scenarios for use by all covered institutions. However, the OCC believes there may be circumstances that would warrant the use of different or additional scenarios or a planning horizon of more than nine quarters. Thus, under the stress test rule the OCC reserves the authority to require a covered institution to use different or additional scenarios and/or planning horizons the agency may deem appropriate. For example, a covered institution may conduct business activities or have risk exposures that would encounter stress under conditions that differ materially from those that would generate stress for other institutions. The OCC expects such situations to be rare and anticipates making every effort to distribute the same scenarios to all covered institutions.

In addition to the minimum three scenarios, the OCC may require a covered institution with significant trading activities to include factors related to trading and counterparty risk in its stress test. Typically, these factors might include additional shocks to specific market prices, interest rates, rate spreads, or other key market variables consistent with historical or hypothetical adverse market events.

IV. DEVELOPMENT AND DISTRIBUTION

As one part of the process of developing scenarios, the OCC will gather information from outside entities and develop themes for the stress test scenarios, including the identification of potentially material vulnerabilities or salient risks to the financial system, and consider potential paths for individual variables. The outside entities may include academic experts, staffs of international organizations, foreign supervisors, financial institutions that regularly provide forecasts, and other private sector risk analysts that regularly conduct stress tests based on U.S. and global economic and financial scenarios. The OCC will use the information gathered in this manner to inform its consideration of potential risks and scenarios.

The OCC, the Board of Governors of the Federal Reserve System (Board), and the Federal Deposit Insurance Corporation (FDIC) (Agencies) expect to consult closely to develop scenarios for stress testing. Absent specific supervisory concerns, the OCC anticipates that the annual stress test scenarios distributed by the OCC will be the same as or nearly identical to the scenarios developed by the Board for the supervisory stress tests conducted by the Board under Section 165(i)(1). This would mean the same economic and financial variables following the same paths as used in the scenarios for the Board's supervisory stress tests.

[3] Id. at 46.6(a).

[4] Id. at 46.2 (Definition of scenarios).

Although the Agencies generally expect to consult closely on scenario development, they may have different views of risks that should be reflected in the stress test scenarios used by covered institutions for the annual stress test. The OCC may distribute scenarios to covered institutions that differ in certain respects from those distributed by the FDIC and the Board if necessary to better reflect specific OCC concerns. The OCC expects such situations to be extremely rare, however, and anticipates making every effort to avoid differences in the scenarios required by each agency.

The OCC anticipates that the stress test scenarios will be revised annually as appropriate to ensure that each scenario remains relevant under prevailing economic and industry conditions. These yearly revisions will enable the scenarios to capture evolving risks and vulnerabilities. The need to ensure that scenarios do not become outdated because of economic and financial developments makes a lengthy process of review and comment concerning scenarios prior to distribution each year impractical. However, the process of consultation with the Board and the FDIC, as well as the ongoing interaction of OCC staff with public and private sector experts to obtain views on salient risks and to obtain suggestions for the behavior of key economic variables, should ensure that the stress conditions reflected in the scenarios are well suited to their purpose.

The scenario development process culminates with the distribution of the scenarios to all covered institutions no later than November 15 of each year. The scenario descriptions provided to covered institutions will include values for economic and financial variables depicting the paths those variables follow under the scenarios. The OCC believes that distribution of the scenarios by November 15 aligns with similar processes at the FDIC and the Board.

Dated: November 6, 2012.

Thomas J. Curry,

Comptroller of the Currency.

[FR Doc. 2012–27660 Filed 11–14–12; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–0488; Directorate Identifier 2011–NM–106–AD; Amendment 39–17244; AD 2012–22–08]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Airbus Model A300 B4–600 and A300 B4–600R, Model A300, and Model A310 series airplanes. This AD was prompted by reports of fatigue cracking in the crossbeams at the junction of the actuator beam of the lower deck cargo door. This AD requires repetitive inspections of the crossbeams of certain fuselage frames, and repair if necessary. We are issuing this AD to detect and correct cracking of the crossbeams at the junction of the actuator beam of the lower deck cargo door, which could result in failure to withstand ultimate load conditions, and consequent reduced structural integrity of the airplane.

DATES: This AD is effective December 20, 2012.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in the AD as of December 20, 2012.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–2125; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM published in the **Federal Register** on May 22, 2012 (77 FR 30228). That NPRM proposed to correct an unsafe condition for the specified products. The Mandatory Continuing Airworthiness Information (MCAI) states:

> Some operators have reported cracked crossbeams at the junction with the lower deck cargo door actuator beam. The investigation results indicate that these cracks initiated in the fastener hole, propagated in a vertical direction and were due to fatigue.
>
> This condition, if not corrected, could lead, in case of cracks propagation in a crossbeam (upper and lower web), to the floor grid being unable to withstand ultimate load condition. For the reasons described above, this [European Aviation Safety Agency (EASA)] AD requires repetitive [high frequency eddy current] inspections [for cracks] of certain crossbeams including those previously repaired by the Structure Repair Manual (SRM) or Repair Approval Sheet (RAS).

The required actions include repairing any cracking. As an option, modifying the crossbeams terminates the repetitive inspections. You may obtain further information by examining the MCAI in the AD docket.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the proposal (77 FR 30228, May 22, 2012) and the FAA's response to each comment.

Request To Clarify That Freighter Airplanes Are Not Affected

UPS stated that the NPRM (77 FR 30228, May 22, 2012) does not apply to its Model A300 F4–622R airplanes.

We infer that the commenter is asking for clarification that its airplanes are not affected by the proposed requirements. Freighter airplanes identified as freighters on the initial certificate of airworthiness are excluded from the applicability in this AD. The loads distribution via the main deck cargo loading system onto the floor grid is different from passenger airplanes. In addition, the European Aviation Safety Agency (EASA), which is the aviation authority for the Member States of the European Community, has granted an alternative method of compliance (AMOC) for Airbus airplanes converted from passenger to freighter configuration by EASA supplemental type certificate (STC). We have changed the applicability in paragraph (c) of this AD to exclude airplanes converted by the equivalent FAA STCs *ST01431NY, ST00177LA–D,* and *ST00100NY.*

Request To Extend Repetitive Inspection Interval/Eliminate Compliance Time for Corrective Action

FedEx asked that the repetitive inspection interval specified in paragraph (g) of the NPRM (77 FR 30228, May 22, 2012), be extended from 600 flight cycles to within 1,500 flight cycles or 24 months after the effective date of the AD, whichever occurs first. FedEx stated that the current repetitive inspection interval is ten times more frequent than the 6,000-flight-cycle interval in the existing airworthiness limitations items and maintenance review board requirements. FedEx added that these maintenance program items have been performed regularly at FedEx and have yielded few findings. FedEx noted that this extension will coincide with its regular maintenance check schedule.

FedEx also stated that paragraph (g)(2) of the NPRM (77 FR 30228, May 22, 2012) specifies that, if a prior repair has

been done on the crossbeam, the corrective action requires accomplishing a repair within 600 flight cycles after the effective date of the AD. This places an additional burden on operators by mandating replacement of the crossbeam.

We disagree with the requests to extend the compliance time for the repetitive inspections and to eliminate the compliance time for the corrective action. Based on the data provided by Airbus, we determined that repetitive intervals of 600 flight hours and doing the repair before the accumulation of 10,000 total flight cycles since first flight of the airplane, or within 600 flight cycles after the effective date of this AD, whichever occurs later, is appropriate to address the identified unsafe condition. In developing an appropriate compliance time for these actions, we considered the urgency associated with the subject unsafe condition, the manufacturer's recommendations, and the practical aspect of accomplishing the required actions within a period of time that corresponds to the normal scheduled maintenance for most affected operators. In addition, our compliance time corresponds with the compliance time of the parallel AD issued by EASA. Under the provisions of paragraph (j)(1) of this AD, we will consider requests for approval of an extension of the compliance time if sufficient data are submitted to substantiate that the new compliance time would provide an acceptable level of safety. We have not changed the AD in this regard.

Product Identification Correction

We have changed the product identification in this AD to specify ''Airbus.'' We inadvertently listed ''The Boeing Company'' in the product identification section of the NPRM (77 FR 30228, May 22, 2012).

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting the AD with the changes described previously. We also determined that these changes will not increase the economic burden on any operator or increase the scope of the AD.

Costs of Compliance

Based on the service information, we estimate that this AD affects about 152 products of U.S. registry. We also estimate that it will take about 1 work-hour per product to comply with the basic requirements of this AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of the AD on U.S. operators to be $12,920, or $85 per product.

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify that this AD:

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

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2012–22–08 Airbus: Amendment 39–17244; Docket No. FAA–2012–0488; Directorate Identifier 2011–NM–106–AD.

(a) Effective Date

This AD is effective December 20, 2012.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Model A300 B2–1A, B2–1C, B2K–3C, B2–203, B4–2C, B4–103, and B4–203 airplanes; Model A300 B4–601, B4–603, B4–620, and B4–622 airplanes; Model A300 B4–605R and B4–622R airplanes; and Model A310–203, -204, -221, -222, -304, -322, -324, and -325 airplanes; certificated in any category; except those airplanes identified in paragraph (c)(1), (c)(2), (c)(3), and (c)(4) of this AD.

(1) Airplanes on which Airbus Service Bulletin A300–53–6166 (Airbus Modification 13434) has been embodied in service (for Model A300 B4–600 and A300 B4–600R series airplanes).

(2) Airplanes on which Airbus Service Bulletin A300–53–0389 (Airbus Modification 13434) has been embodied in service (for Model A300 series airplanes).

(3) Airplanes on which Airbus Service Bulletin A310–53–2133 (Airbus Modification 13434) has been embodied in service (for Model A310 series airplanes).

(4) Airplanes modified by FAA Supplemental Type Certificate (STC) *ST01431NY, ST00177LA–D*, or *ST00100NY*, as applicable.

(d) Subject

Air Transport Association (ATA) of America Code 53: Fuselage.

(e) Reason

This AD was prompted by reports of fatigue cracking in the crossbeams at the junction of the actuator beam of the lower deck cargo door. We are issuing this AD to detect and correct cracking of the crossbeams at the junction of the actuator beam of the lower deck cargo door, which could result in failure to withstand ultimate load conditions, and consequent reduced structural integrity of the airplane.

(f) Compliance

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

(g) Repetitive High Frequency Eddy Current Inspections

(1) For airplanes on which the crossbeams at frames (FR) 22/23 and FR 61/62 have not

been repaired as specified in an Airbus structural repair manual or repair approval sheet as of the effective date of this AD: Before the accumulation of 10,000 total flight cycles since first flight of the airplane, or within 600 flight cycles after the effective date of this AD, whichever occurs later, perform a high frequency eddy current (HFEC) inspection for cracking of the crossbeam fuselage frame stations FR 22/23 and FR 61/62, in accordance with the Accomplishment Instructions of the applicable service bulletin identified in paragraph (g)(1)(i), (g)(1)(ii), or (g)(1)(iii) of this AD. Repeat the inspection thereafter at intervals not to exceed 600 flight cycles until the modification specified in paragraph (i) of this AD has been done.

(i) Airbus Mandatory Service Bulletin A300–53–0390, dated January 15, 2010 (for Model A300 series airplanes).

(ii) Airbus Mandatory Service Bulletin A310–53–2134, dated January 15, 2010 (for Model A310 series airplanes).

(iii) Airbus Mandatory Service Bulletin A300–53–6168, dated January 15, 2010 (for Model A300–600 series airplanes).

(2) For airplanes on which the crossbeams at FR 22/23 and FR 61/62 have been repaired as specified in an Airbus structural repair manual or repair approval sheet as of the effective date of this AD: Before the accumulation of 10,000 total flight cycles since first flight of the airplane, or within 600 flight cycles after the effective date of this AD, whichever occurs later, repair in accordance with a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA) (or its delegated agent).

(h) Corrective Action

If any crack is found during any inspection required by paragraph (g) of this AD: Before further flight, repair any crack using a method approved by the Manager, International Branch, ANM–116; or EASA (or its delegated agent).

(i) Optional Terminating Action

Modifying the crossbeam fuselage frame stations FR 22/23 and FR 61/62, including doing rotating probe inspections for cracks of fastener holes, in accordance with the Accomplishment Instructions of the applicable service bulletin identified in paragraph (i)(1), (i)(2), or (i)(3) of this AD, and repairing any crack using a method approved by the Manager, International Branch, ANM–116; or EASA (or its delegated agent); terminates the repetitive inspections required by paragraph (g)(1) of this AD.

(1) Airbus Service Bulletin A300–53–0389, Revision 02, dated April 27, 2011 (for Model A300 series airplanes).

(2) Airbus Service Bulletin A310–53–2133, Revision 02, dated April 27, 2011 (for Model A310 series airplanes).

(3) Airbus Service Bulletin A300–53–6166, Revision 01, dated May 21, 2010 (for Model A300–600 series airplanes).

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–2125; fax (425) 227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

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

(k) Related Information

Refer to EASA Airworthiness Directive 2011–0086, dated May 12, 2011; and the service information identified in paragraphs (k)(1), (k)(2), (k)(3), (k)(4), (k)(5), and (k)(6) of this AD, for related information.

(1) Airbus Mandatory Service Bulletin A300–53–0390, dated January 15, 2010.

(2) Airbus Mandatory Service Bulletin A300–53–6168, dated January 15, 2010.

(3) Airbus Mandatory Service Bulletin A310–53–2134, dated January 15, 2010.

(4) Airbus Service Bulletin A300–53–0389, Revision 02, dated April 27, 2011.

(5) Airbus Service Bulletin A300–53–6166, Revision 01, dated May 21, 2010.

(6) Airbus Service Bulletin A310–53–2133, Revision 02, dated April 27, 2011.

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Airbus Mandatory Service Bulletin A300–53–0390, dated January 15, 2010.

(ii) Airbus Mandatory Service Bulletin A300–53–6168, dated January 15, 2010.

(iii) Airbus Mandatory Service Bulletin A310–53–2134, dated January 15, 2010.

(iv) Airbus Service Bulletin A300–53–0389, Revision 02, dated April 27, 2011.

(v) Airbus Service Bulletin A300–53–6166, Revision 01, dated May 21, 2010.

(vi) Airbus Service Bulletin A310–53–2133, Revision 02, dated April 27, 2011.

(3) For service information identified in this AD, contact Airbus SAS—EAW (Airworthiness Office), 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.*

(4) 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.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on October 24, 2012.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2012–27055 Filed 11–14–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–0643; Directorate Identifier 2011–NM–190–AD; Amendment 39–17241; AD 2012–22–05]

RIN 2120–AA64

Airworthiness Directives; Fokker Services B.V. Airplanes

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

ACTION: Final rule.

SUMMARY: We are superseding an existing airworthiness directive (AD) for certain Fokker Services B.V. Model F.28 Mark 0070 and 0100 airplanes. That AD currently requires performing a detailed visual inspection for cracks of the pistons on the main landing gear (MLG), and replacing the affected pistons if necessary. This new AD also requires modifying the MLG by installing a piston containing a certain part number, and revising the airplane maintenance program. This AD was prompted by a new modification developed to safeguard the integrity of the MLG assembly and improve surface protection of the affected area of the MLG piston. We are issuing this AD to prevent MLG failure, possibly resulting in loss of control of the airplane during the landing roll-out.

DATES: This AD becomes effective December 20, 2012.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of December 20, 2012.

The Director of the Federal Register approved the incorporation by reference of a certain other publication listed in this AD as of March 22, 2011 (76 FR 8618, February 15, 2011).

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone 425–227–1137; fax 425–227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the **Federal Register** on June 21, 2012 (77 FR 37337), and proposed to supersede AD 2011–04–01, Amendment 39–16601 (76 FR 8618, February 15, 2011). That NPRM proposed to correct an unsafe condition for the specified products. The Mandatory Continuing Airworthiness Information (MCAI) states:

During a normal walk around check on a F28 Mark 0100 aeroplane, a large crack was discovered in the lower portion of the right (RH) MLG piston. The affected MLG unit had accumulated 7,909 flight cycles (FC) at the time of detection. The piston was sent to Goodrich, the landing gear manufacturer, for detailed investigation, which revealed that the crack had been initiated by corrosion pits. The extent of the corrosion indicates that the initial crack existed for a substantial period before a high loading event caused the crack to grow further by ductile overload.

This condition, if not detected and corrected, could lead to MLG failure during the landing roll-out, possibly resulting in damage to the aeroplane and injury to occupants.

To address this potential unsafe condition, EASA [European Aviation Safety Agency] issued AD 2009–0221 [which corresponds with FAA AD 2011–04–01, Amendment 39–16601 (76 FR 8618, February 15, 2011)] to require a one-time detailed visual inspection of the MLG pistons, the replacement of any MLG pistons on which cracks are detected, and the reporting of all findings to the aeroplane TC [type certificate] holder. No cracks were reported as a result of this inspection.

Subsequently, a repetitive inspection was introduced in the Airworthiness Limitations Section (Fokker Services report SE–623 Issue 8) in Appendix 1 of the Maintenance Review Board (MRB) document to safeguard the integrity of the MLG assembly, pending the accomplishment of a terminating action.

Goodrich issued Service Bulletin (SB) 41000–32–29 to introduce an improved surface protection (nickel plate) of the affected area of the MLG piston P/N [part number] 41141–3 and re-identification as P/N 41141–5, which is considered as a terminating action for the repetitive inspections.

For the reasons described above, this [EASA] AD requires repetitive visual inspections of the P/N 41141–3 MLG piston for cracks and, depending on findings, replacement or modification of the MLG piston. This [EASA] AD also requires modification of the affected MLG by installing a piston P/N 41141–5.

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

Change Made to This AD

We have revised paragraphs (k), (l), and (n), of this final rule to clarify the document citation of Fokker Report SE–623 to meet the Office of Federal Register's guidelines for materials incorporated by reference. There is no change to the requirements specified in those paragraphs.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM (77 FR 37337, June 21, 2012) or on the determination of the cost to the public.

Conclusion

We reviewed the available data and determined that air safety and the public interest require adopting the AD as proposed—except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM (77 FR 37337, June 21, 2012) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (77 FR 37337, June 21, 2012).

Costs of Compliance

We estimate that this AD will affect about 2 products of U.S. registry.

The actions that are required by AD 2011–04–01, Amendment 39–16601 (76 FR 8618, February 15, 2011), and retained in this AD take about 3 work-hours per product, at an average labor rate of $85 per work-hour. Based on these figures, the estimated cost of the currently required actions is $255 per product.

We estimate that it will take about 24 work-hours per product to comply with the new basic requirements of this AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of this AD to the U.S. operators to be $4,080, or $2,040 per product.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify that this AD:

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

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

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket

contains the NPRM (77 FR 37337, June 21, 2012), the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing airworthiness directive (AD) 2011–04–01, Amendment 39–16601 (76 FR 8618, February 15, 2011), and adding the following new AD:

2012–22–05 Fokker Services B.V.: Amendment 39–17241. Docket No. FAA–2012–0643; Directorate Identifier 2011–NM–190–AD.

(a) Effective Date

This airworthiness directive (AD) becomes effective December 20, 2012.

(b) Affected ADs

This AD supersedes AD 2011–04–01, Amendment 39–16601 (76 FR 8618, February 15, 2011).

(c) Applicability

(1) This AD applies to Fokker Services B.V. Model F.28 Mark 0070 and 0100 airplanes, certificated in any category, all serial numbers, equipped with Goodrich (formerly Menasco, Colt Industries) main landing gear (MLG) units, part numbers (P/N) 41050–7, 41050–8, 41050–9, 41050–10, 41050–11, 41050–12, 41050–13, 41050–14, 41050–15, 41050–16, 41060–1, 41060–2, 41060–3, 41060–4, 41060–5, or 41060–6.

(2) This AD requires revisions to certain operator maintenance documents to include new actions (e.g., inspections). Compliance with these inspections is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by these actions, the operator may not be able to accomplish the actions described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative method of compliance (AMOC) according to paragraph (m)(1) of this AD. The request should include a description of changes to the required inspections that will ensure the continued operational safety of the airplane.

(d) Subject

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

(e) Reason

This AD was prompted by a new modification developed to safeguard the integrity of the MLG assembly and improve surface protection of the affected area of the MLG piston. We are issuing this AD to prevent MLG failure, possibly resulting in loss of control of the airplane during the landing roll-out.

(f) Compliance

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

(g) Retained Initial Inspection

This paragraph restates the initial inspection required by paragraph (g) of AD 2011–04–01, Amendment 39–16601 (76 FR 8618, February 15, 2011). Within 30 days after March 22, 2011 (the effective date of AD 2011–04–01), do a detailed visual inspection for cracks of the MLG pistons, in accordance with the Accomplishment Instructions of Fokker Service Bulletin SBF100–32–158, dated October 2, 2009.

(h) Retained Replacement

This paragraph restates the replacement required by paragraph (h) of AD 2011–04–01, Amendment 39–16601 (76 FR 8618, February 15, 2011). If any cracked MLG piston is found during the inspection required by paragraph (g) of this AD, before further flight, replace the affected piston with a serviceable part, in accordance with the Accomplishment Instructions of Fokker Service Bulletin SBF100–32–158, dated October 2, 2009.

(i) New Modification

Within 120 months, or during a scheduled overhaul of the MLG, whichever occurs first after the effective date of this AD: Modify the MLG by installing a piston containing P/N 41141–5, in accordance with the Accomplishment Instructions of Fokker Service Bulletin SBF100–32–161, dated April 7, 2011. Re-installation of a MLG piston that has been modified and re-identified as P/N 41141–5, in accordance with the Accomplishment Instructions of Goodrich Service Bulletin 41000–32–29, dated November 10, 2010, is an optional method of compliance for the requirements specified in paragraph (i) of this AD. It is acceptable to operate an airplane with one MLG having a P/N 41141–5 piston installed, and the other MLG having a P/N 41141–3 piston installed, provided all MLG P/N 41141–3 are replaced within the compliance times specified in paragraph (i) of this AD.

(j) New Parts Installation Prohibition

After 120 months after the effective date of this AD: No person may install a MLG piston, P/N 41141–3, or a MLG unit equipped with a MLG piston P/N 41141–3, on any airplane.

(k) New Revision of the Airplane Maintenance Program

Within 2 months after the effective date of this AD: Revise the airplane maintenance program by incorporating Task 321100–01–16, Inspection of MLG Piston, and associated thresholds and intervals described in Fokker Report, SE–623, Fokker 70/100 Airworthiness Limitation Items and Safe Life Items, Issue 8, dated December 20, 2010. The initial compliance time for Task 321100–01–16 is within 2 months after the effective date of this AD.

(l) No Alternative Actions or Intervals

After accomplishing the revisions required by paragraph (k) of this AD, no alternative actions (e.g., inspections) or intervals may be used other than those specified in Fokker Report, SE–623, Fokker 70/100 Airworthiness Limitation Items and Safe Life Items, Issue 8, dated December 20, 2010, unless the actions and intervals are approved as an AMOC in accordance with the procedures specified in paragraph (m)(1) of this AD.

(m) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone 425–227–1137; fax 425–227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov*. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

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

(n) Related Information

Refer to MCAI European Aviation Safety Agency Airworthiness Directive 2011–0159, dated August 26, 2011, and the service information specified in paragraphs (n)(1)through (n)(4) of this AD, for related information.

(1) Fokker Service Bulletin SBF100–32–158, dated October 2, 2009.

(2) Fokker Service Bulletin SBF100–32–161, dated April 7, 2011.

(3) Fokker Report, SE–623, Fokker 70/100 Airworthiness Limitation Items and Safe Life Items, Issue 8, dated December 20, 2010.

(4) Goodrich Service Bulletin 41000–32–29, dated November 10, 2010.

(o) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(3) The following service information was approved for IBR on December 20, 2012.

(i) Fokker Service Bulletin SBF100–32–161, dated April 7, 2011.

(ii) Fokker Report, SE–623, Fokker 70/100 Airworthiness Limitation Items and Safe Life Items, Issue 8, dated December 20, 2010.

(iii) Goodrich Service Bulletin 41000–32–29, dated November 10, 2010.

(4) The following service information was approved for IBR on March 22, 2011 (76 FR 8618, February 15, 2011).

(i) Fokker Service Bulletin SBF100–32–158, dated October 2, 2009.

(ii) Reserved.

(5) For service information identified in this AD, contact Fokker Services B.V., Technical Services Dept., P.O. Box 231, 2150 AE Nieuw-Vennep, the Netherlands; telephone +31 (0)252–627–350; fax +31 (0)252–627–211; email *technicalservices.fokkerservices@stork.com;* Internet *http://www.myfokkerfleet.com.* For Goodrich Corporation service information identified in this AD, contact Goodrich, 1400 South Service Road, West Oakville, L6L 5Y7, Ontario, Canada, telephone +1–905–827–7777; fax +1–905–825–1583; Internet *http://www.goodrich.com/TechPubs.*

(6) You may review copies of the service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(7) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on October 24, 2012.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2012–26781 Filed 11–14–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–0530; Directorate Identifier 2011–SW–075–AD; Amendment 39–17247; AD 2012–22–11]

RIN 2120–AA64

Airworthiness Directives; Bell Helicopter Textron Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for Bell Helicopter Textron (BHT) Model 412, 412EP, and 412CF helicopters. This AD requires a repetitive inspection of the collective lever for a crack, and if there is a crack, before further flight, replacing the collective lever with an airworthy collective lever. This AD was prompted by a reported failure of a collective lever. The actions are intended to detect a crack in the collective lever, which could lead to failure of the collective lever and subsequent loss of control of the helicopter.

DATES: This AD is effective December 20, 2012.

The Director of the Federal Register approved the incorporation by reference of certain documents listed in this AD as of December 20, 2012.

ADDRESSES: For service information identified in this AD, contact Bell Helicopter Textron, Inc., P.O. Box 482, Fort Worth, Texas 76101; telephone (817) 280–3391; fax (817) 280–6466; or at *http://www.bellcustomer.com/files/.* You may review a copy of the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

Examining the AD Docket: You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, any incorporated-by-reference service information, the economic evaluation, any comments received, and other information. The street address for the Docket Operations Office (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations Office, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Martin Crane, Aerospace Engineer, Rotorcraft Certification Office, Rotorcraft Directorate, FAA, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone (817) 222–5170; email *martin.r.crane@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

On May 22, 2012, at 77 FR 30232, the **Federal Register** published our notice of proposed rulemaking (NPRM), which proposed to amend 14 CFR part 39 to include an AD that would apply to certain serial-numbered BHT Model 412, 412EP, and 412CF helicopters with a collective lever, part number (P/N) 412–010–408–101. That NPRM proposed to require within 25 hours time-in-service (TIS) or 30 days, whichever occurs first, and thereafter at intervals not to exceed 100 hours TIS, cleaning the collective lever and inspecting it for cracks with a 10X or higher power magnifying glass. If there is a crack in the collective lever paint finish, the NPRM proposed to require removing the collective lever from the swashplate and performing a fluorescent penetrant inspection, and if there is a crack in the collective lever, before further flight, replacing the collective lever with an airworthy collective lever. The proposed requirements were intended to detect a crack in the collective lever, which could lead to failure of the collective lever and subsequent loss of control of the helicopter.

Comments

We gave the public the opportunity to participate in developing this AD, but we did not receive any comments on the NPRM (77 FR 30232, May 22, 2012).

FAA's Determination

We have reviewed the relevant information and determined that an unsafe condition exists and is likely to exist or develop on other products of these same type designs and that air safety and the public interest require adopting the AD requirements as proposed.

Related Service Information

We reviewed Bell Helicopter Alert Service Bulletin (ASB) No. 412–11–148 and ASB No. 412CF–11–47, both Revision A, and both dated December 12, 2011, which describe procedures for repetitively inspecting the collective lever with a magnifying glass and a strong light source and, if necessary, a fluorescent penetrant inspection. If there is a crack, the ASBs require replacing the collective lever.

Differences Between This AD and the Service Information

The BHT ASBs require compliance within 100 hours of flight time for the initial inspection; this AD requires compliance within 25 hours TIS or 30 days, whichever occurs first. If there is a crack, the BHT ASBs require reporting the defect to Bell Product Support Engineering; this AD does not. The BHT ASBs allow a portion of the collective lever to be inspected by a mirror and light only without a magnifying glass; this AD requires using a 10X or higher power magnifying glass for the entire inspection.

Costs of Compliance

We estimate that this AD will affect 83 helicopters of U.S. Registry. We estimate that operators may incur the following costs in order to comply with this AD. Inspecting the collective lever requires one work-hour at an average labor rate of $85 per work-hour, for a cost per helicopter of $85 and a total cost to the U.S. operator fleet of $7,055 per inspection cycle. Replacing a cracked collective lever requires 10 work-hours at an average labor rate of $85 per work-hour and required parts will cost $12,883, for a total cost of $13,733 per helicopter.

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

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

For the reasons discussed above, I certify that this AD:

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

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

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and

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

We prepared an economic evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2012–22–11 Bell Helicopter Textron: Amendment 39–17247; Docket No. FAA–2012–0530; Directorate Identifier 2011–SW–075–AD.

(a) Applicability

This AD applies to Model 412 and 412EP helicopters, serial numbers (S/N) 33001 through 33213, 34001 through 34036, and 36001 and higher; and Model 412CF helicopters, S/N 46400 and higher; with a collective lever part number (P/N) 412–010–408–101 installed, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as a cracked collective lever, which could result in failure of the collective lever and subsequent loss of control of the helicopter.

(c) Effective Date

This AD becomes effective December 20, 2012.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

Within 25 hours time-in-service (TIS) or 30 days, whichever occurs first, and thereafter at intervals not to exceed 100 hours TIS:

(1) Using cleaning compound (C–318) or equivalent, thoroughly clean the collective lever.

(2) Using a 10X or higher power magnifying glass, inspect the collective lever in the areas shown in Figure 1 of Bell Helicopter Textron Alert Service Bulletin (ASB) 412–11–148, Revision A, dated December 12, 2011 or Bell Helicopter Textron ASB 412CF–11–47, Revision A, dated December 12, 2011, as appropriate for your model helicopter.

(3) If there is a crack in the paint, remove the collective lever from the swashplate assembly.

(i) Remove paint and primer from the area around the crack.

(ii) Fluorescent penetrant inspect the area of the crack.

(4) If there is a crack in the collective lever, before further flight, replace the collective lever with an airworthy collective lever.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Rotorcraft Certification Office, FAA, may approve AMOCs for this AD. Send your proposal to: Martin Crane, Aerospace Engineer, Rotorcraft Certification Office, Rotorcraft Directorate, FAA, 2601 Meacham Blvd., Fort Worth, Texas 76137, telephone (817) 222–5170, email *martin.r.crane@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(g) Subject

Joint Aircraft Service Component (JASC) Code: 6230, Main Rotor.

(h) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Bell Helicopter Textron Alert Service Bulletin No. 412–11–148, Revision A, dated December 12, 2011.

(ii) Bell Helicopter Textron Alert Service Bulletin No. 412CF–11–47, Revision A, dated December 12, 2011.

(3) For Bell Helicopter service information identified in this AD, contact Bell Helicopter Textron, Inc., P.O. Box 482, Fort Worth, Texas 76101, telephone (817) 280–3391, fax (817) 280–6466, or at *http://www.bellcustomer.com/files/.*

(4) You may view this service information at FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137. For

information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Fort Worth, Texas, on October 26, 2012.

Kim Smith,

Directorate Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2012–27059 Filed 11–14–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–0340; Directorate Identifier 2011–SW–073–AD; Amendment 39–17250; AD 2012–22–13]

RIN 2120–AA64

Airworthiness Directives; Sikorsky Aircraft Corporation Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Sikorsky Aircraft Corporation (Sikorsky) Model S–76C helicopters. This AD requires installing an improved throttle stop and a wider trigger on the engine control levers (ECL). This AD was prompted by a bird-strike to the windshield that resulted in unintended movement of the engine control levers from the forward position and towards the flight-idle position, which reduced power on both engines. These actions are intended to prevent unintended movement of the ECLs, resulting in main rotor speed decay and subsequent loss of control of the aircraft.

DATES: This AD is effective December 20, 2012.

The Director of the Federal Register approved the incorporation by reference of a certain document listed in this AD as of December 20, 2012.

ADDRESSES: For service information identified in this AD, contact Sikorsky Aircraft Corporation, Attn: Manager, Commercial Technical Support, mailstop s581a, 6900 Main Street, Stratford, CT, telephone (203) 383–4866, email address *tsslibrary@sikorsky.com,* or at *http://www.sikorsky.com.* You may review a copy of the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

Examining The AD Docket: You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, any incorporated-by-reference service information, the economic evaluation, any comments received, and other information. The street address for the Docket Operations Office (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations Office, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Kirk Gustafson, Aerospace Engineer, FAA, Boston Aircraft Certification Office, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; telephone (781) 238–7190; email *kirk.gustafson@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

On March 29, 2012, at 77 FR 18969, the **Federal Register** published our notice of proposed rulemaking (NPRM), which proposed to amend 14 CFR part 39 to include an AD that would apply to Sikorsky Model S–76C helicopters with serial numbers 760506 and 760607 through 760812. That NPRM proposed to require within 6 months after the effective date of the AD, installing an improved throttle stop and a wider trigger on each ECL as specified in Sikorsky Alert Service Bulletin (ASB) No. 76–76–6A, Revision A, dated May 18, 2011.

The proposed requirements were intended to prevent unintended in-flight movement of the ECLs from the normal ''FLY'' position towards the ''IDLE'' position, which significantly reduces engine power, resulting in an unrecoverable loss of main rotor speed and subsequent loss of control of the helicopter.

Comments

Two commenters, one anonymous and one from the National Transportation Safety Board, commented that they support the NPRM (77 FR 18969, March 29, 2012).

FAA's Determination

We have reviewed the relevant information and determined that an unsafe condition exists and is likely to exist or develop on other products of the same type design and that air safety and the public interest require adopting the AD requirements as proposed.

Related Service Information

We reviewed ASB 76–76–6A, which describes procedures for partially disassembling the engine control quadrant assembly, removing the existing throttle stop, and installing a new airworthy throttle stop. The ASB also describes procedures to remove the existing trigger assembly from each ECL and install a new airworthy wide trigger assembly.

Costs of Compliance

We estimate that this AD will affect 52 helicopters of U.S. Registry. We estimate that operators may incur the following costs in order to comply with this AD. To replace the engine control lever stop and trigger assemblies will require 2 work-hours at an average labor cost of $85 per hour. Required parts will cost about $939. Based upon these costs, we estimate a total cost of $1,109 per helicopter and a total cost of $57,668 for the entire U.S. operator fleet.

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

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

For the reasons discussed above, I certify that this AD:

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

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

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and

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

We prepared an economic evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2012–22–13 Sikorsky Aircraft Corporation: Amendment 39–17250; Docket No. FAA–2012–0340; Directorate Identifier 2011–SW–073–AD.

(a) Applicability

This AD applies to Sikorsky Aircraft Corporation (Sikorsky) Model S–76C helicopters, serial numbers 760506 and 760607 through 760812, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as unintended movement of the engine control levers due to an external force to the windshield or canopy. This condition could result in significantly reduced engine power, unrecoverable loss of main rotor speed, and subsequent loss of control of the helicopter.

(c) Effective Date

This AD becomes effective December 20, 2012.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Action

Within 6 months, replace the throttle stop and trigger assembly on each engine control lever and perform a throttle position check as specified in the Accomplishment Instructions, Sections 3.A and 3.B, of Sikorsky Alert Service Bulletin No. 76–76–6A Revision A, dated May 18, 2011.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Boston Aircraft Certification Office, FAA, may approve AMOCs for this AD. Send your proposal to: Kirk Gustafson, Aerospace Engineer, FAA, Boston Aircraft Certification Office, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; telephone (781) 238–7190; email *kirk.gustafson@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(g) Subject

Joint Aircraft Service Component (JASC) Code: 7600: Engine Controls.

(h) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Sikorsky Alert Service Bulletin No. 76–76–6A Revision A, dated May 18, 2011.

(ii) Reserved.

(3) For Sikorsky service information identified in this AD, contact Sikorsky Aircraft Corporation, Attn: Manager, Commercial Technical Support, mailstop s581a, 6900 Main Street, Stratford, CT, telephone (203) 383–4866, email address *tsslibrary@sikorsky.com,* or at *http://www.sikorsky.com.*

(4) You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

(5) You may also view this service information at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Fort Worth, Texas, on October 30, 2012.

Kim Smith,

Directorate Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2012–27049 Filed 11–14–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–1182; Directorate Identifier 2012–SW–062–AD; Amendment 39–17251; AD 2012–22–14]

RIN 2120–AA64

Airworthiness Directives; Sikorsky Aircraft Corporation Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: We are superseding an existing Emergency airworthiness directive (AD) for Sikorsky Aircraft Corporation (Sikorsky) Model S–70, S–70A, S–70C, S–70C(M), and S–70C(M1) helicopters with a certain part-numbered intermediate gearbox (IGB). The existing Emergency AD requires a one-time inspection of the internal oil passages of the IGB for an obstruction. That Emergency AD was prompted by an accident that resulted from blockage of oil in the IGB by a plug that was inadvertently left in the IGB during the coating of the IGB housing. We are issuing this supersedure to that Emergency AD to include two additional part numbers of affected IGBs and identify a specific date since new or overhaul of the affected IGBs. The actions specified by this AD are intended to detect a plug in the IGB and prevent overheating and seizing of the IGB, failure of the tail rotor drive output shaft, loss of tail rotor drive, and subsequent loss of control of the helicopter.

DATES: This AD becomes effective November 30, 2012.

The Director of the Federal Register approved the incorporation by reference of a certain document listed in this AD as of November 30, 2012.

We must receive comments on this AD by January 14, 2013.

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

- *Federal eRulemaking Docket:* Go to *http://www.regulations.gov.* Follow the online instructions for sending your comments electronically.
- *Fax:* 202–493–2251.
- *Mail:* Send comments to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to the ''Mail'' address between 9 a.m. and 5

p.m., Monday through Friday, except Federal holidays.

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

For service information identified in this AD, contact Sikorsky Aircraft Corporation, Attn: Manager, Commercial Technical Support, mailstop s581a, 6900 Main Street, Stratford, CT 06614; telephone (800) 562–4409; email *tsslibrary@sikorsky.com;* or at *http://www.sikorsky.com.* You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

FOR FURTHER INFORMATION CONTACT: Mike Davison, Flight Test Engineer, Boston Aircraft Certification Office, FAA, 12 New England Executive Park, Burlington, MA 01803; telephone (781) 238–7156; fax (781) 238–7170; email *michael.davison@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not provide you with notice and an opportunity to provide your comments prior to it becoming effective. However, we invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that resulted from adopting this AD. The most helpful comments reference a specific portion of the AD, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit them only one time. We will file in the docket all comments that we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this rulemaking during the comment period. We will consider all the comments we receive and may conduct additional rulemaking based on those comments.

Discussion

On October 13, 2011, we issued Emergency AD 2011–22–51, which was made immediately effective to all known U.S. owners and operators of Sikorsky Model S–70, S–70A, S–70C, S 70C(M), and S–70C(M1) helicopters. That Emergency AD requires a one-time inspection for any obstruction of the internal oil passages of the IGB, part number (P/N) 70357–06300–044, with 100 or less hours time-in-service since new or overhaul. If there is an obstruction in an oil passage, the Emergency AD requires replacing the IGB with an airworthy IGB before further flight. That action was prompted by an accident involving a Model MH–60R helicopter in which the IGB output shaft failed and the tail rotor drive was lost after the IGB overheated and seized up. The output shaft failed because a protective plug, which was installed in an oil passage of the IGB to protect the oil passage during coating of the IGB housing as part of the manufacturing process, was inadvertently left in the IGB and blocked the internal oil passages of the IGB. The IGBs for Model MH–60R helicopters are manufactured and overhauled in the same facility as IGBs for Model S–70, S–70A, S–70C, S–70C(M), and S–70C(M1) helicopters.

Actions Since Existing Emergency AD Was Issued

Since we issued Emergency AD 2011–22–51, we discovered we inadvertently omitted two P/Ns and a specific date since new or overhaul of the affected IGBs in the emergency AD. Emergency AD 2011–22–51 is applicable to Model S–70, S–70A, S–70C, S–70C(M), and S–70C(M1) helicopters with an IGB, P/N 70357–06300–044, with 100 or less hours time-in-service (TIS) since new or overhaul. In issuing this superseding AD, we are requiring the same actions, but revising the applicability to include IGB P/Ns 70357–06300–042 and 70357–06300–043, in addition to IGB P/N 70357–06300–044. We are also adding a specific date, so that the applicability only includes those IGBs that had 100 or less hours time-in-service since new or overhaul on October 11, 2011.

FAA's Determination

We are issuing this AD because we reviewed the relevant information and determined that an unsafe condition exists and is likely to exist or develop in other products of these same type designs.

Related Service Information

We reviewed Sikorsky Aircraft Corporation Alert Service Bulletin No. 70–06–29A, dated October 11, 2011 (ASB). The ASB specifies:

- A one-time borescope inspection of the lubrication passages from the oil scupper to the input and output housing.
- Disassembling the IGB for inspection as an alternative to the borescope inspection.
- Adding an ''A'' suffix to the serial number of any IGB that has been inspected.

AD Requirements

This AD requires, before further flight, borescope inspecting the IGB for any obstruction in the oil passages. As an alternative to the borescope inspection, this AD allows disassembling the IGB and inspecting the oil passages for any obstruction. If there is any obstruction in any oil passage, replace the IGB with an airworthy IGB before further flight. These actions must be accomplished in accordance with specified portions of the ASB described previously.

Differences Between This AD and the Service Information

This AD does not apply to the Model H–60 helicopter as it does not have a U.S. type certificate. This AD does not require returning any parts to Sikorsky nor does it require marking the IGB after inspection.

Costs of Compliance

We estimate that this AD will affect 9 helicopters of U.S. Registry. We estimate that operators may incur the following costs in order to comply with this AD. It will take about 2 work-hours to perform a borescope inspection at an average labor rate of $85 per work-hour. Based on these figures, we estimate the cost of the inspection on U.S. operators to be $1,530 or $170 per helicopter. If any obstruction is found in any oil passage, we estimate that it will take about 3 work-hours to replace the IGB and required parts will cost about $21,283, for a total cost of $21,538 per helicopter.

FAA's Justification and Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because the required corrective actions must be accomplished before further flight. Therefore, we find that notice and opportunity for prior public comment are impracticable and contrary

to the public interest and that good cause exists for making this amendment effective in less than 30 days.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed, I certify that this AD:

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

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

3. Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and

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

We prepared an economic evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2012–22–14 Sikorsky Aircraft Corporation: Amendment 39–17251; Docket No. FAA–2012–1182; Directorate Identifier 2012–SW–062–AD.

(a) Applicability

This AD applies to Sikorsky Aircraft Corporation (Sikorsky) Model S–70, S–70A, S–70C, S–70C(M), and S–70C(M1) helicopters with an intermediate gearbox (IGB), part number 70357–06300–042, 70357–06300–043, or 70357–06300–044, with 100 or less hours time-in-service since new or overhaul of the IGB on October 11, 2011, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as blockage of the internal oil passages of the IGB by a protective plug, that could result in overheating and seizing of the IGB, failure of the tail rotor drive output shaft, loss of tail rotor drive, and subsequent loss of control of the helicopter.

(c) Other Affected ADs

This AD supersedes Emergency AD No. 2011–22–51, Directorate ID 2011–SW–056–AD, dated October 13, 2011.

(d) Effective Date

This AD becomes effective November 30, 2012.

(e) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(f) Required Actions

Before further flight:

(1) Borescope inspect the IGB for any obstruction in the oil passages. Borescope inspect in accordance with the following portions of Sikorsky Alert Service Bulletin No. 70–06–29A, dated October 11, 2011 (ASB), except this AD does not require returning any parts to ''depot'' or Sikorsky:

(i) The Accomplishment Instructions, Section 3., paragraphs A.(1) through A.(3)(a);

(ii) Equipment and Materials and Inspection sections of Appendix I; and

(iii) Figures 1 through 10 of Appendix I.

(2) As an alternative to the requirements of paragraph (f)(1) of this AD, disassemble the IGB and inspect the oil passages for any obstruction. Removing any obstruction from the IGB does not make it airworthy.

(3) If there is any obstruction in any oil passage, replace the IGB with an airworthy IGB before further flight.

(g) Special Flight Permits

Special flight permits are prohibited.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Boston Aircraft Certification Office, FAA, may approve AMOCs for this AD. Send your proposal to: Mike Davison, Flight Test Engineer, Boston Aircraft Certification Office, FAA, 12 New England Executive Park, Burlington, MA 01803; telephone (781) 238–7156; fax (781) 238–7170; email *michael.davison@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(i) Subject

Joint Aircraft Service Component (JASC) Code: 6520, Tail Rotor Gearbox.

(j) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Sikorsky Aircraft Corporation Alert Service Bulletin No. 70–06–29A, dated October 11, 2011.

(ii) Reserved.

(3) For Sikorsky service information identified in this AD, contact Sikorsky Aircraft Corporation, Attn: Manager, Commercial Technical Support, mailstop s581a, 6900 Main Street, Stratford, CT 06614; telephone (800) 562–4409; email *tsslibrary@sikorsky.com;* or at *http://www.sikorsky.com.*

(4) You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may also view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Fort Worth, Texas, on October 30, 2012.

Kim Smith,

Directorate Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2012–27050 Filed 11–14–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–0216; Directorate Identifier 2010–SW–025–AD; Amendment 39–17245; AD 2012–22–09]

RIN 2120–AA64

Airworthiness Directives; Sikorsky Aircraft Corporation Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for the Sikorsky Aircraft Corporation (Sikorsky) Model S–92A helicopters. This AD requires inspecting the tail rotor (T/R) pylon for a loose or missing fastener, a crack, damage, or corrosion and adding an internal doubler to the aft shear deck tunnel assembly. This AD was prompted by the discovery of cracks in T/R pylons. The actions are intended to detect a loose or missing fastener, a crack, damage, or corrosion on the T/R pylon and, if present, to repair the T/R pylon and install a doubler on the aft shear deck tunnel assembly or to replace the T/R pylon and install a doubler on the aft shear deck tunnel assembly. The actions are intended to prevent failure of the T/R pylon or other T/R components, which could lead to the loss of control of the helicopter.

DATES: This AD is effective December 20, 2012.

The Director of the Federal Register approved the incorporation by reference of certain documents listed in this AD as of December 20, 2012.

ADDRESSES: For service information identified in this AD, contact Sikorsky Aircraft Corporation, Attn: Manager, Commercial Technical Support, mailstop s581a, 6900 Main Street, Stratford, CT 06614; telephone (800) 562–4409; email *tsslibrary@sikorsky.com;* or at *http://www.sikorsky.com.* You may review a copy of the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth Texas 76137.

Examining the AD Docket: You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, any incorporated-by-reference service information, the economic evaluation, any comments received, and other information. The street address for the Docket Operations Office (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations Office, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Nicholas Faust, Aviation Safety Engineer, Boston Aircraft Certification Office, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; telephone (781) 238–7763; email *nicholas.faust@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

On May 14, 2012, at 77 FR 28328, the **Federal Register** published our notice of proposed rulemaking (NPRM), which proposed to amend 14 CFR part 39 to include an AD that would apply to Sikorsky Model S–92A helicopters with a T/R pylon, part number (P/N) 92000–06102–041. That NPRM proposed to require inspecting the T/R pylon for a loose or missing fastener, a crack, damage, or corrosion, and repairing or replacing the T/R pylon if any of these conditions exist. That NPRM also proposed adding an internal doubler to the aft shear deck tunnel assembly. That NPRM was prompted by the discovery of cracks in the forward lower spar region of the T/R pylons. The T/R pylon supports the T/R and the horizontal stabilizer, and a crack of the T/R pylon could alter vibration characteristics of the T/R pylon, which could adversely affect fatigue lives of T/R components. This condition, if not corrected, could result in failure of the T/R pylon or other T/R components and subsequent loss of control of the helicopter.

Comments

We gave the public the opportunity to participate in developing this AD, but we received no comments on the NPRM (77 FR 28328, May 14, 2012).

FAA's Determination

We have reviewed the relevant information and determined that an unsafe condition exists and is likely to exist or develop on other products of these same type designs and that air safety and the public interest require adopting the AD requirements as proposed.

Related Service Information

We have reviewed Sikorsky Alert Service Bulletin (ASB) No. 92–53–001, dated June 23, 2008 (ASB No. 92–53–001), and ASB No. 92–53–004B, Revision B, dated June 21, 2011 (ASB No. 92–53–004B). ASB No. 92–53–001 specifies for a T/R pylon with more than 500 flight-hours a one-time inspection of the T/R pylon ''components and structure for obvious damage, cracks, corrosion, and security.'' ASB No. 92–53–004B specifies a one-time replacement of the T/R pylon, P/N 92000–06102–041, with T/R pylon, P/N 92070–20058–042, and installation of a doubler on the aft shear deck tunnel assembly. The ASB specifies a replacement schedule based on the T/R pylon's hours for specified serial numbered helicopters.

Costs of Compliance

We estimate that this AD will affect 20 helicopters of U.S. Registry and that labor rates average $85 a work-hour. We also estimate that it will take about 1 work-hour per helicopter to inspect and 120 work-hours per helicopter to replace the T/R pylon and install the doubler. Required parts will cost about $339,080. Based on these figures, we estimate the annual cost will total $356,505 per helicopter and $7,130,100 for the U.S. fleet, assuming 85 inspections per year on each helicopter and assuming replacement of the T/R pylon and installation of a doubler on each helicopter.

According to the Sikorsky service information, some of the costs of this proposed AD may be covered under warranty, reducing the cost on affected individuals. We do not control warranty coverage. Accordingly, we have included all costs in our 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

This AD will not have federalism implications under Executive Order 13132. This AD will not have a

substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

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

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

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and

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

We prepared an economic evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2012–22–09 Sikorsky Aircraft Corporation Helicopters: Amendment 39–17245; Docket No. FAA–2012–0216; Directorate Identifier 2010–SW–025–AD.

(a) Applicability

This AD applies to Sikorsky Aircraft Corporation (Sikorsky) Model S–92A helicopters, with a tail rotor (T/R) pylon, part number (P/N) 92000–06102–041, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as a loose or missing fastener, a crack, damage, or corrosion on the T/R pylon that could result in failure of the T/R pylon or other T/R components, and subsequent loss of control of the helicopter.

(c) Effective Date

This AD becomes effective December 20, 2012.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

(1) For helicopters with 500 or more hours time-in-service (TIS), within 25 hours TIS and thereafter at intervals not to exceed 10 hours TIS, inspect each T/R pylon for a crack, damage, corrosion, or a loose or missing fastener in accordance with the Accomplishment Instructions, paragraph 3.A.(4)(a) through paragraph 3.A.(4)(f), and referring to Figure 1 of Sikorsky Alert Service Bulletin (ASB) No. 92–53–001, dated June 23, 2008, except that you are not required to contact Sikorsky Customer Service Engineering per paragraph 3.A.(4)(c)*1* of ASB 92–53–001, dated June 23, 2008.

(2) If there is a crack, damage, corrosion, or a loose or missing fastener, before further flight, either:

(i) If within allowable tolerances, repair each crack and each area of damage or corrosion and replace any loose or missing fastener; or

(ii) Replace the T/R pylon, (P/N) 92000–06102–041, with T/R pylon, P/N 92070–20058–042, as follows:

(A) Conduct the Total Indicated Run-out procedure on the No. 4 and No. 5 T/R drive shafts and remove the T/R pylon; and

(B) Install the doubler, P/N 92070–20087–101, as follows:

(*1*) For helicopters, serial numbers (S/Ns) 920006 through 920082, on the aft shear deck tunnel assembly, P/N 92204–05103–041 or –045, in accordance with the Accomplishment Instructions, paragraph 3.B.(1) through 3.B.(30) and while referring to Figures 1, 2, and 4 of Sikorsky ASB No. 92–53–004B, Revision B, dated June 21, 2011 (92–53–004B).

(*2*) For helicopters, S/Ns 920083 through 920124, on the aft shear deck tunnel assembly, P/N 92204–05103–043, in accordance with the Accomplishment Instructions, paragraph 3.C.(1) through 3.C.(21) and referring to Figures 3 and 4 of ASB 92–53–004B.

(3) If there is no crack in the T/R pylon, replace T/R pylon, P/N 92000–06102–041, with T/R pylon, P/N 92070–20058–042, and install doubler, P/N 92070–20087–101, on the aft shear deck tunnel assembly as specified in paragraphs (2)(ii)(A) through (2)(ii)(B) of this AD, according to the following:

(i) For a T/R pylon with 3,750 or more hours TIS, replace and install doubler within 12 months.

(ii) For a T/R pylon with 1,500 through 3,749 hours TIS, replace and install doubler within 24 months.

(iii) For a T/R pylon with 1,499 or less hours TIS, replace and install doubler within 36 months.

(4) Replacing T/R pylon, P/N 92000–06102–041, with T/R pylon, P/N 92070–20058–042, and installing internal tail cone doubler, P/N 92070–20087–101, on the aft shear deck tunnel assembly, constitutes terminating action for the requirements of this AD.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Boston Aircraft Certification Office, FAA, may approve AMOCs for this AD. Send your proposal to: Nicholas Faust, Aviation Safety Engineer, Boston Aircraft Certification Office, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; telephone (781) 238–7763; email *nicholas.faust@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(g) Subject

Joint Aircraft Service Component (JASC) Code: 5340, Fuselage Main, Attach Fittings.

(h) Material Incorporated by Reference.

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Sikorsky Alert Service Bulletin No. 92–53–001, dated June 23, 2008.

(ii) Sikorsky Alert Service Bulletin No. 92–53–004B, Revision B, dated June 21, 2011

(3) For Sikorsky Aircraft Corporation service information identified in this AD, contact Sikorsky Aircraft Corporation, Attn: Manager, Commercial Technical Support, mailstop s581a, 6900 Main Street, Stratford, CT 06614; telephone (800) 562–4409; email *tsslibrary@sikorsky.com;* or at *http://www.sikorsky.com.*

(4) You may view this service information at FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Fort Worth, Texas, on October 25, 2012.

Lance T. Gant,

Acting Directorate Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2012–26907 Filed 11–14–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–0143; Directorate Identifier 2011–NM–077–AD; Amendment 39–17252; AD 2012–22–15]

RIN 2120–AA64

Airworthiness Directives; Fokker Services B.V. Airplanes

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

ACTION: Final rule.

SUMMARY: We are superseding an existing airworthiness directive (AD) for all Fokker Services B.V. Model F.28 Mark 0070 and 0100 airplanes. That AD currently requires revising the airworthiness limitations section (ALS) of the instructions for continued airworthiness for certain airplanes, and the FAA-approved maintenance program for certain other airplanes, to incorporate new limitations. This new AD requires revising the maintenance program to incorporate the limitations, tasks, thresholds, and intervals specified in certain revised Fokker maintenance review board (MRB) documents. This AD was prompted by a revised Fokker 70/100 MRB document with revised limitations, tasks, thresholds, and intervals. We are issuing this AD to reduce the potential of structural failures or of ignition sources inside fuel tanks, which, in combination with flammable fuel vapors, could result in fuel tank explosions and consequent loss of the airplane.

DATES: This AD becomes effective December 20, 2012.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of December 20, 2012.

The Director of the Federal Register approved the incorporation by reference of certain other publications listed in this AD as of August 31, 2004 (69 FR 44586, July 27, 2004).

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–1137; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a supplemental notice of proposed rulemaking (SNPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That SNPRM was published in the **Federal Register** on August 14, 2012 (77 FR 48473), and proposed to supersede AD 2004–15–08, Amendment 39–13742 (69 FR 44586, July 27, 2004). That SNPRM proposed to correct an unsafe condition for the specified products. The Mandatory Continuing Airworthiness Information (MCAI) states:

> Fokker Services published issue 3 of report SE–672 dated 3 January 2012 and issue 9 of report SE–473 dated 11 January 2012, both part of the Airworthiness Limitations Section (ALS) of the Instructions for Continued Airworthiness, referred to in Section 06, Appendix 1, of the Fokker 70/100 Maintenance Review Board (MRB) document. The complete ALS currently consists of:
>
> —Certification Maintenance Requirements (CMRs)—report SE–473, issue 9
>
> —Airworthiness Limitation Items (ALIs) and Safe Life Items (SLIs)—report SE–623, issue 8
>
> —Fuel ALIs and Critical Design Configuration Control Limitations (CDCCLs)—report SE–672, issue 3
>
> The instructions contained in those reports have been identified as mandatory actions for continued airworthiness.
>
> For the reasons described above, this [European Aviation Safety Agency (EASA)] AD retains the requirements of EASA AD 2011–0157, which is superseded, and requires the implementation of the inspections and limitations as specified in the ALS of the Instructions for Continued Airworthiness, referred to in Section 06, Appendix 1 of the Fokker 70/100 MRB document, reports SE–473, SE–623 and SE–672 at the above-mentioned issues.

We have determined that the actions identified in this AD are necessary to reduce the potential of structural failures or of ignition sources inside fuel tanks, which, in combination with flammable fuel vapors, could result in fuel tank explosions and consequent loss of the airplane. You may obtain further information by examining the MCAI in the AD docket.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the SNPRM (77 FR 48473, August 14, 2012) or on the determination of the cost to the public.

Conclusion

We reviewed the available data and determined that air safety and the public interest require adopting the AD as proposed, except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the SNPRM (77 FR 48473, August 14, 2012) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the SNPRM (77 FR 48473, August 14, 2012).

Costs of Compliance

Based on the service information, we estimate that this AD will affect about 13 products of U.S. registry.

The actions that are required by AD 2004–15–08, Amendment 39–13742 (69 FR 44586, July 27, 2004), and retained in this AD take about 1 work-hour per product, at an average labor rate of $85 per work hour. The actions that are required by AD 2008–06–20, Amendment 39–15432 (73 FR 14661, March 19, 2008), and retained in this AD take about 1 work-hour per product, at an average labor rate of $85 per work hour. Based on these figures, the estimated cost of the currently required actions is $170 per product.

We estimate that it would take about 1 work-hour per product to comply with the new basic requirements of this AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of the AD on U.S. operators to be $1,105, or $85 per product.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify that this AD:

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

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

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains the SNPRM (77 FR 48473, August 14, 2012), the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing airworthiness directive (AD) 2004–15–08, Amendment 39–13742 (69 FR 44586, July 27, 2004), and adding the following new AD:

2012–22–15 Fokker Services B.V.: Amendment 39–17252. Docket No. FAA–2012–0143; Directorate Identifier 2011–NM–077–AD.

(a) Effective Date

This airworthiness directive (AD) becomes effective December 20, 2012.

(b) Affected ADs

This AD supersedes AD 2004–15–08, Amendment 39–13742 (69 FR 44586, July 27, 2004). This AD also affects AD 2008–06–20, Amendment 39–15432 (73 FR 14661, March 19, 2008).

(c) Applicability

(1) This AD applies to Fokker Services B.V. Model F.28 Mark 0070 and 0100 airplanes, certificated in any category, all serial numbers.

(2) This AD requires revisions to certain operator maintenance documents to include new actions (*e.g.,* inspections) and/or Critical Design Configuration Control Limitations (CDCCLs). Compliance with these actions and/or CDCCLs is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by this AD, the operator may not be able to accomplish the actions described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative method of compliance according to paragraph (n) of this AD. The request should include a description of changes to the required actions that will ensure the continued operational safety of the airplane.

(d) Subject

Air Transport Association (ATA) of America Code 28, Fuel.

(e) Reason

This AD was prompted by a revised Fokker 70/100 maintenance review board (MRB) document with revised limitations, tasks, thresholds, and intervals. We are issuing this AD to reduce the potential of structural failures or of ignition sources inside fuel tanks, which, in combination with flammable fuel vapors, could result in fuel tank explosions and consequent loss of the airplane.

(f) Compliance

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

(g) Retained Airworthiness Limitations Revision

This paragraph restates the requirements of paragraph (c) of AD 2004–15–08, Amendment 39–13742 (69 FR 44586, July 27, 2004). Within 6 months after August 31, 2004 (the effective date of AD 2004–15–08), revise the Airworthiness Limitations section (ALS) of the Instructions for Continued Airworthiness by incorporating Fokker Services B.V. Report SE–623, ''Fokker 70/100 Airworthiness Limitations Items and Safe Life Items,'' Issue 2, dated September 1, 2001; and Fokker Services B.V. Report SE–473, ''Fokker 70/100 Certification Maintenance Requirements,'' Issue 5, dated July 16, 2001; into Section 6 of the Fokker 70/100 MRB document. (These reports are already incorporated into Fokker 70/100 MRB document, Revision 10, dated October 1, 2001.) Once the actions required by this paragraph have been accomplished, the original issue of Fokker Services B.V. Report SE–623, ''Fokker 70/100 Airworthiness Limitations Items and Safe Life Items,'' dated June 1, 2000, may be removed from the ALS of the Instructions for Continued Airworthiness. Doing the actions specified in paragraph (i) of this AD terminates the requirements of paragraph (g) of this AD.

(h) Retained Requirement for No Alternative Inspections or Intervals

This paragraph restates the requirements of paragraph (e) of AD 2004–15–08, Amendment 39–13742 (69 FR 44586, July 27, 2004).

(1) After the actions required by paragraph (g) of this AD have been accomplished, no alternative inspections or inspection intervals may be approved for the structural elements specified in the documents identified in paragraph (g) of this AD, except as required by paragraph (k) of this AD.

(2) Notwithstanding any other maintenance or operational requirements, components that have been identified as airworthy or installed on the affected airplanes before the revision of the ALS for certain airplanes, and the maintenance program for certain other airplanes, as required by paragraph (i) of this AD, do not need to be reworked in accordance with the critical design configuration control limitations (CDCCLs). However, once the ALS for certain airplanes, and the maintenance program for certain other airplanes, has been revised, future maintenance actions on these components must be done in accordance with the CDCCLs.

(i) New Maintenance Program Revision

Within 3 months after the effective date of this AD, revise the maintenance program to incorporate the airworthiness limitations specified in the Fokker MRB documents identified in paragraphs (i)(3), (i)(4), and (i)(5) of this AD. For all tasks and retirement lives identified in the Fokker MRB documents identified in paragraphs (i)(3), (i)(4), and (i)(5) of this AD, the initial compliance times start from the later of the times specified in paragraphs (i)(1) and (i)(2) of this AD, and the repetitive inspections must be accomplished thereafter at the applicable interval specified in the Fokker MRB documents identified in paragraphs (i)(3), (i)(4), and (i)(5) of this AD.

(1) Within 3 months after the effective date of this AD.

(2) At the time specified in the documents identified in paragraphs (i)(3), (i)(4), and (i)(5) of this AD.

(3) Fokker Report SE–473, ''Fokker 70/100 Certification Maintenance Requirements,'' Issue 9, released January 11, 2012.

(4) Fokker Report SE–623, ''Fokker 70/100 Airworthiness Limitation Items and Safe Life Items,'' Issue 8, released March 17, 2011.

(5) Fokker Report SE–672, ''Fokker 70/100 Fuel Airworthiness Limitation Items (ALI)

and Critical Design Configuration Control Limitations (CDCCL),'' Issue 3, released January 4, 2012.

(j) New Corrective Actions

If any discrepancy (as defined in the documents specified in paragraphs (i)(3), (i)(4), and (i)(5) of this AD) is found during accomplishment of any task specified in the documents specified in paragraphs (i)(3), (i)(4), and (i)(5) of this AD: Within the applicable compliance time specified in the applicable documents specified in paragraphs (i)(3), (i)(4), and (i)(5) of this AD, accomplish the corrective actions in accordance with the applicable documents specified in paragraphs (i)(3), (i)(4), and (i)(5) of this AD. If no compliance time is identified in the applicable documents specified in paragraphs (i)(3), (i)(4), and (i)(5) of this AD, accomplish the applicable corrective actions before further flight. If any discrepancy is found and there is no corrective action specified in the applicable documents specified in paragraphs (i)(3), (i)(4), and (i)(5) of this AD: Before further flight contact the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, or the European Aviation Safety Agency (EASA) (or its delegated agent), for approved corrective actions, and accomplish those actions before further flight.

(k) No Alternative Actions, Intervals, and/or CDCCLs

After accomplishing the revision required by paragraph (i) of this AD, no alternative actions (*e.g.,* inspections), intervals, or CDCCLs may be used unless the actions, intervals, or CDCCLs are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (n)(1) of this AD.

(l) Terminating Action

Accomplishing the actions specified in paragraph (i) of this AD terminates the requirements of paragraph (g) of this AD.

(m) Method of Compliance With AD 2008–06–20, Amendment 39–15432 (73 FR 14661, March 19, 2008)

Accomplishing the actions specified in paragraph (i) of this AD terminates the requirements of paragraphs (f)(1) through (f)(5) of AD 2008–06–20, Amendment 39–15432 (73 FR 14661, March 19, 2008).

(n) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–1137; fax (425) 227–1149. Information may be emailed to: *9–ANM–116–AMOC–REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

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

(o) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(3) The following service information was approved for IBR on December 20, 2012.

(i) Fokker Report SE–473, ''Fokker 70/100 Certification Maintenance Requirements,'' Issue 9, released January 11, 2012.

(ii) Fokker Report SE–623, ''Fokker 70/100 Airworthiness Limitation Items and Safe Life Items,'' Issue 8, released March 17, 2011.

(iii) Fokker Report SE–672, ''Fokker 70/100 Fuel Airworthiness Limitation Items (ALI) and Critical Design Configuration Control Limitations (CDCCL),'' Issue 3, released January 4, 2012.

(4) The following service information was approved for IBR on August 31, 2004 (69 FR 44586, July 27, 2004).

(i) Fokker Services B.V. Report SE–473, ''Fokker 70/100 Certification Maintenance Requirements,'' Issue 5, dated July 16, 2001.

(ii) Fokker Services B.V. Report SE–623, ''Fokker 70/100 Airworthiness Limitation Items and Safe Life Items,'' Issue 2, dated September 1, 2001.

(5) For service information identified in this AD, contact Fokker Services B.V., Technical Services Dept., P.O. Box 1357, 2130 EL Hoofddorp, the Netherlands; telephone +31 (0)88–6280–350; fax +31 (0)88–6280–111; email *technicalservices@fokker.com;* Internet *http://www.myfokkerfleet.com.*

(6) You may review copies of the service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(7) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on October 30, 2012.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2012–27057 Filed 11–14–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2012–0384; Airspace Docket No. 12–ANM–9]

Amendment of Class D and Class E Airspace; Lewiston, ID

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies the Class D and Class E airspace areas at Lewiston, ID, to accommodate aircraft using Area Navigation (RNAV) (GPS) standard instrument approach procedures at Lewiston-Nez Perce County Airport. Also, the geographic coordinates are updated for the airport and navigational aids. This improves the safety and management of Instrument Flight Rules (IFR) operations at the airport.

DATES: Effective date, 0901 UTC, January10, 2013. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Eldon Taylor, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA, 98057; telephone (425) 203–4537.

SUPPLEMENTARY INFORMATION:

History

On June 4, 2012, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to amend controlled airspace at Lewiston-Nez Perce County Airport, Lewiston, ID (77 FR 32921). Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. The FAA received one comment from the National Business Aviation Association (NBAA).

The NBAA recommended making the Class E airspace area extending upward from 1,200 feet above the surface larger by lowering some of the adjacent Class E airspace, which begins from between

10,000 Mean Sea Level (MSL) and 14,500 MSL, for aircraft safety. The FAA found merit in this comment and further amended the NPRM with a supplemental NPRM (SNPRM) published in the **Federal Register** of August 21, 2012 (77 FR 50417). Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class D and Class E airspace designations are published in paragraphs, 5000, 6002, 6004 and 6005, respectively, of FAA Order 7400.9W dated August 8, 2012, and effective September 15, 2012, which is incorporated by reference in 14 CFR Part 71.1. The Class D airspace and Class E airspace designations listed in this document will be published subsequently in that Order.

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) Part 71 by modifying the Class E airspace area extending upward from 700 and 1,200 feet above the surface at Lewiston-Nez Perce County Airport, Lewiston, ID, to accommodate aircraft using RNAV (GPS) standard instrument approach procedures at the airport. This action also updates the geographic coordinates of the airport, the Nez Perce VHF Omni-Directional Radio Range/Distance Measuring Equipment (VOR/DME), and the Lewiston-Nez Perce Instrument Landing System (ILS) Localizer navigation aids to coincide with the FAA's aeronautical database. This action is necessary for the safety and management of IFR operations.

The FAA has determined this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1, Section 106 discusses the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it modifies controlled airspace at Lewiston-Nez Perce County Airport, Lewiston, ID.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1E, ''Environmental Impacts: Policies and Procedures,'' paragraph 311a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR Part 71.1 of the Federal Aviation Administration Order 7400.9W, Airspace Designations and Reporting Points, dated August 8, 2012, and effective September 15, 2012 is amended as follows:

Paragraph 5000 Class D airspace.

* * * * *

ANM ID D Lewiston, ID [Modified]

Lewiston-Nez Perce County Airport, ID
(Lat. 46°22′28″ N., long. 117°00′55″ W.)

That airspace extending upward from the surface to and including 3,900 feet MSL within a 4.1-mile radius of the Lewiston-Nez Perce County Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Paragraph 6002 Class E airspace designated as surface areas.

* * * * *

ANM ID E2 Lewiston, ID [Modified]

Lewiston-Nez Perce County Airport, ID
(Lat. 46°22′28″ N., long. 117°00′55″ W.)

Within a 4.1-mile radius of the Lewiston-Nez Perce County Airport. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Paragraph 6004 Class E airspace designated as an extension to a Class D surface area.

* * * * *

ANM ID E4 Lewiston, ID [Modified]

Lewiston-Nez Perce County Airport, ID
(Lat. 46°22′28″ N., long. 117°00′55″ W.)
Nez Perce VOR/DME
(Lat. 46°22′54″ N., long. 116°52′10″ W.)
Lewiston-Nez Perce ILS Localizer
(Lat. 46°22′27″ N., long. 117°01′54″ W.)

That airspace extending upward from the surface within 2.7 miles each side of the Lewiston-Nez Perce ILS localizer course extending from the 4.1-mile radius of the airport to 14 miles east of the airport and within 3.5 miles each side of the Nez Perce VOR/DME 266° radial extending from the 4.1-mile radius of the airport to 13.1 miles west of the airport. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

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

* * * * *

ANM ID E5 Lewiston, ID [Modified]

Lewiston-Nez Perce County Airport, ID
(Lat. 46°22′28″ N., long. 117°00′55″ W.)

That airspace extending upward from 700 feet above the surface bounded by a line beginning at lat. 46°33′00″ N., long. 117°38′00″ W.; to lat. 46°31′30″ N., long 117°14′00″ W.; to lat. 46°40′00″ N., long. 116°48′00″ W.; to lat. 46°26′00″ N., long. 116°26′00″ W.; to lat. 46°13′00″ N., long. 116°30′00″ W.; to lat. 46°14′00″ N., long. 116°35′00″ W.; to lat. 46°06′00″ N., long. 116°47′00″ W.; to lat. 46°17′00″ N., long. 116°49′00″ W.; to lat. 46°18′00″ N., long 117°00′00″ W.; to lat. 46°17′30″ N., long. 117°22′00″ W.; to lat. 46°10′30″ N., long. 117°26′30″ W.; to lat. 46°12′00″ N., long. 117°36′00″ W.; thence to the point of origin; that airspace extending upward from 1,200 feet above the surface within a 62-mile radius of the Lewiston-Nez Perce County Airport, and within 24 miles each side of the 056° bearing of the airport, extending from the 62-mile radius to 92 miles northeast of the airport.

Issued in Seattle, Washington, on October 23, 2012.

Vered Lovett,

Acting Manager, Operations Support Group, Western Service Center.

[FR Doc. 2012–27659 Filed 11–14–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2012–0705; Airspace Docket No. 12–AWP–4]

Establishment of Class E Airspace; Coaldale, NV

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace at Coaldale VHF Omni-Directional Radio Range Tactical Air Navigational Aid (VORTAC), Coaldale, NV to facilitate vectoring of Instrument Flight Rules (IFR) aircraft under control of Oakland Air Route Traffic Control Center (ARTCC). This action enhances the safety and management of IFR operations within the National Airspace System.

DATES: Effective date, 0901 UTC, January 10, 2013. The Director of the Federal Register approves this incorporation by reference action under 1 CFR Part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Eldon Taylor, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203–4537.

SUPPLEMENTARY INFORMATION:

History

On July 24, 2012, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to establish controlled airspace at Coaldale, NV (77 FR 43181). Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. The FAA received one comment from the National Business Aviation Association (NBAA).

The NBAA felt the reasons put forth in the NPRM for lowering the Class E airspace down to 1,200 feet above the surface was vague and did not name the terminal areas specifically that would benefit from lowering the Class E airspace. The commenter also recommended that the FAA lower the Class E airspace in a much larger area pushing the airspace north to the boundaries of Oakland ARTCC and Seattle ARTCC airspace, and east to the boundaries of Oakland ARTCC and Salt Lake City ARTCC airspace.

The FAA is creating this airspace at the request of the Oakland ARTCC to aid with the navigation of aircraft within the ARTCC's airspace area by assisting aircraft arriving and departing numerous terminal areas. The FAA feels that making the area larger is not needed at this time and is outside the scope of this rulemaking. Further widening of the airspace would not serve the immediate purpose of establishing the Class E–6 en route airspace area to assist Oakland ARTCC.

Class E airspace designations are published in paragraph 6006, of FAA Order 7400.9W dated August 8, 2012, and effective September 15, 2012, which is incorporated by reference in 14 CFR Part 71.1. The Class E airspace designations listed in this document will be published subsequently in that Order.

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) Part 71 by establishing Class E airspace extending upward from 1,200 feet above the surface, in the vicinity of the Coaldale VORTAC navigation aid, Coaldale, NV, to accommodate IFR aircraft under control of the Oakland ARTCC by vectoring aircraft from en route airspace to terminal areas. This action is necessary for the safety and management of IFR operations.

The FAA has determined this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1, Section 106 discusses the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes controlled airspace at the Coaldale VORTAC, Coaldale, NV.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1E, ''Environmental Impacts: Policies and Procedures,'' paragraph 311a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

■ 1. The authority citation for 14 CFR Part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR part 71.1 of the Federal Aviation Administration Order 7400.9W, Airspace Designations and Reporting Points, dated August 8, 2012, and effective September 15, 2012 is amended as follows:

Paragraph 6006 En Route Domestic Airspace Areas.

* * * * *

AWP NV E6 Coaldale, NV [New]

Coaldale VORTAC

(Lat. 38°00′12″ N., long. 117°46′14″ W.)

That airspace extending upward from 1,200 feet above the surface bounded by a line beginning at lat. 38°55′20″ N., long. 119°22′42″ W.; to lat. 38°57′46″ N., long. 119°14′44″ W.; to lat. 38°41′13″ N., long. 118°53′31″ W.; to lat. 38°44′27″ N., long.

118°48′52″ W.; to lat. 38°37′03″ N., long. 118°40′45″ W.; to lat. 38°23′17″ N., long. 118°20′35″ W.; to lat. 38°16′55″ N., long. 118°13′39″ W.; to lat. 38°02′23″ N., long. 117°56′00″ W.; to lat. 37°45′08″ N., long. 117°41′19″ W.; to lat. 37°45′58″ N., long. 117°39′55″ W.; to lat. 37°29′37″ N., long. 117°25′57″ W.; to lat. 37°15′12″ N., long. 117°13′46″ W.; to lat. 37°12′00″ N., long. 117°20′00″ W.; to lat. 37°12′02″ N., long. 117°38′40″ W.; to lat. 37°19′09″ N., long. 117°58′15″ W.; to lat. 37°28′23″ N., long. 117°54′28″ W.; to lat. 37°55′00″ N., long. 118°10′30″ W.; to lat. 38°04′06″ N., long. 119°15′00″ W.; thence to the point of origin.

Issued in Seattle, Washington, on October 23, 2012.

Vered Lovett,

Acting Manager, Operations Support Group, Western Service Center.

[FR Doc. 2012–27666 Filed 11–14–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2012–0648; Airspace Docket No. 12–ANM–19]

Modification of Class E Airspace; Pullman, WA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies Class E airspace at Pullman/Moscow Regional Airport, Pullman, WA. Controlled airspace is necessary to accommodate aircraft using Area Navigation (RNAV) Global Positioning System (GPS) standard instrument approach procedures at Pullman/Moscow Regional Airport. This action also makes a minor change to the legal description in reference to Class E airspace extending upward from 700 feet above the surface. This improves the safety and management of Instrument Flight Rules (IFR) operations at the airport.

DATES: Effective date, 0901 UTC, January 10, 2013. The Director of the Federal Register approves this incorporation by reference action under 1 CFR Part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Eldon Taylor, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA, 98057; telephone (425) 203–4537.

SUPPLEMENTARY INFORMATION:

History

On August 21, 2012, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to modify controlled airspace at Pullman, WA (77 FR 50419). Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

The FAA's Aeronautical Products Office requested the legal description for the Class E airspace extending upward from 700 feet above the surface be rewritten for clarity. With the exception of editorial changes and the changes described above, this rule is the same as that proposed in the NPRM.

Class E airspace designations are published in paragraphs 6002 and 6005, respectively, of FAA Order 7400.9W dated August 8, 2012, and effective September 15, 2012, which is incorporated by reference in 14 CFR part 71.1. The Class E airspace designations listed in this document will be published subsequently in that Order.

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) part 71 by modifying Class E surface airspace, and Class E airspace extending upward from 700 feet above the surface, at Pullman/Moscow Regional Airport, to accommodate IFR aircraft executing RNAV (GPS) standard instrument approach procedures at the airport. This action is necessary for the safety and management of IFR operations.

The FAA has determined this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1, Section 106 discusses the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it modifies controlled airspace at Pullman/Moscow Regional Airport, Pullman, WA.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1E, ''Environmental Impacts: Policies and Procedures,'' paragraph 311a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

■ 1. The authority citation for 14 CFR Part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR Part 71.1 of the Federal Aviation Administration Order 7400.9W, Airspace Designations and Reporting Points, dated August 8, 2012, and effective September 15, 2012 is amended as follows:

Paragraph 6002 Class E airspace designated as surface areas.

* * * * *

ANM WA E2 Pullman, WA [Modified]

Pullman/Moscow Regional Airport, WA
(Lat. 46°44′38″ N., long. 117°06′35″ W.)

Within a 4-mile radius of Pullman/Moscow Regional Airport, and within 1.7 miles each side of the Pullman/Moscow Regional Airport 046° bearing extending from the 4-mile radius to 8 miles northeast of the airport, and within 1.7 miles each side of the Pullman/Moscow Regional Airport 227°

bearing extending from the 4-mile radius to 6 miles southwest of the airport. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

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

* * * * *

ANM WA E5 Pullman, WA [Modified]

Pullman/Moscow Regional Airport, WA
(Lat. 46°44′38″ N., long. 117°06′35″ W.)

That airspace extending upward from 700 feet above the surface within a 10-mile radius of the Pullman/Moscow Regional Airport, and within 1.7 miles each side of the Pullman/Moscow Regional Airport 229° bearing extending from the 10-mile radius to 13 miles southwest of the airport, and that airspace bounded by a line beginning at the intersection of the 10-mile radius of the airport and the Pullman/Moscow Regional Airport 307° bearing to the intersection of the of the 23-mile radius of the airport and the Pullman/Moscow Regional Airport 328° bearing extending clockwise within a 23-mile radius of the Pullman/Moscow Regional Airport; thence to the intersection of the 23-mile radius of the airport and the Pullman/Moscow Regional Airport 064° bearing of the airport to the intersection of the 10-mile radius of the airport and the Pullman/Moscow Regional Airport 066° bearing of the airport; thence clockwise along the 10-mile radius to the point of origin. That airspace extending upward from 1,200 feet above the surface bounded by a line beginning at lat. 46°46′00″ N., long. 117°51′00″ W.; to lat. 47°06′00″ N., long. 117°29′00″ W.; to lat. 47°10′00″ N., long. 117°13′00″ W.; to lat. 47°07′00″ N., long. 116°50′00″ W.; to lat. 46°57′00″ N., long. 116°28′00″ W.; to lat. 46°38′00″ N., long. 116°41′00″ W.; to lat. 46°31′00″ N., long. 116°23′00″ W., to lat. 46°12′00″ N., long. 116°25′00″ W.; to lat. 46°19′00″ N., long. 116°57′00″ W.; to lat. 46°24′00″ N., long. 117°30′00″ W.; thence to the point of origin.

Issued in Seattle, Washington, on October 23, 2012.

Vered Lovett,

Manager, Operations Support Group,

Western Service Center.

[FR Doc. 2012–27668 Filed 11–14–12; 8:45 am]

BILLING CODE 4910–13–P

POSTAL SERVICE

39 CFR Part 20

Outbound International Mailings of Lithium Batteries

AGENCY: Postal Service™.

ACTION: Final rule.

SUMMARY: The Postal Service is revising the *Mailing Standards of the United States Postal Service,* International Mail Manual (IMM®) to new standards when mailing primary and secondary lithium cells or lithium batteries internationally, or to and from an APO, FPO, or DPO destinations.

DATES: *Effective date:* November 15, 2012.

FOR FURTHER INFORMATION CONTACT: Rick Klutts at 813–877–0372.

SUPPLEMENTARY INFORMATION: In the final rule published on May 14, 2012, (77 FR 28259–28261), the Postal Service implemented new international standards effective May 16, 2012, that prohibited the mailing of lithium batteries and cells internationally and when sent to and from any Army Post Office™ (APO), Fleet Post Office (FPO), or Diplomatic Post Office (DPO) location. The Postal Service took this action to bring its international mailing standards into compliance with international standards for the acceptance of dangerous goods in international mail. We also stated in that notice that we anticipated on January 1, 2013, customers would be able to mail specific quantities of lithium batteries internationally (including to and from an APO, FPO, or DPO location) when the batteries are properly installed in the personal electronic devices they are intended to operate. Through recent discussions with the Federal Aviation Administration (FAA), the International Civil Aviation Organization (ICAO) and the Universal Postal Union (UPU), we are pleased to announce that we will be able to implement the following changes effective November 15, 2012. In addition, we will also make parallel changes to other USPS publications that make reference to the international mailing of lithium batteries such as *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM) and Publication 52, *Hazardous, Restricted, and Perishable Mail.*

The Postal Service hereby adopts the following changes to *Mailing Standards of the United States Postal Service,* International Mail Manual (IMM), which is incorporated by reference in the *Code of Federal Regulations.* See 39 CFR 20.1.

List of Subjects in 39 CFR Part 20

Foreign relations, International postal services.

Accordingly, 39 CFR part 20 is revised to read as follows:

PART 20—[AMENDED]

■ 1. The authority citation for 39 CFR part 20 continues to read as follows:

Authority: 5 U.S.C. 552(a); 13 U.S.C. 301–307; 18 U.S.C. 1692–1737; 39 U.S.C. 101, 401, 403, 404, 407, 414, 416, 3001–3011, 3201–3219, 3403–3406, 3621, 3622, 3626, 3632, 3633, and 5001.

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

Mailing Standards of the United States Postal Service, International Mail Manual (IMM)

1 International Mail Services

* * * * *

130 Mailability

* * * * *

135 Mailable Dangerous Goods

* * * * *

[Insert new 135.6 to read as follows:]

135.6 Batteries

135.61 General

Only lithium cells and batteries under 135.62 and 135.63 that are properly installed *in* the equipment they are intended to operate may be sent internationally or to APO, FPO, or DPO locations when not restricted or prohibited by the destination country or APO, FPO, or DPO location. For specific country restrictions, see the applicable Individual Country Listing. For specific APO, FPO, or DPO restrictions, see the information for the destination ZIP Code in the article titled ''Overseas Military/Diplomatic Mail'' published in each issue of the *Postal Bulletin.*

Lithium batteries packed *with* equipment and lithium batteries sent *separate* from equipment are prohibited. Damaged or recalled batteries are prohibited and may not be mailed internationally under any circumstances.

135.62 Primary Lithium (Non-Rechargeable) Cells and Batteries

Small consumer-type primary lithium cells and batteries (lithium metal or lithium alloy) like those used to power cameras and flashlights are mailable in a single shipment with the following restrictions:

a. The batteries must be installed *in* the equipment being shipped.

b. Each shipment may contain a maximum of only four lithium cells or two lithium batteries.

c. The lithium content must not exceed 1 gram (g) per cell.

d. The total aggregate lithium content must not exceed 2 g per battery.

e. The batteries installed in the equipment must be protected from damage and short circuit.

f. The equipment must be equipped with an effective means of preventing it from being turned on or activated.

g. The equipment must be contained in a strong sealed package and cushioned to prevent movement or damage.

135.63 Secondary Lithium-ion (Rechargeable) Cells and Batteries

Small consumer-type lithium-ion cells and batteries like those used to power cell phones and laptop computers are mailable in a single shipment with the following restrictions:

a. The batteries must be installed *in* the equipment being shipped.

b. Each shipment may contain a maximum of only four lithium-ion cells or two lithium-ion batteries.

c. The lithium content must not exceed 20 Watt-hour rating (Wh) per cell.

d. The total aggregate lithium content must not exceed 100 Wh per battery.

e. Each battery must bear the Wh marking on the battery to determine if it is within the limits defined in 123.63c and 123.63d.

f. The batteries installed in the equipment must be protected from damage and short circuit.

g. The equipment must be equipped with an effective means of preventing it from being turned on or activated.

h. The equipment must be contained in a strong sealed package and cushioned to prevent movement or damage.

136 Nonmailable Goods

136.1 Dangerous Goods

* * * Some examples of dangerous goods include the following:

* * * * *

[Delete item ''i'' in its entirety.]

* * * * *

We will publish an amendment to 39 CFR part 20 to reflect these changes.

Stanley F. Mires,

Attorney, Legal Policy & Legislative Advice.

[FR Doc. 2012–27842 Filed 11–13–12; 11:15 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 85, 86, and 600

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Parts 523, 531, 533, 536, and 537

[EPA–HQ–OAR–2010–0799; FRL–9706–5; NHTSA–2010–0131]

RIN 2060–AQ54; RIN 2127–AK79

2017 and Later Model Year Light-Duty Vehicle Greenhouse Gas Emissions and Corporate Average Fuel Economy Standards

Correction

In rule document 2012–21972 appearing on pages 62623–63200 in the issue of Monday, October 15, 2012, make the following correction:

§ 533.5 Requirements [Corrected]

■ 1. On page 63195, Figure 4, an equation, is corrected to appear as set forth below:

Figure 4:

$$TARGET = MAX\left(\frac{1}{MIN\left[MAX\left(c \times FOOTPRINT + d, \frac{1}{a}\right), \frac{1}{b}\right]}, \frac{1}{MIN\left[MAX\left(g \times FOOTPRINT + h, \frac{1}{e}\right), \frac{1}{f}\right]}\right)$$

[FR Doc. C1–2012–21972 Filed 11–14–12; 8:45 am]

BILLING CODE 1505–01–D

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 90

[PS Docket 12–94; PS Docket No. 06–229; WT Docket 06–150; DA 12–1462]

Implementing Public Safety Broadband Provisions of the Middle Class Tax Relief and Job Creation Act of 2012

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: On October 15, 2012, the Public Safety and Homeland Security Bureau (Bureau) of the Commission published a document announcing that a *Report and Order* implementing public safety broadband provisions of the Middle Class Tax Relief and Job Creation Act of 2012, adopted as DA 12–1462, would become effective November 14, 2012, except for the removal of certain sections. The Bureau explained that it would publish a separate document in the **Federal Register** announcing the subsequent effective date of the removal of these two rule provisions. In this document we announce the effective date of the removal of these two rule provisions.

DATES: The amendments removing 47 CFR 90.18 and 90.528, published October 15, 2012, at 77 FR 62461, are effective November 15, 2012.

FOR FURTHER INFORMATION CONTACT: Gene Fullano, Federal Communications Commission, Public Safety and Homeland Security Bureau, 445 12th Street SW., Room 7–C747, Washington, DC 20554. Telephone: (202)–418–0492, email: *genaro.fullano@fcc.gov.*

SUPPLEMENTARY INFORMATION: On October 15, 2012, the Public Safety and Homeland Security Bureau (Bureau) of the Commission published a document announcing that the *Report and Order* adopted in PS Dockets 06–229 and 12–94 and WT Docket 06–150 on September 7, 2012, DA 12–1462, would become effective November 14, 2012, except for the removal of §§ 90.18 and 90.528.

In this document we announce the effective date of the removal of these two rule provisions, November 15, 2012. This date will be the date of issuance of a license to the First Responder Network Authority (FirstNet) pursuant to Section 6201(a) of the Middle Class Tax Relief and Job Creation Act of 2012.

List of Subjects in 47 CFR Part 90

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

Federal Communications Commission.

Timothy A. Peterson,

Chief of Staff, Public Safety and Homeland Security Bureau.

For the reasons discussed in the preamble, the amendments removing 47 CFR 90.18 and 90.528, published October 15, 2012, at 77 FR 62461 are effective November 15, 2012.

[FR Doc. 2012–27912 Filed 11–14–12; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket Nos. 120709225–2365–01 and 0907271173–0629–03]

RIN 0648–XC332

Snapper-Grouper Fishery of the South Atlantic; Reopening of the 2012 Commercial Sector for South Atlantic Red Snapper, Gag, and South Atlantic Shallow-Water Grouper

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

ACTION: Temporary rule; reopening.

SUMMARY: NMFS reopens the 2012 commercial sector for red snapper, gag, and all other South Atlantic Shallow-Water Grouper (SASWG) in the South Atlantic exclusive economic zone (EEZ). NMFS previously determined the commercial annual catch limit (ACL) for red snapper would be reached by September 24, 2012, and closed the commercial sector for red snapper in the South Atlantic at 12:01 a.m., local time, on September 24, 2012. Additionally, NMFS previously determined the commercial ACL for gag would be reached by October 20, 2012, and closed the commercial sector for gag and all other SASWG in the South Atlantic at 12:01 a.m., local time, on October 20, 2012. However, updated landings estimates indicate neither the commercial red snapper nor the commercial gag ACL has been reached at this time. Therefore, NMFS is reopening the commercial sector for red snapper, gag, and all other SASWG in the South Atlantic. The commercial sector for all of these species will reopen at 12:01 a.m., on November 13, 2012, and close at 12:01 a.m. on November 21, 2012. The intended effect of this temporary rule is to maximize harvest benefits for commercial red snapper, gag, and all other SASWG fishermen. Additionally, this reopening for red snapper provides an opportunity to collect fishery-dependent data that could be useful for the 2014 red snapper stock assessment.

DATES: This temporary rule is effective 12:01 a.m., local time, November 13, 2012, until 12:01 a.m., local time, November 21, 2012.

FOR FURTHER INFORMATION CONTACT: Catherine Hayslip, telephone: 727–824–5305, or email: *catherine.hayslip@noaa.gov.*

SUPPLEMENTARY INFORMATION: NMFS and the South Atlantic Fishery Management Council (Council) manage South Atlantic snapper-grouper including red snapper, gag, and all other SASWG under the Fishery Management Plan for the Snapper-Grouper Fishery of the South Atlantic Region (FMP). In the South Atlantic, SASWG means gag, black grouper, red grouper, scamp, red hind, rock hind, yellowmouth grouper, yellowfin grouper, graysby, and coney. The Council prepared the FMP and NMFS implements the FMP through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

Background

Red Snapper

Red snapper are overfished and undergoing overfishing. The harvest and possession of red snapper has been prohibited since January 4, 2010, initially through temporary rules (74 FR 63673, December 4, 2009, and 75 FR 27658, May 18, 2010), and then through the final rule to implement Amendment 17A to the FMP (75 FR 76874, December 9, 2010). Amendment 17A continued the prohibition on a permanent basis by implementing an ACL for red snapper of zero (landings only). Amendment 17A also implemented a rebuilding plan for red snapper, which specifies that red snapper biomass must increase to the target rebuilt level in 35 years, starting from 2010. At its June 2012 meeting, the Council received new information regarding discard estimates for red snapper. Using these data, the Council and NMFS determined that a limited season for red snapper would be possible in 2012. Therefore, the Council voted for, and NMFS implemented, emergency rulemaking to allow for the limited harvest and possession of red snapper in or from the South Atlantic EEZ in 2012 (77 FR 51939, August 28, 2012).

Through the emergency rule, NMFS implemented an ACL of 20,818 lb (9,443 kg), gutted weight, for the commercial sector. A commercial trip limit of 50-lb (22.7-kg), gutted weight, no size limit, and a 7-day commercial fishing season were implemented to constrain harvest to the ACL. The commercial fishing season opened at 12:01 a.m., local time, September 17, 2012, and closed at 12:01 a.m., local time, September 24, 2012. The Southeast Fisheries Science Center (SEFSC) monitored commercial landings during the 7-day season to determine whether the commercial ACL had been harvested. The AMs specified in 50 CFR 622.49(b)(25)(i) state that if the SEFSC determines the ACL has not been harvested during the 7-day season, the Regional Administrator may reopen the commercial sector for an additional limited time. The SEFSC has determined that the ACL was not harvested during the first 7-day season, therefore, NMFS is reopening the commercial sector for red snapper beginning at 12:01 a.m., on November 13, 2012, and closing at 12:01 a.m., on November 21, 2012. During the reopening, harvest will again be limited to the 50-lb (22.7-kg), gutted weight, daily trip limit and there will be no size limit.

After the commercial sector closes, an operator of a vessel with a valid commercial vessel permit for South Atlantic snapper-grouper having red snapper onboard must have landed and bartered, traded or sold such red snapper prior to 12:01 a.m., local time, November 21, 2012. During the closure, all sale or purchase of red snapper is prohibited and, because the recreational sector is also closed, the bag and possession limit of red snapper is zero. This bag and possession limit applies in the South Atlantic on board a vessel for which a valid Federal charter vessel/headboat permit for South Atlantic snapper-grouper has been issued, without regard to where such species were harvested, *i.e.,* in state or Federal waters. The prohibition on sale or purchase does not apply to the sale or purchase of red snapper that were harvested, landed ashore, and sold prior to 12:01 a.m., local time, November 21, 2012, and were held in cold storage by a dealer or processor.

Gag and SASWG

The commercial ACL (commercial quota) for gag in the South Atlantic is 352,940 lb (160,091 kg), gutted weight, for the current fishing year, as specified in 50 CFR 622.42(e)(7).

In accordance with regulations at 50 CFR 622.49(b)(3)(i), NMFS is required to close the commercial sector for gag and all other SASWG when the commercial ACL (commercial quota) for gag has

been reached, or is projected to be reached, by filing a notification to that effect with the Office of the Federal Register. NMFS determined that the commercial ACL (commercial quota) for South Atlantic gag was reached and published a temporary rule on October 15, 2012 (77 FR 62463) to close gag and all other SASWG on October 20, 2012. Accordingly, the commercial sector for South Atlantic gag and all other SASWG closed effective 12:01 a.m., local time, October 20, 2012, until the new fishing year begins at 12:01 a.m., local time, January 1, 2013. However, since that closure, the SEFSC has received additional landings data and has determined that the ACL was not harvested prior to October 20, 2012. Therefore, in accordance with 50 CFR 622.43(c), NMFS is reopening the commercial sector for gag and all other SASWG beginning at 12:01 a.m., on November 13, 2012, and closing at 12:01 a.m., on November 21, 2012. The recreational sectors for gag and for all other SASWG are not closed and continue to remain open until December 31, 2012.

Additionally, a seasonal closure is in place for the recreational and commercial sectors for gag and all other SASWG from January through April each fishing year as specified in 50 CFR 622.35(j). Therefore, after the commercial sector for gag and all other SASWG close at 12:01 a.m., on November 21, 2012, the commercial harvest of gag and all other SASWG will not commence until May 1, 2013.

The operator of a vessel with a valid commercial vessel permit for South Atlantic snapper-grouper having gag or other SASWG onboard must have landed and bartered, traded, or sold such gag or other SASWG prior to 12:01 a.m., local time, November 21, 2012. During this commercial closure, the bag limit and possession limits specified in 50 CFR 622.39(d)(1) and (d)(2), respectively, apply to all harvest or possession of gag or other SASWG in or from the South Atlantic EEZ, and the sale or purchase of gag or other SASWG taken from the EEZ is prohibited. The prohibition on sale or purchase does not apply to the sale or purchase of gag or other SASWG that were harvested, landed ashore, and sold prior to 12:01 a.m., local time, November 21, 2012, and were held in cold storage by a dealer or processor. For a person on board a vessel for which a Federal commercial permit for the South Atlantic snapper-grouper fishery has been issued, the sale and purchase provisions of the commercial closure for gag or other SASWG would apply regardless of whether the fish are harvested in state or Federal waters, as specified in 50 CFR 622.43(a)(5)(iii).

During the seasonal closure for the recreational and commercial sectors for gag and all other SASWG from January through April each fishing year, no person may fish for, harvest, or possess in or from the South Atlantic EEZ any SASWG. In addition, for a person on board a vessel for which a valid Federal commercial or charter vessel/headboat permit for South Atlantic snapper-grouper has been issued, the provisions of this closure apply in the South Atlantic, regardless of where such fish are harvested, *i.e.,* in state or Federal waters as specified in 50 CFR 622.35(j).

Classification

The Regional Administrator, Southeast Region, NMFS, has determined this temporary rule is necessary for the conservation and management of South Atlantic red snapper, gag, and all other SASWG and is consistent with the Magnuson-Stevens Act and other applicable laws.

This action is taken under 50 CFR 622.49(b)(25)(i) and is exempt from review under Executive Order 12866.

These measures are exempt from the procedures of the Regulatory Flexibility Act because the temporary rule is issued without opportunity for prior notice and comment.

This action responds to the best available information recently obtained from the snapper-grouper fishery. Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive the requirements to provide prior notice and the opportunity for public comment on this temporary rule. Such procedures are unnecessary and contrary to the public interest regarding red snapper because the commercial ACL and AMs for red snapper were established in emergency rulemaking to allow for the limited harvest and possession of red snapper in 2012 (77 FR 51939, August 28, 2012), and the AMs allow the Regional Administrator to reopen the commercial sector if the ACL has been determined to have not been reached during the first 7-day commercial season. Such procedures are unnecessary and contrary to the public interest regarding gag because NMFS previously determined the commercial ACL for gag would be reached by October 20, 2012, and closed the commercial sector for gag and all other SASWG in the South Atlantic at 12:01 a.m., local time, on October 20, 2012. However, updated landings estimates indicate the ACL for the commercial sector for gag has not been reached at this time, and therefore additional harvest is available in order to achieve optimum yield. All that remains is to notify the public that additional harvest is available under the established ACLs and, therefore, the commercial sector for red snapper, gag, and all other SASWG will reopen.

Additionally, reopening the commercial sector for red snapper, gag, and all other SASWG will likely result in revenue increases to commercial vessels. Fishermen will be able to keep the red snapper, gag, and all other SASWG that they are currently required to discard. Additionally, reopening the commercial sector for red snapper will provide an opportunity to collect fishery-dependent data that will likely be useful for the 2014 red snapper stock assessment. Delaying the implementation of this rulemaking to provide prior notice and the opportunity for public comment would reduce the likelihood of reopening the commercial sector for red snapper, gag, and all other SASWG in the 2012 fishing year.

For the aforementioned reasons, the AA also finds good cause to waive the 30-day delay in the effectiveness of this action under 5 U.S.C. 553(d)(3).

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

Dated: November 9, 2012.

Emily H. Menashes,

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

[FR Doc. 2012–27786 Filed 11–9–12; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 77, No. 221
Thursday, November 15, 2012

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

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 532

RIN 3206–AM70

Prevailing Rate Systems; Redefinition of the St. Louis, MO; Southern Missouri; Cleveland, OH; and Pittsburgh, PA, Appropriated Fund Federal Wage System Wage Areas

AGENCY: U.S. Office of Personnel Management.

ACTION: Proposed rule with request for comments.

SUMMARY: The U.S. Office of Personnel Management is issuing a proposed rule that would redefine the geographic boundaries of the St. Louis, MO; Southern Missouri; Cleveland, OH; and Pittsburgh, PA, appropriated fund Federal Wage System wage areas. The proposed rule would redefine Bollinger, Cape Girardeau, and Perry Counties, MO, from the Southern Missouri wage area to the St. Louis wage area and Mercer County, PA, from the Pittsburgh wage area to the Cleveland wage area. These changes are based on recent consensus recommendations of the Federal Prevailing Rate Advisory Committee to best match the counties proposed for redefinition to a nearby FWS survey area. This proposed rule makes two additional corrections. It renames the Champaign-Urbana, IL, wage area as the Central Illinois wage area and updates the name of the White Sands Proving Ground in the Albuquerque, NM, and El Paso, TX, wage areas to White Sands Missile Range.

DATES: We must receive comments on or before December 17, 2012.

ADDRESSES: Send or deliver comments to Jerome D. Mikowicz, Deputy Associate Director for Pay and Leave, Employee Services, U.S. Office of Personnel Management, Room 7H31, 1900 E Street NW., Washington, DC 20415–8200; email *pay-leave-policy@opm.gov;* or FAX: (202) 606–4264.

FOR FURTHER INFORMATION CONTACT: Madeline Gonzalez, (202) 606–2838; email *pay-leave-policy@opm.gov;* or FAX: (202) 606–4264.

SUPPLEMENTARY INFORMATION: The U.S. Office of Personnel Management is issuing a proposed rule that would redefine the geographic boundaries of the St. Louis, MO; Southern Missouri; Cleveland, OH; and Pittsburgh, PA, appropriated fund Federal Wage System (FWS) wage areas. The proposed rule would redefine Bollinger, Cape Girardeau, and Perry Counties, MO, from the Southern Missouri wage area to the St. Louis wage area and Mercer County, PA, from the Pittsburgh wage area to the Cleveland wage area.

OPM considers the following regulatory criteria under 5 CFR 532.211 when defining FWS wage area boundaries:

(i) Distance, transportation facilities, and geographic features;

(ii) Commuting patterns; and

(iii) Similarities in overall population, employment, and the kinds and sizes of private industrial establishments.

In addition, OPM regulations at 5 CFR 532.211 do not permit splitting Metropolitan Statistical Areas (MSAs) for the purpose of defining a wage area, except in very unusual circumstances.

OPM recently completed reviews of the definitions of the Cape Girardeau-Jackson, MO-IL and Youngstown-Warren-Boardman, OH-PA MSAs and, based on analyses of the regulatory criteria for defining wage areas, is proposing the changes described below. The Federal Prevailing Rate Advisory Committee (FPRAC), the national labor-management committee responsible for advising OPM on matters concerning the pay of FWS employees, recommended these changes by consensus. These changes would be effective on the first day of the first applicable pay period beginning on or after 30 days following publication of the final regulations. FPRAC recommended no other changes in the geographic definitions of the St. Louis, Southern Missouri, Cleveland, and Pittsburgh wage areas.

Cape Girardeau-Jackson, MO-IL Metropolitan Statistical Area

Alexander County, IL, and Bollinger and Cape Girardeau Counties, MO, comprise the Cape Girardeau-Jackson, MO-IL MSA. The Cape Girardeau-Jackson MSA is currently split between the St. Louis, MO, and Southern Missouri wage areas. Alexander County is part of the area of application of the St. Louis wage area and Bollinger and Cape Girardeau Counties are part of the area of application of the Southern Missouri wage area.

Based on an analysis of the regulatory criteria for Cape Girardeau County, the core county in the Cape Girardeau-Jackson MSA, we recommend that the entire Cape Girardeau-Jackson MSA be defined to the St. Louis area of application. The distance criterion for Cape Girardeau County favors the St. Louis wage area more than the Southern Missouri wage area. The commuting patterns criterion does not favor one wage area more than another. Cape Girardeau County does not resemble one survey area more than another survey area in terms of the overall population, employment, and the kinds and sizes of private industrial establishments criteria. Based on this analysis, we find that Cape Girardeau County would be more appropriately defined to the St. Louis wage area. Since there appear to be no unusual circumstances that would permit splitting the Cape Girardeau-Jackson MSA, OPM proposes to also redefine Bollinger County to the St. Louis wage area so that the entire Cape Girardeau-Jackson MSA is in one wage area. There are currently nine FWS employees working in Cape Girardeau County. There are currently no FWS employees working in Bollinger County.

Because Perry County, MO, borders Bollinger and Cape Girardeau Counties to the north and is located in between the Cape Girardeau-Jackson MSA and the St. Louis wage area, Perry County would be redefined to the St. Louis wage area. The distance criterion for Perry County favors the St. Louis wage area more than the Southern Missouri wage area. The commuting patterns criterion favors the St. Louis wage area more than the Southern Missouri wage area. Perry County does not resemble one survey area more than another survey area in terms of the overall population, employment, and the kinds and sizes of private industrial establishments criteria. Based on this analysis, we find that Perry County would be more appropriately defined to the St. Louis wage area. There are

currently no FWS employees working in Perry County.

Youngstown-Warren-Boardman, OH-PA Metropolitan Statistical Area

Trumbull and Mahoning Counties, OH, and Mercer County, PA, comprise the Youngstown-Warren-Boardman, OH-PA MSA. The Youngstown-Warren-Boardman MSA is currently split between the Cleveland, OH, and Pittsburgh, PA, wage areas. Trumbull and Mahoning Counties are part of the area of application of the Cleveland wage area, and Mercer County is part of the area of application of the Pittsburgh wage area.

Based on an analysis of the regulatory criteria for Mahoning County, the core county in the Youngstown-Warren-Boardman MSA, the entire Youngstown-Warren-Boardman MSA would be defined to the Cleveland wage area. The distance criterion does not favor one wage area more than another. We believe distance is not a determining factor in this case. The commuting patterns criterion does not favor one wage area more than another. The difference between the resident workforce commuting to work in the Cleveland and Pittsburgh survey areas is insignificant; however, marginally more people commute into the Cleveland survey area (1.23 percent) than into the Pittsburgh survey area (0.76 percent). The overall population and employment and the kinds and sizes of private industrial establishments criteria do not favor one wage area more than another.

Based on the mixed nature of the regulatory analysis findings, we believe the fact that the city of Youngstown in Mahoning County is generally considered to be part of the greater Cleveland area provides sufficient evidence that Mahoning County is appropriately defined to the Cleveland wage area. OPM regulations at 5 CFR 532.211 permit splitting MSAs only in very unusual circumstances. Since there appear to be no unusual circumstances that would permit splitting the Youngstown-Warren-Boardman MSA, OPM proposes to redefine Mercer County to the Cleveland wage area so that the entire Youngstown-Warren-Boardman MSA is in one wage area. The remaining county in the Youngstown-Warren-Boardman MSA, Trumbull County, is already defined to the Cleveland wage area. There are currently two FWS employees working in Mercer County.

CFR Corrections

In addition, this proposed rule renames the Champaign-Urbana, IL, FWS wage area as the Central Illinois FWS wage area because this name better describes the boundaries of the wage area. This proposed rule also updates the name of the White Sands Proving Ground in the Albuquerque, NM, and El Paso, TX, wage areas because the Department of Defense now refers to it as that White Sands Missile Range. OPM announced these changes in interim (65 FR 48641) and final (65 FR 64337) rules published in 2000. However, Champaign-Urbana and White Sands Proving Ground continue to appear incorrectly in Appendix A to Subpart B of Part 532 and/or Appendix C to Subpart B of Part 532.

Regulatory Flexibility Act

I certify that these regulations would not have a significant economic impact on a substantial number of small entities because they would affect only Federal agencies and employees.

List of Subjects in 5 CFR Part 532

Administrative practice and procedure, Freedom of information, Government employees, Reporting and recordkeeping requirements, Wages.

U.S. Office of Personnel Management.

John Berry,

Director.

Accordingly, the U.S. Office of Personnel Management is proposing to amend 5 CFR part 532 as follows:

PART 532—PREVAILING RATE SYSTEMS

1. The authority citation for part 532 continues to read as follows:

Authority: 5 U.S.C. 5343, 5346; § 532.707 also issued under 5 U.S.C. 552.

Appendix A to Subpart B of Part 532 [Amended]

2. In appendix A to subpart B of part 532, under the State of Illinois, revise the wage-area entry ''Champaign-Urbana'' to read ''Central Illinois''.

3. In appendix C to subpart B of part 532, under the State of Illinois, revise the wage-area entry ''Champaign-Urbana'' to read ''Central Illinois'' and revise the wage area listings for the Southern Missouri; St. Louis, MO; Albuquerque, NM; Cleveland, OH; Pittsburgh, PA; and El Paso, TX, wage areas to read as follows:

Appendix C to Subpart B of Part 532—Appropriated Fund Wage and Survey Areas

* * * * *

MISSOURI

* * * * *

St. Louis

Survey Area

Illinois:
Clinton
Madison
Monroe
St. Clair

Missouri: (city)
St. Louis

Missouri: (counties)
Franklin
Jefferson
St. Charles
St. Louis

Area of Application. Survey area plus:

Illinois:
Alexander
Bond
Calhoun
Clay
Effingham
Fayette
Franklin
Greene
Hamilton
Jackson
Jefferson
Jersey
Johnson
Macoupin
Marion
Massac
Montgomery
Morgan
Perry
Pike
Pope
Pulaski
Randolph
Saline
Scott
Union
Washington
Wayne
Williamson

Missouri:
Audrain
Bollinger
Boone
Callaway
Cape Girardeau
Clark
Cole
Crawford
Gasconade
Knox
Lewis
Lincoln
Marion
Moniteau
Monroe
Montgomery
Osage
Perry
Pike
Ralls
Randolph
St. Francois
Ste. Genevieve
Scotland
Shelby
Warren
Washington

Southern Missouri

Survey Area

Missouri:
Christian
Greene
Laclede
Phelps
Pulaski
Webster

Area of Application. Survey area plus:

Kansas:
Cherokee
Crawford

Missouri:
Barry
Barton
Benton
Butler
Camden
Carter
Cedar
Dade
Dallas
Dent
Douglas
Hickory
Howell
Iron
Jasper
Lawrence
Madison
Maries
Miller
Mississippi
Morgan
New Madrid
Newton
Oregon
Ozark
Polk
Reynolds
Ripley
St. Clair
Scott
Shannon
Stoddard
Stone
Taney
Texas
Vernon
Wayne
Wright

* * * * *

NEW MEXICO

Albuquerque

Survey Area

New Mexico:
Bernalillo
Sandoval

Area of Application. Survey area plus:

New Mexico:
Catron
Cibola
Colfax
Curry
De Baca
Guadalupe
Harding
Lincoln (Does not include White Sands Missile Range portion)
Los Alamos
Mora
Quay
Rio Arriba
Roosevelt
San Miguel
Santa Fe
Socorro (Does not include White Sands Missile Range portion)
Taos
Torrance
Union
Valencia

* * * * *

OHIO

* * * * *

Cleveland

Survey Area

Ohio:
Cuyahoga
Geauga
Lake
Medina

Area of Application. Survey area plus:

Ohio:
Ashland
Ashtabula
Carroll
Columbiana
Erie
Huron
Lorain
Mahoning
Ottawa
Portage
Sandusky
Seneca
Stark
Summit
Trumbull
Wayne

Pennsylvania:
Mercer

* * * * *

PENNSYLVANIA

* * * * *

Pittsburgh

Survey Area

Pennsylvania:
Allegheny
Beaver
Butler
Washington
Westmoreland

Area of Application. Survey area plus:

Ohio:
Belmont
Harrison
Jefferson
Tuscarawas

Pennsylvania:
Armstrong
Bedford
Blair
Cambria
Cameron
Centre
Clarion
Clearfield
Clinton
Crawford
Elk (Does not include the Allegheny National Forest portion)
Erie
Fayette
Forest (Does not include the Allegheny National Forest portion)
Greene
Huntingdon
Indiana
Jefferson
Lawrence
Potter
Somerset
Venango

West Virginia:
Brooke
Hancock
Marshall
Ohio

* * * * *

TEXAS

* * * * *

El Paso

Survey Area

New Mexico:
Dona Ana
Otero

Texas:
El Paso

Area of Application. Survey area plus:

New Mexico:
Chaves
Eddy
Grant
Hidalgo
Lincoln (Only White Sands Missile Range portion)
Luna
Sierra
Socorro (Only White Sands Missile Range portion)

Texas:
Culberson
Hudspeth

* * * * *

[FR Doc. 2012–27671 Filed 11–14–12; 8:45 am]

BILLING CODE 6325–39–P

LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 201 and 210

[Docket No. 2012–7]

Mechanical and Digital Phonorecord Delivery Compulsory License

AGENCY: Copyright Office, Library of Congress.

ACTION: Notice of proposed rulemaking: Extension of reply comment periods.

SUMMARY: The Copyright Office is extending the deadline for filing reply comments regarding its Notice of Proposed Rulemaking concerning

regulations for reporting Monthly and Annual Statements of Account for the making and distribution of phonorecords under a compulsory license.

DATES: Reply comments on the proposed regulation must be received in the Office of the General Counsel of the Copyright Office no later than 5 p.m. Eastern Daylight Time (EDT) on December 10, 2012.

ADDRESSES: The Copyright Office strongly prefers that reply comments be submitted electronically. A comment submission page is posted on the Copyright Office Web site at *http://www.copyright.gov/docs/section115/soa/comments/*. The Web site interface requires submitters to complete a form specifying name and other required information, and to upload comments as an attachment. To meet accessibility standards, all comments must be uploaded in a single file in either the Adobe Portable Document File (PDF) format that contains searchable, accessible text (not an image); Microsoft Word; WordPerfect; Rich Text Format (RTF); or ASCII text file format (not a scanned document). The maximum file size is 6 megabytes (MB). The name of the submitter and organization should appear on both the form and the face of the comments. All comments will be posted publicly on the Copyright Office Web site exactly as they are received, along with names and organizations if provided. If electronic submission of comments is not feasible, please contact the Copyright Office at (202) 707–8380 for special instructions.

FOR FURTHER INFORMATION CONTACT: Tanya Sandros, Deputy General Counsel, or Stephen Ruwe, Attorney Advisor, Copyright GC/I&R, P.O. Box 70400, Washington, DC 20024. *Telephone:* (202) 707–8380. *Telefax:* (202) 707–8366.

SUPPLEMENTARY INFORMATION: On July 27, 2012, the Copyright Office published a notice of proposed rulemaking and request for comments concerning a new regulation that would amend the regulations for reporting Monthly and Annual Statements of Account for the making and distribution of phonorecords under the compulsory license, 17 U.S.C. 115, to bring the regulations up-to-date to reflect recent and pending rate determinations by the Copyright Royalty Judges, which among other things provide new rates for limited downloads, interactive streaming and incidental digital phonorecord deliveries, and to harmonize these reporting requirements with the existing regulations for reporting the making and distribution of physical phonorecords, permanent downloads and ringtones. The notice of proposed rulemaking stated that comments would be due no later than September 25, 2012 and that reply comments would be due October 25, 2012. Upon the request of several active institutional participants in the mechanical compulsory license system, the Copyright Office extended the comment deadline, making the comments due on October 25, 2012 and reply comments due on November 26, 2012. 77 FR 55783 (September 11, 2012). The Copyright Office posted all comments received by the October 25, 2012 deadline on the Copyright Office Web site at *http://www.copyright.gov/docs/docket2012–7/comments/initial/*.

On November 7, 2012, the Copyright Office received a joint motion filed on behalf of the Recording Industry Association of America, Inc., National Music Publishers Association, Digital Media Association, and Music Reports, Inc., (''Joint Requestors'') to extend the reply comment period by two weeks (*i.e.* until December 10, 2012). The Joint Requestors stated that they hope to be in a position to suggest specific certification language in their reply comments. However, they note that several key individuals involved in the Joint Requesters' discussions were adversely affected by Hurricane Sandy, and that discussions have been disrupted for over a week. They stated that a two week extension would allow them to discuss consensus positions and prepare a written submission setting forth whatever consensus positions are able to be reached.

In the interest of giving the Joint Requestors, the necessary time to conclude the process of formulating consensus positions, the progress of which was interrupted by Hurricane Sandy, the Copyright Office has decided to grant the request and extend the reply comment period by two weeks, making the reply comments due on December 10, 2012).

Dated: November 8, 2012.

Maria Pallante,

Register of Copyrights.

[FR Doc. 2012–27774 Filed 11–14–12; 8:45 am]

BILLING CODE 1410–30–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R03–OAR–2012–0174; FRL–9752–1]

Approval and Promulgation of Air Quality Implementation Plans; West Virginia; Redesignation of the West Virginia Portion of the Huntington-Ashland, WV-KY-OH 1997 Annual $PM_{2.5}$ Nonattainment Area to Attainment and Approval of the Associated Maintenance Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a redesignation request and State Implementation Plan (SIP) revision submitted by the State of West Virginia. The West Virginia Department of Environmental Protection (WVDEP) is requesting that the West Virginia portion of the Huntington-Ashland, WV-KY-OH-fine particulate matter ($PM_{2.5}$) nonattainment area (''Huntington-Ashland Area'' or ''Area'') be redesignated as attainment for the 1997 annual $PM_{2.5}$ national ambient air quality standard (NAAQS). The Huntington-Ashland Area is comprised of Cabell and Wayne Counties and a portion of Mason County in West Virginia (West Virginia portion of the Area); Boyd County and a portion of Lawrence County in Kentucky; and Lawrence and Scioto Counties and portions of Adams and Gallia Counties in Ohio. In this rulemaking action, EPA is proposing to approve the $PM_{2.5}$ redesignation request for the West Virginia portion of the Area. EPA is also proposing to approve the maintenance plan SIP revision that the State submitted in conjunction with its redesignation request. The maintenance plan provides for continued attainment of the 1997 annual $PM_{2.5}$ NAAQS for 10 years after redesignation of the West Virginia portion of the Area. The maintenance plan includes an insignificance determination for the on-road motor vehicle contribution of $PM_{2.5}$, nitrogen oxides (NO_x), and sulfur dioxide (SO_2) for the West Virginia portion of the Area for purposes of transportation conformity. EPA is proposing to find that West Virginia's insignificance determination for transportation conformity is adequate.[1]

[1] On November 5, 2012, EPA initiated the comment period for this proposed insignificance determination on the Office of Transportation and Air Quality (OTAQ) Web site (*http://www.epa.gov/otaq/stateresources/transconf/currsips*) in order to

EPA is also proposing to find that the Area continues to attain the standard. This action to propose approval of the 1997 annual $PM_{2.5)}$ NAAQS redesignation request, maintenance plan, and insignificance determination for transportation conformity for the West Virginia portion of the Area is based on EPA's determination that the Area has met the criteria for redesignation to attainment specified in the Clean Air Act (CAA). EPA is taking separate action to propose redesignation of the Kentucky and Ohio portions of the Huntington-Ashland Area.

DATES: Written comments must be received on or before December 6, 2012.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2012–0174 by one of the following methods:

A. *www.regulations.gov.* Follow the on-line instructions for submitting comments.

B. *Email: mastro.donna@epa.gov*

C. *Mail:* EPA–R03–OAR–2012–0174, Donna Mastro, Acting Associate Director, Office of Air Quality Planning, Mailcode 3AP30, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R03–OAR–2012–0174. 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.

Docket: All documents in the electronic docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the West Virginia Department of Environmental Protection, Division of Air Quality, 601 57th Street SE., Charleston, West Virginia 25304.

FOR FURTHER INFORMATION CONTACT: Marilyn Powers, (215) 814–2308, or by e-mail at *powers.marilyn@epa.gov*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA.

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I. Summary of Actions

On June 30, 2011, the State of West Virginia through WVDEP formally submitted a request to redesignate the West Virginia portion of the Area from nonattainment to attainment of the 1997 annual $PM_{2.5}$ NAAQS. Concurrently, West Virginia submitted a maintenance plan for the Area as a SIP revision to ensure continued attainment throughout the Area over the next 10 years.

EPA is proposing to take several actions related to redesignation of the West Virginia portion of the Area to attainment for the 1997 annual $PM_{2.5}$ NAAQS. EPA is proposing to find that the West Virginia portion of the Area meets the requirements for redesignation of the $PM_{2.5}$ NAAQS under section 107(d)(3)(E) of the CAA. EPA is thus proposing to approve West Virginia's request to change the legal definition of the West Virginia portion of the Area from nonattainment to attainment for the 1997 annual $PM_{2.5}$ NAAQS. This action does not impact the legal definition of the Kentucky or Ohio portions of the Area. EPA is taking separate action to redesignate these portions.

EPA is also proposing to approve the maintenance plan for the West Virginia portion of the Area as a revision to the West Virginia SIP. Such approval is one of the CAA criteria for redesignation of an area to attainment. The maintenance plan is designed to ensure continued attainment in the West Virginia portion of the Area for 10 years after redesignation. The maintenance plan includes an insignificance determination for the on-road motor vehicle contribution of $PM_{2.5}$, NO_x and SO_2 in the West Virginia portion of the Area for transportation conformity purposes. EPA has determined that the on-road motor vehicle insignificance finding that is included as part of West Virginia's maintenance plan for the 1997 annual $PM_{2.5}$ NAAQS is adequate, and is proposing to approve the insignificance determination. EPA's analysis of these proposed actions is discussed in Sections VI and VII of today's proposed rulemaking action.

II. Background

A. General

The first air quality standards for $PM_{2.5}$ were established on July 16, 1997. 62 FR 38652 (July 18, 1997). EPA promulgated an annual standard at a level of 15 micrograms per cubic meter ($\mu g/m^3$), based on a three-year average of annual mean $PM_{2.5}$ concentrations. In the same rulemaking action, EPA promulgated a 24-hour standard of 65 $\mu g/m^3$, based on a three-year average of the 98th percentile of 24-hour concentrations. On October 17, 2006, at 71 FR 61144, EPA retained the annual average standard at 15 $\mu g/m^3$ but revised the 24-hour standard to 35 $\mu g/m^3$, based again on the three-year average of the 98th percentile of 24-hour concentrations.

On January 5, 2005 at 70 FR 944, as supplemented on April 14, 2005 at 70 FR 19844, EPA designated the

allow for a full 30 day public comment period in conjunction with this proposed rulemaking.

Huntington-Ashland Area as nonattainment for the 1997 p.m.$_{2.5}$ air quality NAAQS. The Huntington-Ashland Area is comprised of Cabell and Wayne Counties and the Graham tax district in Mason County, West Virginia; Boyd County and the portion of Lawrence County described by U.S. Census 2000 block group identifier 21–127–9901–6 in Kentucky; and Lawrence and Scioto Counties, Monroe and Sprigg Townships in Adams County, and Addison and Cheshire Townships in Gallia County in Ohio. On November 13, 2009 at 74 FR 58688, EPA promulgated designations for the 24-hour standard set in 2006, designating the Huntington-Ashland Area as attaining this standard. In that action, EPA also clarified the designations for the NAAQS promulgated in 1997, stating that the Huntington-Ashland Area remained designated nonattainment for the 1997 annual $PM_{2.5}$ standard, but was designated attainment for the 1997 24-hour standard. Today's action therefore does not address attainment of either the 1997 or the 2006 24-hour NAAQS.

In response to legal challenges of the annual standard promulgated in 2006, the DC Circuit remanded this standard to EPA for further consideration. *See American Farm Bureau Federation and National Pork Producers Council, et al.* v. *EPA,* 559 F.3d 512 (DC Cir. 2009). However, given that the 1997 and 2006 annual standards are essentially identical, attainment of the 1997 annual standard would also indicate attainment of the remanded 2006 annual standard. Since the Huntington-Ashland Area is designated nonattainment only for the annual standard promulgated in 1997, today's action addresses redesignation to attainment only for this standard.

In a final rulemaking action dated September 7, 2011 at 76 FR 55542, EPA determined, pursuant to 40 CFR 51.1004(c), that the entire Huntington-Ashland Area is attaining the 1997 annual $PM_{2.5}$ NAAQS. This determination of attainment was based upon complete, quality-assured and certified ambient air quality monitoring data for the period of 2007–2009 showing that the Area had attained the NAAQS by its applicable attainment date of April 5, 2010.

B. Clean Air Interstate Rule (CAIR) and Cross State Air Pollution Rule (CSAPR or the Transport Rule)

On May 12, 2005, EPA published CAIR, which requires significant reductions in emissions of SO_2 and NO_x from electric generating units to limit the interstate transport of these pollutants and the ozone and fine particulate matter they form in the atmosphere. *See* 70 FR 25162. The DC Circuit initially vacated CAIR, *North Carolina* v. *EPA,* 531 F.3d 896 (DC Cir. 2008), but ultimately remanded the rule to EPA without vacatur to preserve the environmental benefits provided by CAIR, *North Carolina* v. *EPA,* 550 F.3d 1176, 1178 (DC Cir. 2008). In response to the court's decision, EPA issued the Transport Rule, also known as CSAPR, to address interstate transport of NO_x and SO_2 in the eastern United States. *See* 76 FR 48208 (August 8, 2011). On August 21, 2012, the DC Circuit issued a decision to vacate the Transport Rule. In that decision, it also ordered EPA to continue administering CAIR ''pending the promulgation of a valid replacement.'' *EME Homer City Generation, L.P.* v. *EPA,* No. 11–1302 (DC Cir., August 21, 2012).[2]

In light of the above and as explained below, EPA proposes to approve the redesignation request and the related SIP revision for Cabell and Wayne Counties and the Graham tax district in Mason County in West Virginia, including West Virginia's plan for maintaining attainment of the 1997 annual $PM_{2.5}$ NAAQS standard in the West Virginia portion of the Area. The air quality modeling analysis conducted for the Transport Rule demonstrates that the Huntington-Ashland Area would be able to attain the 1997 annual $PM_{2.5}$ NAAQS even in the absence of either CAIR or the Transport Rule. *See* ''Air Quality Modeling Final Rule Technical Support Document,'' App. B, B–115 to B–134. This modeling is available in the docket for the Transport Rule rulemaking action. *See* Docket ID No. EPA–HQ–OAR–2009–0491. Nothing in the DC Circuit's August 2012 decision disturbs or calls into question that conclusion or the validity of the air quality analysis on which it is based.

In addition, CAIR remains in place and enforceable until substituted by a ''valid'' replacement rule. West Virginia's SIP revision lists CAIR as a control measure that became state-effective on May 1, 2008 and was approved by EPA on August 4, 2009 for the purpose of reducing SO_2 and NO_x emissions. The monitoring data used to demonstrate the Area's attainment of the 1997 annual $PM_{2.5}$ NAAQS by the April 2010 attainment deadline was also impacted by CAIR. To the extent that the State is relying on CAIR in its maintenance plan, the recent directive from the DC Circuit in *EME Homer* ensures that the reductions associated with CAIR will be permanent and enforceable for the necessary time period. EPA has been ordered by the Court to develop a new rule, and the opinion makes clear that after promulgating that new rule EPA must provide states an opportunity to draft and submit SIPs to implement that rule. CAIR thus cannot be replaced until EPA has promulgated a final rule through a notice-and-comment rulemaking process, states have had an opportunity to draft and submit SIPs, EPA has reviewed the SIPs to determine if they can be approved, and EPA has taken action on the SIPs, including promulgating a FIP if appropriate. These steps alone will take many years, even with EPA and the states acting expeditiously. The Court's clear instruction to EPA that it must continue to administer CAIR until a ''valid replacement'' exists provides an additional backstop; by definition, any rule that replaces CAIR and meets the Court's direction would require upwind states to eliminate significant downwind contributions.

Further, in vacating the Transport Rule and requiring EPA to continue administering CAIR, the DC Circuit emphasized that the consequences of vacating CAIR ''might be more severe now in light of the reliance interests accumulated over the intervening four years.'' *EME Homer,* slip op. at 60. The accumulated reliance interests include the interests of states who reasonably assumed they could rely on reductions associated with CAIR which brought certain nonattainment areas into attainment with the NAAQS. If EPA were prevented from relying on reductions associated with CAIR in redesignation actions, states would be forced to impose additional, redundant reductions on top of those achieved by CAIR. EPA believes this is precisely the type of irrational result the court sought to avoid by ordering EPA to continue administering CAIR. For these reasons also, EPA believes it is appropriate to allow states to rely on CAIR, and the existing emissions reductions achieved by CAIR, as sufficiently permanent and enforceable pending a valid replacement rule for purposes such as redesignation. Following promulgation of the replacement rule, EPA will review SIPs as appropriate to identify whether there are any issues that need to be addressed.

III. Criteria for Redesignation to Attainment

The CAA provides the requirements for redesignating a nonattainment area to attainment. Specifically, section 107(d)(3)(E) of the CAA allows for redesignation providing that:

[2] The court's judgment is not final, as of November 7, 2012, as the mandate has not yet been issued.

1. EPA determines that the area has attained the applicable NAAQS;
2. EPA has fully approved the applicable implementation plan for the area under section 110(k);
3. EPA determines that the improvement in air quality is due to permanent and enforceable reductions in emissions resulting from implementation of the applicable SIP and applicable Federal air pollutant control regulations and other permanent and enforceable reductions;
4. EPA has fully approved a maintenance plan for the area as meeting the requirements of CAA section 175A; and
5. The state containing such area has met all requirements applicable to the area under CAA section 110 and Part D.

EPA has provided guidance on redesignation in the General Preamble for the Implementation of title I of the CAA Amendments of 1990 (April 16, 1992, 57 FR 13498) (supplemented on April 28, 1992, 57 FR 18070) and has provided further guidance on processing redesignation requests in the following documents:

1. ''Procedures for Processing Requests to Redesignate Areas to Attainment,'' Memorandum from John Calcagni, Director, Air Quality Management Division, September 4, 1992 (hereafter referred to as the ''Calcagni Memorandum'');
2. ''State Implementation Plan (SIP) Actions Submitted in Response to Clean Air Act (CAA) Deadlines,'' Memorandum from John Calcagni, Director, Air Quality Management Division, October 28, 1992; and
3. ''Part D New Source Review (Part D NSR) Requirements for Areas Requesting Redesignation to Attainment,'' Memorandum from Mary D. Nichols, Assistant Administrator for Air and Radiation, October 14, 1994.

IV. Reasons for Proposing These Actions

On June 30, 2011, the WVDEP requested redesignation of the West Virginia portion of the Area to attainment for the 1997 annual $PM_{2.5}$ standard. As a part of the redesignation request, WVDEP submitted a maintenance plan for the West Virginia portion of the Area as a SIP revision, to ensure continued attainment of the 1997 annual $PM_{2.5}$ NAAQS over the next 10 years until 2022. EPA has determined that the Huntington-Ashland Area has attained the 1997 annual $PM_{2.5}$ standard and that West Virginia has met the requirements set forth in CAA section 107(d)(3)(E) for redesignation of the West Virginia portion of the Area.

V. Effects of These Proposed Actions

Final approval of the redesignation request would change the official designation of the West Virginia portion of the Area for the 1997 annual $PM_{2.5}$ NAAQS, found at 40 CFR part 81, from nonattainment to attainment. It would incorporate into the West Virginia SIP a maintenance plan ensuring continued attainment of the 1997 annual $PM_{2.5}$ NAAQS in the Area for the next 10 years until 2022. The maintenance plan includes, among other components, contingency measures to remedy any future violations of the 1997 annual $PM_{2.5}$ NAAQS (should they occur). Approval of the maintenance plan would also result in approval of the insignificance determination for $PM_{2.5}$, NO_x, and SO_2 for transportation conformity purposes in the West Virginia portion of the Area.

VI. Analysis of West Virginia's Redesignation Request

EPA proposes to redesignate the West Virginia portion of the Area to attainment for the 1997 annual $PM_{2.5}$ NAAQS and to approve into the West Virginia SIP the 1997 annual $PM_{2.5}$ NAAQS maintenance plan for the West Virginia portion of the Area. These actions are based upon EPA's determination that the Area continues to attain the 1997 annual $PM_{2.5}$ NAAQS and that all other redesignation criteria have been met for the West Virginia portion of the Area, provided EPA approves the base year emissions inventory that has been proposed in a separate rulemaking action. *See* 77 FR 60085 (Oct. 2, 2012). The following is a description of how the WVDEP June 30, 2011 submittal satisfies the requirements of section 107(d)(3)(E) of the CAA.

1. Attainment

As noted above, in a final rulemaking action dated September 7, 2011, at 76 FR 55542, EPA determined, pursuant to 40 CFR 51.1004(c), that the entire Huntington-Ashland Area is attaining the 1997 annual $PM_{2.5}$ NAAQS. This determination of attainment was based upon complete, quality-assured and certified ambient air quality monitoring data for the period of 2007–2009 showing that the Area had attained the NAAQS by its applicable attainment date of April 5, 2010. Further discussion of pertinent air quality issues underlying this determination was provided in the notice of proposed rulemaking action for EPA's determination of attainment for this Area, published on May 11, 2011 (76 FR 27290). EPA has reviewed more recent data in its Air Quality System (AQS) database, including certified, quality-assured data for the periods from 2008–2010 and 2009–2011. This data, shown in Table 1, shows that the Huntington-Ashland Area continues to attain the 1997 annual $PM_{2.5}$ NAAQS. In addition, as discussed below with respect to the maintenance plan, WVDEP has committed to continue monitoring air quality in accordance with 40 CFR part 58. In summary, EPA has determined that the data submitted by West Virginia, as well as data taken from AQS, indicate that the Huntington-Ashland Area has attained and continues to attain the 1997 annual $PM_{2.5}$ NAAQS.

TABLE 1—DESIGN VALUE CONCENTRATIONS FOR THE HUNTINGTON-ASHLAND AREA FOR THE 1997 ANNUAL $PM_{2.5}$ NAAQS ($\mu g/m^3$) FOR 2008–2010 AND 2009–2011

County	Monitor ID	3-Year annual design values	
		2008–2010	2009–2011
Cabell, WV	54–011–0006	13.1	12.3
Boyd, KY	21–019–0017	11.4	10.8
Scioto, OH	39–145–0013	11.6	10.9
Lawrence, OH	39–087–0012	12.2	11.4

Note: Monitor 39–087–0010 in Lawrence, Ohio was shut down in February 2008 due to demolition of the building. It was replaced by monitor 39–087–0012 located approximately one mile away and began monitoring in February 2008.

2. The Area Has Met All Applicable Requirements Under Section 110 and Part D of the CAA and Has a Fully Approved SIP Under Section 110(k) of the CAA

EPA has determined that the West Virginia portion of the Area has met all SIP requirements applicable for purposes of this redesignation under section 110 of the CAA (General SIP Requirements) and that, upon final approval of the 2002 base year inventory as discussed in section VI, it will have met all applicable SIP requirements under Part D of Title I of the CAA, in accordance with CAA section 107(d)(3)(E)(v). In addition, EPA is proposing to find that all applicable requirements of the West Virginia SIP for purposes of redesignation have been approved in accordance with CAA section 107(d)(3)(E)(ii). In making these proposed determinations, EPA ascertained which SIP requirements are applicable for purposes of redesignation of this area, and concluded that the applicable portions of the SIP meeting these requirements are fully approved under CAA section 110(k). We note that SIPs must be fully approved only with respect to applicable requirements.

a. CAA Section 110 General SIP Requirements

Section 110(a)(2) of Title I of the CAA delineates the general requirements for a SIP, which include enforceable emissions limitations and other control measures, means, or techniques, provisions for the establishment and operation of appropriate devices necessary to collect data on ambient air quality, and programs to enforce the limitations. The general SIP elements and requirements set forth in CAA section 110(a)(2) include, but are not limited to the following:

- Submittal of a SIP that has been adopted by the state after reasonable public notice and hearing;
- Provisions for establishment and operation of appropriate procedures needed to monitor ambient air quality;
- Implementation of a source permit program; provisions for the implementation of Part C requirements (Prevention of Significant Deterioration (PSD));
- Provisions for the implementation of Part D requirements for New Source Review (NSR) permit programs;
- Provisions for air pollution modeling; and
- Provisions for public and local agency participation in planning and emission control rule development.

Section 110(a)(2)(D) of the CAA requires that SIPs contain certain measures to prevent sources in a state from significantly contributing to air quality problems in another state. To implement this provision for various NAAQS, EPA has required certain states to establish programs to address transport of air pollutants in accordance with the NO_x SIP Call, October 27, 1998 (63 FR 57356), amendments to the NO_x SIP Call, May 14, 1999 (64 FR 26298) and March 2, 2000 (65 FR 11222), and CAIR, May 12, 2005 (70 FR 25162). However, the CAA section 110(a)(2)(D) requirements for a state are not linked with a particular nonattainment area's designation and classification in that state. EPA believes that the requirements linked with a particular nonattainment area's designation and classifications are the relevant measures to evaluate in reviewing a redesignation request. The transport SIP submittal requirements, where applicable, continue to apply to a state regardless of the designation of any one particular area in the state. Thus, we do not believe that these requirements are applicable requirements for purposes of redesignation.

In addition, EPA believes that the other CAA section 110(a)(2) elements not connected with nonattainment plan submissions and not linked with an area's attainment status are not applicable requirements for purposes of redesignation. The Area will still be subject to these requirements after it is redesignated. We conclude that the CAA section 110(a)(2) and Part D requirements which are linked with a particular area's designation and classification are the relevant measures to evaluate in reviewing a redesignation request, and that CAA section 110(a)(2) elements not linked to the area's nonattainment status are not applicable for purposes of redesignation. This approach is consistent with EPA's existing policy on applicability of conformity (i.e., for redesignations) and oxygenated fuels requirement. *See* Reading, Pennsylvania, proposed and final rulemakings (61 FR 53174, October 10, 1996), (62 FR 24826, May 7, 1997); Cleveland-Akron-Lorain, Ohio final rulemaking (61 FR 20458, May 7, 1996); and Tampa, Florida, final rulemaking (60 FR 62748, December 7, 1995). See also, the discussion on this issue in the Cincinnati redesignation (65 FR at 37890, June 19, 2000), and in the Pittsburgh redesignation (66 FR at 53099, October 19, 2001).

We have reviewed the West Virginia SIP and have concluded that it meets the general SIP requirements under section 110(a)(2) of the CAA to the extent they are applicable for purposes of redesignation. EPA has previously approved provisions of West Virginia's SIP addressing CAA section 110(a)(2) requirements, including provisions addressing $PM_{2.5}$. *See* 76 FR 47062 (August 4, 2011). These requirements are, however, statewide requirements that are not linked to the $PM_{2.5}$ nonattainment status of the Huntington-Ashland Area. Therefore, EPA believes that these SIP elements are not applicable requirements for purposes of review of the State's $PM_{2.5}$ redesignation request.

b. Part D Nonattainment Requirements Under the Standard

Subpart 1 of part D, sections 172 to 175 of the CAA, sets forth the basic nonattainment plan requirements applicable to $PM_{2.5}$ nonattainment areas. Under CAA section 172, states with nonattainment areas must submit plans providing for timely attainment and must meet a variety of other requirements. On May 28, 2009, WVDEP submitted an attainment plan and base year inventory for the West Virginia portion of the Area. On September 7, 2011 (76 FR 55542), EPA made a determination that the Huntington-Ashland Area is attaining the 1997 Annual $PM_{2.5}$ NAAQS. Pursuant to 40 CFR 51.1004(c), upon a determination by EPA that an area designated nonattainment for the $PM_{2.5}$ NAAQS has attained the standard, the requirement for such an area to submit an attainment demonstration and associated reasonably available control measures (RACM), a reasonable further progress plan (RFP), contingency measures, and other planning SIPs related to the attainment of the $PM_{2.5}$ NAAQS are suspended until the area is redesignated to attainment or EPA determines that the area has again violated the $PM_{2.5}$ NAAQS, at which time such plans are required to be submitted. The May 28, 2009 submittal is relevant to this proposed action to redesignate the West Virginia portion of the Area only with respect to the base year inventory that was submitted with the attainment plan. In a separate rulemaking action, as detailed below, EPA has proposed approval of the base year inventory, which, upon final approval, will meet the requirements of CAA section 172(c)(3), one of the criteria for redesignation. *See* 77 FR 60085 (Oct. 2, 2012).

The General Preamble for Implementation of Title I also discusses the evaluation of these requirements in the context of EPA's consideration of a redesignation request. The General Preamble sets forth EPA's view of applicable requirements for purposes of evaluating redesignation requests when

an area is attaining the standard. *See* General Preamble for Implementation of Title I (57 FR 13498 (April 16, 1992)).

Because attainment has been reached for the Area, no additional measures are needed to provide for attainment, and CAA section 172(c)(1) requirements for an attainment demonstration and RACM are no longer considered to be applicable for purposes of redesignation as long as the area continues to attain the standard until redesignation. *See* 40 CFR 51.1004(c). The RFP requirement under CAA section 172(c)(2) and contingency measures requirement under CAA section 172(c)(9) are similarly not relevant for purposes of redesignation.

Section 172(c)(3) of the CAA requires submission of a comprehensive, accurate, and current inventory of actual emissions. As part of West Virginia's attainment plan submittal, the State submitted a 2002 emissions inventory. As previously noted, on September 7, 2011 (76 FR 55542), EPA determined that the Huntington-Ashland Area attained the 1997 annual $PM_{2.5}$ NAAQS, based on complete, quality-assured data for the period of 2007–2009. That rulemaking action suspended certain planning requirements related to attainment, including the RACT/RACM requirement of section 172(c)(1), the RFP requirement of CAA section 172(c)(2), the attainment demonstration requirement of CAA section 172(c)(3), and the requirement for contingency measures in CAA section 172(c)(9). As a result of the determination of attainment, the only remaining requirement under CAA section 172 to be considered for purposes of redesignation of the West Virginia portion of the Area is the emissions inventory required under CAA section 172(c)(3). On October 2, 2012 (77 FR 60085), EPA proposed approval of the base year inventory for the West Virginia portion of the Area for the 1997 annual $PM_{2.5}$ NAAQS. An evaluation of West Virginia's 2002 base year inventory for the West Virginia portion of the Area is provided in the Technical Support Document (TSD) prepared by EPA for that rulemaking action. In that action, EPA determined that the emissions inventory and emissions statement requirements for the West Virginia portion of the Area have been satisfied, and proposed to approve the inventory as meeting the requirements of CAA section 172. Final approval of the emissions inventory in that action will satisfy the emissions inventory requirement for redesignation under CAA section 172(c)(3).

Section 172(c)(4) of the CAA requires the identification and quantification of allowable emissions for major new and modified stationary sources in an area, and CAA section 172(c)(5) requires source permits for the construction and operation of new and modified major stationary sources anywhere in the nonattainment area. EPA has determined that, since prevention of significant deterioration (PSD) requirements will apply after redesignation, areas being redesignated need not comply with the requirement that a nonattainment new source review (NSR) program be approved prior to redesignation, provided that the area demonstrates maintenance of the NAAQS without part D NSR. A more detailed rationale for this view is described in a memorandum from Mary Nichols, Asssistant Administrator for Air and Radiation, dated October 14, 1994, entitled, *''Part D New Source Review Requirements for Areas Requesting Redesignation to Attainment.''* Nevertheless, West Virginia currently has an approved NSR program, codified in 45 CSR 19. *See* 71 FR 64468 (November 2, 2006) (approving NSR program into the SIP) and 77 FR 63736 (October 17, 2012) (approving revisions to West Virginia's PSD program). However, the State's PSD program for annual $PM_{2.5}$ will become effective in the Huntington-Ashland Area upon redesignation to attainment.

Section 172(c)(6) of the CAA requires the SIP to contain control measures necessary to provide for attainment of the standard. Because attainment has been reached for the Area, no additional measures are needed to provide for attainment.

Section 172(c)(7) of the CAA requires the SIP to meet the applicable provisions of CAA section 110(a)(2). As noted previously, we believe the West Virginia SIP meets the requirements of CAA section 110(a)(2) that are applicable for purposes of redesignation.

Section 176(c) of the CAA requires states to establish criteria and procedures to ensure that Federally supported or funded projects conform to the air quality planning goals in the applicable SIP. The requirement to determine conformity applies to transportation plans, programs, and projects that are developed, funded or approved under title 23 of the United States Code (U.S.C.) and the Federal Transit Act (transportation conformity) as well as to all other Federally supported or funded projects (general conformity). State transportation conformity SIP revisions must be consistent with Federal conformity regulations relating to consultation, enforcement and enforceability which EPA promulgated pursuant to its authority under the CAA.

EPA interprets the conformity SIP requirements as not applying for purposes of evaluating a redesignation request under CAA section 107(d) because state conformity rules are still required after redesignation, and Federal conformity rules apply where state rules have not been approved. *See Wall* v. *EPA,* 265 F. 3d 426 (6th Cir. 2001) (upholding this interpretation); *see also* 60 FR 62748 (Dec. 7, 1995) (discussing Tampa, Florida). Thus, EPA determines that the Huntington-Ashland Area has satisfied all applicable requirements for purposes of redesignation under CAA section 110 and, upon final approval of the 2002 base year inventory proposed on October 2, 2012, will have satisfied all applicable requirements under part D of title I of the CAA.

c. The West Virginia Portion of the Area Has a Fully Approved Applicable SIP Under Section 110(k) of the CAA

Upon final approval of the 2002 base year inventory, as proposed in the October 2, 2012 rulemaking action, EPA will have fully approved the West Virginia portion of the Area under section 110(k) of the CAA for all requirements applicable for purposes of redesignation to attainment for the 1997 annual $PM_{2.5}$ standard. Therefore, upon final approval of the 2002 base year emissions inventory, EPA will have approved all part D subpart 1 requirements applicable for purposes of this redesignation.

3. The Air Quality Improvement in the West Virginia Portion of the Area Is Due to Permanent and Enforceable Reductions in Emissions Resulting From Implementation of the SIP and Applicable Federal Air Pollution Control Regulations and Other Permanent and Enforceable Reductions

For redesignating a nonattainment area to attainment, CAA section 107(d)(3)(E)(iii) requires EPA to determine that the air quality improvement in the area is due to permanent and enforceable reductions in emissions resulting from implementation of the SIP and applicable Federal air pollution control regulations and other permanent and enforceable reductions. EPA believes that West Virginia has demonstrated that the observed air quality improvement in the West Virginia portion of the Area is due to permanent and enforceable reductions in emissions resulting from implementation of the SIP, Federal measures, and other/state-adopted measures. In making this

demonstration, West Virginia has calculated the change in emissions between 2005, one of the years used to designate the Huntington-Ashland Area as nonattainment, and 2008, one of the years for which the Huntington-Ashland Area monitored attainment. The reduction in emissions and the corresponding improvement in air quality over this time period can be attributed to a number of regulatory control measures that the Huntington-Ashland Area and contributing areas have implemented in recent years.

a. Federal Measures Implemented

Reductions in fine particulate precursor emissions have occurred statewide and in upwind states as a result of Federal emission control measures with additional emission reductions expected to occur in the future. Federal emission control measures include the following:

(1) Tier 2 Emission Standards for Vehicles and Gasoline Sulfur Standards

These emission control requirements result in lower NO_X and SO_2 emissions from new cars and light duty trucks, including sport-utility vehicles. The Federal rules were phased in between 2004 and 2009. EPA has estimated that, after phasing in the new requirements, new vehicles emit less NO_X in the following percentages: Passenger cars (light duty vehicles—77%); light duty trucks, minivans, and sports utility vehicles—86%; and, larger sports utility vehicles, vans, and heavier trucks—69–95%. EPA expects fleet wide average emissions to decline by similar percentages as new vehicles replace older vehicles. The Tier 2 standards also reduced the sulfur content of gasoline to 30 parts per million (ppm) beginning in January 2006, up to a 90 percent reduction.

(2) Heavy-Duty Diesel Engine Rule

EPA issued this rule in July 2000. This rule includes standards limiting the sulfur content of diesel fuel, which went into effect in 2004. A second phase took effect in 2007 which reduced fine particulate emissions from heavy-duty highway engines and further reduced the highway diesel fuel sulfur content to 15 ppm. The total program is estimated to achieve a 90% reduction in direct $PM_{2.5}$ emissions and a 95% reduction in NO_X emissions for these new engines using low sulfur diesel, compared to existing engines using higher sulfur diesel fuel. The reduction in fuel sulfur content also yielded an immediate reduction in particulate sulfate emissions from all diesel vehicles.

(3) Nonroad Diesel Rule

In May 2004, EPA promulgated a new rule for large nonroad diesel engines, such as those used in construction, agriculture, and mining, to be phased in between 2008 and 2014. The rule also reduces the sulfur content in nonroad diesel fuel by over 99%. Prior to 2006, nonroad diesel fuel averaged approximately 3,400 ppm sulfur. This rule limited nonroad diesel sulfur content to 500 ppm by 2006, with a further reduction to 15 ppm by 2010.

b. Controls on $PM_{2.5}$ Precursors

The Area's air quality is strongly affected by regulation of SO_2 and NO_X from power plants. EPA promulgated the NO_X SIP Call, CAIR, and CSAPR to address SO_2 and NO_X emissions from EGUs and certain non-EGUs across the eastern United States. The affected EGUs in the West Virginia portion of the Area are two American Electric Power (AEP) generating stations in Mason County.

(1) NO_X SIP Call

EPA issued the NO_X SIP Call in 1998 to require 22 states and the District of Columbia to reduce NO_X emissions from large EGUs and large non-EGUs such as industrial boilers, internal combustion engines, and cement kilns. (63 FR 57356, October 27, 1998). EPA approved West Virginia's Phase I NO_X SIP Call rule in 2002 and its Phase II rule in 2006. Emission reductions resulting from regulations developed in response to the NO_X SIP Call are permanent and enforceable.

(2) CAIR and CSAPR

EPA approved West Virginia's CAIR rules in 2009 (74 FR 38536, August 4, 2009). The maintenance plan for the West Virginia portion of the Area thus lists CAIR as a control measure for the purpose of reducing SO_2 and NO_X emissions from EGUs. Because the Transport Rule had not been finalized and CAIR was in place when West Virginia submitted its redesignation request and maintenance plan, inclusion of CAIR as a control measure was consistent with EPA policy at that time.

As previously discussed, the D.C. Circuit's 2008 remand of CAIR left the rule in place to ''temporarily preserve the environmental values covered by CAIR'' until EPA replaced it with a rule consistent with the Court's opinion, and the court's August 2012 decision on the Transport Rule also left CAIR in effect until the legal challenges to the Transport Rule are resolved. As noted, EPA believes it is appropriate to allow states to rely on CAIR, and the existing emissions reductions achieved by CAIR, as sufficiently permanent and enforceable pending a valid replacement rule, for purposes such as redesignation.

Furthermore, as previously discussed, the air quality modeling analysis conducted for the Transport Rule demonstrates that the Huntington-Ashland Area would be able to attain the 1997 annual $PM_{2.5}$ NAAQS even in the absence of either CAIR or the Transport Rule. EPA's modeling projections show that all ambient monitors in the Area are expected to continue to maintain compliance in the 2012 and 2014 ''no CAIR'' base cases. Therefore, none of the ambient monitoring sites in the Huntington-Ashland Area are ''receptors'' that EPA projects will have future nonattainment problems or difficulty maintaining the NAAQS.

c. Federal Consent Decrees

EGUs in this Area are subject to Federal consent decrees that have reduced emissions of NO_X and SO_2 in the Area. There are two AEP EGUs in Mason County, the partial county portion of the West Virginia portion of the Area. These are the Mountaineer Power Station (Mountaineer) and the Philip Sporn Power Station (Philip Sporn). As part of a Federally enforceable consent decree, Mountaineer was required, starting in January 2008, to operate its selective catalytic reduction (SCR) continuously to control NO_X emissions, and to operate continuously its Flue Gas Desulfurization (FGD) to reduce SO_2 emissions starting in December 2007.

Since 2008, additional controls have or will be installed on EGUs within the West Virginia portion of the Area and in Kentucky and Ohio, which will continue to contribute to the reductions in precursor pollutants for $PM_{2.5}$. Pursuant to the Federally enforceable consent decree, Philip Sporn installed and began operation of selective non-catalytic reduction (SNCR) to control NO_X emissions on Units 3 and 4 starting in January 2009 and is required to retire, retrofit, or repower Unit 5 by December 31, 2013. Several EGUs in Gallia and Adams Counties in Ohio have installed controls as a result of Federally enforceable consent decrees. Two units at the General J. M. Gavin Station (owned or operated by AEP) in Gallia County, Ohio were required to continuously operate SNCR starting in December 2009, and five units at the Kyger Creek Station in Gallia County have installed and continuously operated SNCRs since January, 2009. Additionally, Kyger Creek Station plans to install and operate FGDs in 2012.

Also, four units at the J.M. Stuart DP&L Station in Adams County, Ohio have been operating year round SNCR since 2009, and one unit at Big Sandy Power Station (owned and/or operated by AEP) in Lawrence County, KY was required by consent decree to install and continuously operate SCR starting in January 2009 and a FGD starting in December 2015.

A summary of the emissions reductions from 2005 to 2009 for the entire Huntington-Ashland Area is provided in Table 2 below. As discussed below, West Virginia's maintenance plan provides for verification of continued attainment by performing triennial reviews of emissions inventories for all $PM_{2.5}$ precursors, as well as contingency measures to ensure that the NAAQS is maintained into the future if monitored increases in ambient $PM_{2.5}$ concentrations occur.

TABLE 2—ACTUAL EMISSION REDUCTIONS FROM COAL FIRED UTILITIES IN THE HUNTINGTON-ASHLAND AREA FOR THE PERIOD 2005–2009

Facility—county	Emission differences from 2005–2009 (tpy)			
	SO_2	Percent reduction	NO_X	Percent reduction
Kentucky				
Big Sandy—Lawrence County	9,783	20	7,624	61
West Virginia				
Mountaineer—Mason County	40,214	94	10,073	79
Philip Sporn—Mason County	22,433	57	5,020	56
Ohio				
JM Stuart—Adams County	42,224	40	16,124	66
Killen Station—Adams County	17,592	90	3,083	52
Gen JM Gavin—Gallia County	1,701	6	31,800	82
Kyger Creek—Gallia County	16,032	22	15,209	82

Source: Clean Air Markets Data and Maps database (*http://camddataandmaps.epa.gov/*).

Based on the information summarized above, West Virginia has adequately demonstrated that the improvement in air quality is due to permanent and enforceable emissions reductions. The reductions result from Federal requirements, regulation of precursors under the NO_X SIP Call and CAIR, and Federal consent decrees affecting EGUs in the Huntington-Ashland Area, which are permanent and enforceable.

Additionally, because $PM_{2.5}$ concentrations in the Huntington-Ashland Area are impacted by the transport of sulfates and nitrates, as noted previously, the Area's air quality is strongly affected by regulation of SO_2 and NO_X emissions from EGUs in states in the region that significantly contribute to the Area. Table 3 shows statewide EGU emissions data for the years 2002, 2008 and 2010 for the states that are significantly contributing to the air quality in the Huntington-Ashland Area. Emissions for 2008 and 2010 reflect the implementation of CAIR.

TABLE 3—COMPARISON OF 2002, 2008, AND 2010 EGU NO_X AND SO_2 EMISSIONS FOR STATES THAT CONTRIBUTE TO THE HUNTINGTON-ASHLAND AREA

State	NO_X (tpy)				SO_2 (tpy)			
	2002	2008	2010	Net change 2002–2008 (percent)	2002	2008	2010	Net change 2002–2008 (percent)
Alabama	161,559	112,625	63,289	−30	448,248	357,546	204,189	−20
Georgia	146,456	105,894	60,521	−27	512,654	514,539	218,836	<1
Illinois	174,247	119,976	76,299	−31	353,699	257,431	220,092	−27
Indiana	281,146	196,580	120,924	−30	778,868	595,966	414,764	−23
Kentucky	198,599	157,847	91,824	−20	482,653	344,356	266,204	−22
Michigan	132,624	103,473	76,130	−20	342,999	326,501	242,188	−4
Missouri	139,799	88,600	58,364	−36	235,532	258,269	236,216	9
Ohio	370,497	235,018	104,839	−36	1,132,069	709,444	572,126	−37
Pennsylvania	200,909	175,219	125,486	−12	889,766	631,915	393,196	−28
Tennessee	155,996	85,543	31,073	−43	336,995	208,069	119,023	−38
West Virginia	225,371	97,331	51,393	−56	507,110	301,574	106,087	−40
Total	2,025,644	1,478,106	860,142	−27	5,785,061	4,505,610	2,992,921	−22

Source: Clean Air Markets Data and Maps database (*http://camddataandmaps.epa.gov/*).

Table 3 shows that the states impacting the Huntington-Ashland Area reduced NO_X and SO_2 emissions from EGUs by 547,538 tpy and 979,451 tpy, respectively, between 2002 and 2008. This table also includes emissions from the contributing states in 2010, which shows the continuing, generally downward trend of NO_X and SO_2 emissions from these states.

4. The West Virginia Portion of the Area Has a Fully Approvable Maintenance Plan Pursuant to Section 175A of the CAA

In conjunction with its request to redesignate the West Virginia portion of the Area to attainment status, West

Virginia submitted a SIP revision to provide for maintenance of the 1997 annual $PM_{2.5}$ NAAQS in the Area for at least 10 years after redesignation. West Virginia is requesting that EPA approve this SIP revision as meeting the requirement of CAA section 175A. Once approved, the maintenance plan for the West Virginia portion of the Area will ensure that the SIP for West Virginia meets the requirements of the CAA regarding maintenance of the 1997 annual $PM_{2.5}$ NAAQS for this area.

a. Requirements of a Maintenance Plan

Section 175 of the CAA sets forth the elements of a maintenance plan for areas seeking redesignation from nonattainment to attainment. Under CAA section 175A, the plan must demonstrate continued attainment of the applicable NAAQS for at least 10 years after approval of a redesignation of an area to attainment. Eight years after the redesignation, West Virginia must submit a revised maintenance plan demonstrating that attainment will continue to be maintained for the 10 years following the initial 10-year period. To address the possibility of future NAAQS violations, the maintenance plan must contain such contingency measures, with a schedule for implementation, as EPA deems necessary to assure prompt correction of any future $PM_{2.5}$ violations. The John Calcagni memorandum entitled *''Procedures for Processing Requests to Redesignate Areas to Attainment,''* dated September 4, 1992, provides additional guidance on the content of a maintenance plan. The memorandum states that a $PM_{2.5}$ maintenance plan should address the following provisions:

(1) An attainment emissions inventory;

(2) A maintenance demonstration showing maintenance for 10 years;

(3) A commitment to maintain the existing monitoring network;

(4) Verification of continued attainment; and

(5) A contingency plan to prevent or correct future violations of the NAAQS.

b. Analysis of the Maintenance Plan

(1) Attainment Emissions Inventory

An attainment inventory is comprised of the emissions during the time period associated with the monitoring data showing attainment. WVDEP developed emissions inventories for NO_X, direct $PM_{2.5}$, and SO_2 for 2008, one of the years in the period during which the Huntington-Ashland Area monitored attainment of the 1997 annual $PM_{2.5}$ standard, as described previously. The 2008 point source inventory contained emissions for EGUs and non-EGUs in Cabell and Wayne Counties. For the portion of Mason County that is part of this nonattainment area, the Mountaineer Plant, Sporn Plant, and New Haven Plant are included in the inventory. WVDEP used data from EPA's CAMD database to compile the EGU and non-EGU inventory. For the 2008 Area and Nonroad Mobile source emissions, WVDEP used the 2008 National Emissions Inventory (NEI) version 1.5 data developed by EPA. The 2008 Onroad Mobile source inventory was developed using the most current version of EPA's highway mobile source emissions model MOVES2010a. WVDEP used the Kentucky, Ohio, and West Virginia (KYOVA) Travel Demand Model, which is the most recent travel demand model provided by the KYOVA Interstate Planning Commission that covers the nonattainment counties in WV. Information from the travel demand models combined with Highway Performance Monitoring Systems (HPMS) county-level data from each area were used in the emissions analysis. Additional data needed for input into the MOVES2010a model was provided by the Ohio Department of Transportation (ODOT), Ohio EPA, West Virginia Department of Transportation (WVDOT), WVDEP, Kentucky Transportation Cabinet (KYTC) and the Kentucky Division of Air Quality (KDAQ).

(2) Maintenance Demonstration

On June 30, 2011, the WVDEP submitted a maintenance plan for the West Virginia portion of the Area as required by section 175A of the CAA. WVDEP uses projection inventories to show that the Area will remain in attainment and developed projection inventories for an interim year of 2015 and a maintenance plan end year of 2022 to show that future emissions of NO_X, SO_2, and direct $PM_{2.5}$ will remain at or below the attainment year 2008 emissions levels throughout the West Virginia portion of the Area through the year 2022. A maintenance demonstration need not be based on modeling. *See Wall* v. *EPA, supra; Sierra Club* v. *EPA, supra. See also* 66 FR at 53099–53100; 68 FR at 25430–32. The projection inventories for the 2015 and 2022 point, area, and nonroad sources were based on the 2012 and 2018 Visibility Improvement State and Tribal Assoiation of the Southeast (VISTAS)/Association of Southeastern Integrated Planning (ASIP) modeling inventory.

(a) Point Sources

West Virginia developed the 2015 point source inventory by interpolation between VISTAS/ASIP 2012 and 2018 modeling inventory. The 2022 EGU inventory for $PM_{2.5}$, NO_X, and SO_2 was kept the same as the VISTAS/ASIP 2018 inventory. The 2022 non-EGU inventory was extrapolated from the 2012 and 2018 inventory. Point source emissions for 2012 and 2018 were developed for EGUs and non-EGUs. For EGUs, WVDEP used the projection inventory developed by VISTAS/ASIP. VISTAS/ASIP analysis was based on EPA's IPM model. The VISTAS/ASIP analysis projected future year emissions for EGUs under several scenarios based on the best information available at the time of the analysis. WVDEP used the ''on the way'' (OTW) projections, which took into account the reductions required by CAIR, as a basis for 2012 and 2018 EGU emissions. VISTAS/ASIP used EPA's EGAS, Version 4.0 to make the projections for non-EGUs, incorporating the growth factors suggested in the reports entitled Development of Growth Factors for Future Year Modeling Inventories (April 30, 2004) and CAIR Emission Inventory Overview (July 23, 2004). EPA has reviewed the VISTAS documentation provided by WVDEP and found the methodologies acceptable.

(b) Area Sources

Area source emissions for 2015 were interpolated from the VISTAS/ASIP 2012 and 2018 inventories. The 2022 emissions were extrapolated from the VISTAS/ASIP 2012 and 2018 inventories. Growth and controls for emissions were based on the methodologies applied by EPA for the CAIR analysis.

(c) Nonroad Sources

Nonroad source emissions, including aircraft, locomotives, and commercial marine vessels (CMV) for 2015 were interpolated from the VISTAS/ASIP 2012 and 2018 inventories. CMV source emissions for SO_2 included in the 2022 inventory were held constant at 2018 levels because no further reduction in fuel sulfur content is expected. All other nonroad source emissions for 2022 were extrapolated from the VISTAS/ASIP 2012 and 2018 inventories.

(d) Onroad Mobile Sources

The 2015 and 2022 onroad mobile source emissions were prepared using MOVES2010a following the same procedure as the 2008 inventory as described previously.

EPA has determined that the emissions inventories provided by

WVDEP are approvable. For more information on EPA's analysis of the emissions inventories, see the TSD dated April 9, 2012, available in the docket for this rulemaking action at *www.regulations.gov.* Table 4 shows the inventories for the 2008 attainment base year, the 2015 interim year, and the 2022 maintenance plan end year for the entire nonattainment area.

TABLE 4—COMPARISON OF 2008, 2015, 2022 SO_2, NO_X, AND DIRECT $PM_{2.5}$ EMISSION TOTALS, IN TPY FOR THE ENTIRE HUNTINGTON-ASHLAND AREA WV-KY-OH

	2008	2015	2022	Decrease from 2008 to 2022
SO_2 (tpy)	221,210	139,263	88,432	132,778
NO_X (tpy)	145,527	94,932	68,313	77,214
$PM_{2.5}$ (tpy)	11,701	11,262	11,317	384

Table 4 shows that, between 2008 and 2015, the entire Huntington-Ashland Area is projected to reduce SO_2 emissions by 81,947 tpy, NO_X emissions by 50,595 tpy, and direct $PM_{2.5}$ emissions by 439 tons. Between 2008 and 2022, the area is projected to reduce SO_2 emissions by 77,214 tpy, NO_X emissions by 132,778 tpy, and direct $PM_{2.5}$ emissions by 384 tpy. Thus, the projected emissions inventories show that the area will continue to maintain the 1997 annual $PM_{2.5}$ NAAQS during the 10 year maintenance period.

(3) Maintenance Demonstration Through 2023

As noted in section 4.a of this document, CAA section 175A requires a State seeking redesignation to attainment to submit a SIP revision to provide for the maintenance of the NAAQS in the area ''for at least 10 years after the redesignation.'' EPA has interpreted this as a showing of maintenance ''for a period of ten years following redesignation.'' September 4, 1992 Memorandum from John Calcagni, Director, AQMD, *''Procedures for Processing Requests to Redesignate Areas to Attainment,''* p. 9. Where the emissions inventory method of showing maintenance is used, its purpose is to show that emissions during the maintenance period will not increase over the attainment year inventory. Calcagni Memorandum, pp. 9–10.

As discussed in detail above, the State's maintenance plan submission expressly documents that the Area's emissions inventories will remain below the attainment year inventories through 2022. In addition, for the reasons set forth below, EPA believes that the State's submission, in conjunction with additional supporting information, further demonstrates that the Area will continue to maintain the 1997 annual $PM_{2.5}$ NAAQS at least through 2023:

• Significant emissions controls remain in place, and will continue to provide reductions that keep the Area in attainment. The Mountaineer Power Station was required by a permanent and enforceable consent decree to install SCR for NO_X in 2008 and to operate its FGD continuously for SO_2 in 2007. Philip Sporn Power Station installed SNCR to control NO_X in 2009, and must retire, retrofit, or repower Unit 5 by the end of 2013.

• West Virginia has committed to maintain all of the control measures that are relied on, and will submit any changes to EPA for approval as a SIP revision.

• Emissions inventory levels for SO_2 and NO_X in 2022 are well below the attainment year inventory levels (see Table 4), and it is highly improbable that sudden increases would occur that could exceed the attainment year inventory levels in 2023.

• The mobile source contribution has been determined to be insignificant, and is expected to remain insignificant in 2023 with fleet turnover in upcoming years that will result in cleaner vehicles and cleaner fuels.

• Air quality concentrations well below the standard, coupled with the emissions inventory projections through 2022 show that it would be very unlikely for a violation to occur in 2023. The 2009–2011 design value of 12.1 μg/m³ provides a sufficient margin in the event emissions increase, and continues the downward trend of monitored data in this Area for the last several years.

Thus, if EPA finalizes its proposed approval of the redesignation request and maintenance plans in 2013, it is based on a showing, in accordance with CAA section 175A, that the State's maintenance plan provides for maintenance for at least ten years after redesignation, and into 2023.

(4) Monitoring Network

West Virginia's maintenance plan includes a commitment to continue to operate its EPA-approved monitoring network, as necessary to demonstrate ongoing compliance with the NAAQS. West Virginia currently operates a $PM_{2.5}$ monitor in Cabell County. Two of the remaining monitors are located in Ohio, and one monitor is located in Kentucky. West Virginia will consult with EPA prior to making any necessary changes to the network and will continue to quality assure the monitoring data in accordance with the requirements of 40 CFR part 58.

(5) Verification of Continued Attainment

To provide for tracking of the emission levels in the area, WVDEP requires major point sources to submit air emissions information annually and prepares a new periodic inventory for all $PM_{2.5}$ precursors every three years in accordance with EPA's Air Emissions Reporting Requirements (AERR). Emissions information will be compared to the attainment year inventory to assure continued attainment with the 1997 annual $PM_{2.5}$ NAAQS and will be used to assess emissions trends, as necessary.

(6) The Maintenance Plan's Contingency Measures

The contingency plan provisions are designed to promptly correct a violation of the NAAQS that occurs after redesignation. Section 175A of the CAA requires that a maintenance plan include such contingency measures as EPA deems necessary to ensure that West Virginia will promptly correct a violation of the NAAQS that occurs after redesignation. The maintenance plan should identify the events that would ''trigger'' the adoption and implementation of a contingency measure(s), the contingency measure(s) that would be adopted and implemented, and the schedule indicating the time frame by which the state would adopt and implement the measure(s).

The ability of the West Virginia portion of the Area to stay in compliance with the 1997 annual $PM_{2.5}$ NAAQS after redesignation depends upon NO_X and SO_2 emissions in the Huntington-Ashland Area remaining at

or below 2008 levels. West Virginia's maintenance plan projects NO_X and SO_2 emissions to decrease and stay below 2008 levels through at least the year 2022. West Virginia's maintenance plan outlines the procedures for the adoption and implementation of contingency measures to further reduce emissions should a violation occur.

West Virginia's contingency measures include a Warning Level Response and an Action Level response. An initial Warning Level Response is triggered when the average weighted annual mean for a single calendar year exceeds 15.5 ug/m3 within the maintenance area. In that case, a study will be conducted to determine if the emissions trends show increases; if action is necessary to reverse emissions increases, West Virginia will follow the same procedures for control selection and implementation as for an Action Level Response, and implementation of necessary controls will take place as expeditiously as possible, but no later than 12 months from the end of the most recent calendar year.

The Action Level Response will be prompted by any one of the following: A Warning Level Response study that shows emissions increases; a weighted annual mean over a two-year average that exceeds the standard; or a violation of the standard in the maintenance area. If an Action Level Response is triggered, West Virginia will adopt and implement appropriate control measures within 18 months from the end of the year in which monitored air quality triggering a response occurs. West Virginia will also consider whether additional regulations that are not a part of the maintenance plan can be implemented in a timely manner to respond to the trigger.

West Virginia's candidate contingency measures include the following: (1) Diesel reduction emission strategies, (2) alternative fuels and diesel retrofit programs for fleet vehicle operations, (3) $PM_{2.5}$, SO_2, and NO_X emissions offsets for new and modified major sources, (4) concrete manufacturing controls, and (5) additional NO_X reductions. Additionally, West Virginia has identified a list of sources that could potentially be controlled. These include: Industrial, commercial and institutional (ICI) boilers for SO_2 and NO_X controls, EGUs, process heaters, internal combustion engines, combustion turbines, other sources greater than 100 tons per year, fleet vehicles, and aggregate processing plants.

For all of the reasons discussed above, EPA is proposing to approve West Virginia's 1997 annual $PM_{2.5}$ maintenance plan for the West Virginia portion of the Area as meeting the requirements of CAA section 175A.

VII. Analysis of West Virginia's Transportation Conformity Insignificance Determination for the Huntington-Ashland Area

Under section 176(c) of the CAA, new transportation projects, such as the construction of new highways, must ''conform'' to (i.e., be consistent with) the part of the state's air quality plan that addresses pollution from mobile sources. ''Conformity'' to the SIP means that transportation activities will not cause new air quality violations, worsen existing violations, or delay timely attainment of a NAAQS or an interim milestone. This is typically determined by showing that estimated emissions from existing and planned highway and transit systems are less than or equal to the motor vehicle emissions budgets (MVEBs) contained in a SIP. If a transportation plan does not ''conform,'' most new projects that would expand the capacity of roadways cannot go forward. Regulations at 40 CFR part 93 set forth EPA policy, criteria, and procedures for demonstrating and ensuring conformity of such transportation activities to a SIP.

When reviewing submitted ''control strategy'' SIPs or maintenance plans containing MVEBs, EPA must affirmatively find the MVEBs contained therein ''adequate'' for use in determining transportation conformity. The process for determining adequacy is set forth in the guidance *''Transportation Conformity Rule Amendments for the New 8-hour Ozone and $PM_{2.5}$ National Ambient Air Quality Standards and Miscellaneous Revisions for Existing Areas; Transportation Conformity Rule Amendments; Response to Court Decision and Additional Rule Changes.''* 69 FR 40004 (July 1, 2004). After EPA affirmatively finds the submitted MVEBs are adequate for transportation conformity purposes, in accordance with the guidance, the MVEBs can be used by state and Federal agencies in determining whether proposed transportation projects ''conform'' to the SIP as required by section 176(c) of the CAA.

For budgets to be approvable, they must meet, at a minimum, EPA's adequacy criteria in 40 CFR 93.118(e)(4). However, the transportation conformity rule at 40 CFR 93.109(f) allows areas to forego establishment of MVEBs where it is demonstrated that the regional motor vehicle emissions for a particular pollutant or precursor are an insignificant contributor to the air quality problem in an area. EPA's rationale for providing for insignificance determinations may be found in the July 1, 2004 revision to the Transportation Conformity Rule. The general criteria for insignificance determinations, per 40 CFR 93.109(f), are based on a number of factors, including the percentage of motor vehicle emissions in the context of the total SIP inventory; the current state of air quality as determined by monitoring data for the relevant NAAQS; the absence of SIP motor vehicle control measures; and the historical trends and future projections of the growth of motor vehicle emissions in the area.

In West Virginia's June 30, 2011 submittal, the State provided information that projects that onroad mobile source NO_X constitutes six percent or less of the Area's total NO_X emissions in 2015 and 2022 due to continuing fleet turnover and that onroad mobile source $PM_{2.5}$ emissions constitute less than three percent of the Area's total $PM_{2.5}$ emissions. Both projections took into consideration future vehicle miles traveled (VMT) growth. In addition, neither EPA nor the State has made any findings that volatile organic compounds (VOCs), SO_2, or ammonia (NH_3) are significant contributors to $PM_{2.5}$ mobile emissions. The submittal meets the criteria in the relevant portions of 40 CFR 93.102 and 93.118 for an insignificance finding, and EPA agrees with the determination of insignificance for both NO_X and $PM_{2.5}$ for the West Virginia portion of the Area. For more information on EPA's review of the determination of insignificance, see the TSD dated May 30, 2012, available in the docket for this rulemaking action at *www.regulations.gov.*

VIII. Proposed Actions

EPA is proposing to approve the redesignation of the West Virginia portion of the Area from nonattainment to attainment for the 1997 annual $PM_{2.5}$ NAAQS. EPA has evaluated West Virginia's redesignation request and determined that, upon approval of the base year emissions inventory in the separate rulemaking action noted previously, it would meet the redesignation criteria set forth in section 107(d)(3)(E) of the CAA. EPA believes that the monitoring data demonstrate that the Huntington-Ashland Area has attained the 1997 annual $PM_{2.5}$ NAAQS and will continue to attain the standard. Final approval of this redesignation request would change the designation of the West Virginia portion of the Area from nonattainment to attainment for the 1997 annual $PM_{2.5}$ standard. EPA is also proposing to approve the associated

maintenance plan for the West Virginia portion of the Area, submitted on June 30, 2011, as a revision to the West Virginia SIP because it meets the requirements of CAA section 175A as described previously in this notice. EPA is also proposing to approve the insignificance determination for on-road motor vehicle contribution of $PM_{2.5}$, NO_X, and SO_2, submitted by West Virginia for the West Virginia portion of the Area in conjunction with its redesignation request. As noted previously, the 30 day public comment period for the proposed insignificance determination started on November 5, 2012 and will end on December 4, 2012. EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

IX. Statutory and Executive Order Reviews

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

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

In addition, this rule proposing approval of West Virginia's redesignation request, maintenance plan, and transportation conformity insignificance determination for the Huntington-Ashland Area for the 1997 annual $PM_{2.5}$ NAAQS 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

40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen oxides, $PM_{2.5}$, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

40 CFR Part 81

Air pollution control, National parks, Wilderness Areas.

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

Dated: November 7, 2012.

W.C. Early,

Acting Regional Administrator, Region III.

[FR Doc. 2012–27785 Filed 11–14–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R04–OAR–2012–0327; FRL–9751–9]

Approval and Promulgation of Implementation Plans and Designation of Areas for Air Quality Planning Purposes; South Carolina; Redesignation of the Charlotte-Gastonia-Rock Hill, North Carolina-South Carolina 1997 8-Hour Ozone Moderate Nonattainment Area to Attainment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: On June 1, 2011, the State of South Carolina, through the South Carolina Department of Health and Environmental Control (SC DHEC), submitted a request for EPA to redesignate the portion of York County, South Carolina that is within the bi-state Charlotte-Gastonia-Rock Hill, North Carolina-South Carolina 8-hour ozone nonattainment area (hereafter referred to as the ''bi-state Charlotte Area,'' or ''Area'') to attainment for the 1997 8-hour ozone national ambient air quality standards (NAAQS); and to approve a State Implementation Plan (SIP) revision containing a maintenance plan for the South Carolina portion of the bi-state Charlotte Area (hereafter referred to as ''the York County Area''). The bi-state Charlotte Area consists of Cabarrus, Gaston, Lincoln, Mecklenburg, Rowan, Union and a portion of Iredell County (Davidson and Coddle Creek Townships) in North Carolina; and a portion of York County in South Carolina (including the Catawba Indian Nation reservation lands). EPA is proposing to approve the redesignation request for the York County Area, along with the related SIP revision, including South Carolina's plan for maintaining attainment of the ozone standard in the York County Area. EPA is also proposing to approve the motor vehicle emission budgets (MVEB) for nitrogen oxides (NO_X) and volatile organic compounds (VOC) for the years 2013 and 2022 for the York County Area. Additionally, EPA is proposing that the 2022 MVEB are consistent with maintenance in 2023. These actions are being proposed pursuant to the Clean Air Act (CAA or Act) and its implementing regulations. EPA will take action on the North Carolina submission for the 1997 8-hour ozone redesignation request and maintenance plan for its portion of the bi-state Charlotte Area in a separate action.

DATES: Comments must be received on or before December 6, 2012.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2012–0327, by one of the following methods:

1. *www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *Email: R4-RDS@epa.gov.*
3. *Fax:* (404) 562–9019.
4. *Mail:* EPA–R04–OAR–2012–0327, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency,

Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960.

5. *Hand Delivery or Courier:* Ms. Lynorae Benjamin, Chief, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding federal holidays.

Instructions: Direct your comments to Docket ID No. EPA–R04–OAR–2012–0327. 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 through *www.regulations.gov* or email, information that you consider to be CBI or otherwise protected. 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.*

Docket: All documents in the electronic docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding federal holidays.

FOR FURTHER INFORMATION CONTACT: Jane Spann or Sara Waterson of the Regulatory Development Section, in the Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Ms. Spann may be reached by phone at (404) 562–9029, or via electronic mail at *spann.jane@epa.gov*. Ms. Waterson may be reached by phone at (404) 562–9061, or via electronic mail at *waterson.sara@epa.gov*.

SUPPLEMENTARY INFORMATION:

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I. What are the actions EPA is proposing to take?

EPA is proposing to take the following two separate but related actions, one of which involves multiple elements: (1) To redesignate the York County Area (including the Catawba Indian Nation reservation lands) to attainment for the 1997 8-hour ozone NAAQS and (2) to approve into the South Carolina SIP, under section 175A of the CAA, South Carolina's 1997 8-hour ozone NAAQS maintenance plan, including the associated MVEB. EPA is also notifying the public of the status of EPA's adequacy determination for the York County Area MVEB. These actions are summarized below and described in greater detail throughout this notice of proposed rulemaking.

First, EPA proposes to determine that the York County Area has met the requirements for redesignation under section 107(d)(3)(E) of the CAA. In this action, EPA is proposing to approve a request to change the legal designation of the portion of York County (including the Catawba Indian Nation reservation lands) in the bi-state Charlotte Area from nonattainment to attainment for the 1997 8-hour ozone NAAQS.

Second, EPA is proposing to approve South Carolina's 1997 8-hour ozone NAAQS maintenance plan for the York County Area as meeting the requirements of section 175A (such approval being one of the CAA criteria for redesignation to attainment status). The maintenance plan is designed to help keep the York County Area in attainment of the 1997 8-hour ozone NAAQS through 2022. As explained in Section V, EPA is also proposing to approve that attainment can be maintained through 2023. Consistent with the CAA, the maintenance plan that EPA is proposing to approve today also includes NO_X and VOC MVEB for the years 2013 and 2022 for the York County Area. EPA is proposing to approve (into the South Carolina SIP) the 2013 and 2022 MVEB that are included as part of South Carolina's maintenance plan for the 1997 8-hour ozone NAAQS. As explained in Sections V and VI, EPA is also proposing that the MVEB are consistent with maintenance through 2023.

EPA is also notifying the public of the status of EPA's adequacy process for the newly-established NO_X and VOC MVEB for 2013 and 2022 for the York County Area. The Adequacy comment period for the York County Area 2013 and 2022 MVEB began on October 28, 2011, with EPA's posting of the availability of this submittal on EPA's Adequacy Web site (*http://www.epa.gov/otaq/stateresources/transconf/currsips.htm*). The Adequacy comment period for these MVEB closed on November 28, 2011. No comments, adverse or otherwise, were received during EPA's adequacy process for the MVEB associated with South Carolina's 1997 8-hour ozone maintenance plan. Please see section VII of this proposed rulemaking for further explanation of this process and for more details on the MVEB.

Today's notice of proposed rulemaking is in response to South Carolina's June 1, 2011, SIP revision. That document addresses the specific issues summarized above and the necessary elements described in section 107(d)(3)(E) of the CAA for redesignation of the York County Area to attainment of the 1997 8-hour ozone NAAQS.

II. What is the background for EPA's proposed actions?

On July 18, 1997, EPA promulgated a revised 8-hour ozone NAAQS of 0.08 parts per million (ppm) (62 FR 38856, July 18, 1997). Under EPA's regulations at 40 CFR part 50, the 1997 8-hour ozone NAAQS is attained when the 3-year average of the annual fourth highest daily maximum 8-hour average ambient air quality ozone concentrations is less than or equal to 0.08 ppm (i.e., 0.084 ppm when rounding is considered). 69 FR 23857 (April 30, 2004). Ambient air quality monitoring data for the 3-year period must meet a data completeness requirement. The ambient air quality monitoring data completeness requirement is met when the average percent of days with valid ambient monitoring data is greater than 90 percent, and no single year has less than 75 percent data completeness as determined in Appendix I of part 50.

Upon promulgation of a new or revised NAAQS, the CAA requires EPA to designate as nonattainment any area that is violating the NAAQS, based on the three most recent years of ambient air quality data at the conclusion of the designation process. The bi-state Charlotte Area was designated nonattainment for the 1997 8-hour ozone NAAQS on April 30, 2004 (effective June 15, 2004) using 2001–2003 ambient air quality data (69 FR 23857, April 30, 2004). At the time of designation the bi-state Charlotte Area was classified as a moderate nonattainment area for the 1997 8-hour ozone NAAQS. In the April 30, 2004, Phase I Ozone Implementation Rule, EPA established ozone nonattainment area attainment dates based on Table 1 of section 181(a) of the CAA. This established an attainment date six years after the June 15, 2004, effective date for areas classified as moderate areas for the 1997 8-hour ozone nonattainment designations. Section 181 of the CAA explains that the attainment date for moderate nonattainment areas shall be as expeditiously as practicable, but no later than six years after designation, or June 15, 2010. Therefore, the bi-state Charlotte Area's original attainment date was June 15, 2010. *See* 69 FR 23951, April 30, 2004.

On April 29, 2010,[1] South Carolina submitted an attainment demonstration and associated reasonably available control measures (RACM), a reasonable further progress (RFP) plan, contingency measures, emissions statement, a 2002 base year emissions inventory and other planning SIP revisions related to attainment of the 1997 8-hour ozone NAAQS in the York County Area.

The bi-state Charlotte Area did not attain the 1997 8-hour ozone NAAQS by June 15, 2010 (the applicable attainment date for moderate nonattainment areas); however, the Area qualified for an extension of the attainment date. Under certain circumstances, the CAA allows for extensions of the attainment dates prescribed at the time of the original nonattainment designation. In accordance with CAA section 181(a)(5), EPA may grant up to 2 one-year extensions of the attainment date under specified conditions. On May 31, 2011, EPA determined that the Area met the CAA requirements to obtain a one-year extension of the attainment date for the 1997 8-hour ozone NAAQS. *See* 76 FR 31245. As a result, EPA extended the bi-state Charlotte Area's attainment date from June 15, 2010, to June 15, 2011, for the 1997 8-hour ozone NAAQS.

On June 1, 2011, South Carolina requested redesignation of the York County Area to attainment for the 1997 8-hour ozone NAAQS. The redesignation request included three years of complete, quality-assured ambient air quality data for the 1997 8-hour ozone NAAQS for 2008–2010, indicating that the 1997 8-hour ozone NAAQS had been achieved for the bi-state Charlotte Area. Under the CAA, nonattainment areas may be redesignated to attainment if sufficient, complete, quality-assured data is available for the Administrator to determine that the area has attained the standard and the area meets the other CAA redesignation requirements in section 107(d)(3)(E).

Subsequently, on March 7, 2012 (77 FR 13493), EPA determined that the bi-state Charlotte Area attained the 1997 8-hour ozone NAAQS by its applicable attainment date. The determination of attaining data was based upon complete, quality-assured and certified ambient air monitoring data for the 2008–2010 period, showing that the Area had monitored attainment of the 1997 8-hour ozone NAAQS. The requirements for the Area to submit an attainment demonstration and associated RACM, RFP plan, contingency measures, and other planning SIP revisions related to attainment of the standard were suspended as a result of the determination of attainment, so long as the Area continues to attain the 1997 8-hour ozone NAAQS. *See* 40 CFR 52.2125(a). The Area continues to attain the standard with 2009–2011 data.

On January 12, 2012, South Carolina withdrew the York County portion of the Area's attainment demonstration (except RFP, emissions statements, and the emissions inventory) as allowed by 40 CFR 51.918. EPA approved the baseline emissions inventory portion of the attainment demonstration SIP revision on May 18, 2012 (77 FR 29540). Additionally, EPA approved the emissions statements portion of the attainment demonstration SIP revision on June 25, 2012 (77 FR 37812). No comments were received on either action. EPA is considering action on South Carolina's RFP plan in a separate action; however, as mentioned previously, the determination of attainment suspended South Carolina's obligation to meet this requirement for the 1997 8-hour ozone NAAQS.

III. What are the criteria for redesignation?

The CAA provides the requirements for redesignating a nonattainment area to attainment. Specifically, section 107(d)(3)(E) of the CAA allows for redesignation providing that: (1) The Administrator determines that the area has attained the applicable NAAQS; (2) the Administrator has fully approved the applicable implementation plan for the area under section 110(k); (3) the Administrator determines that the improvement in air quality is due to permanent and enforceable reductions in emissions resulting from implementation of the applicable SIP and applicable federal air pollutant control regulations and other permanent and enforceable reductions; (4) the Administrator has fully approved a maintenance plan for the area as meeting the requirements of section 175A; and, (5) the state containing such area has met all requirements applicable to the area for purposes of redesignation under section 110 and part D of the CAA.

On April 16, 1992, EPA provided guidance on redesignation in the General Preamble for the

[1] South Carolina withdrew an August 31, 2007, attainment demonstration SIP for its portion of the Charlotte-Gastonia-Rock Hill 1997 8-hour ozone area on December 22, 2008. EPA issued a finding of failure to submit for the attainment demonstration for the Charlotte NC–SC Area on May 8, 2009. *See* 74 FR 21550. On April 29, 2010, South Carolina resubmitted the attainment demonstration SIP with an updated supplement for the South Carolina portion of the Charlotte-Gastonia-Rock Hill 1997 8-hour ozone area.

Implementation of title I of the CAA Amendments of 1990 (57 FR 13498), and supplemented this guidance on April 28, 1992 (57 FR 18070). EPA has provided further guidance on processing redesignation requests in the following documents:

1. ''Ozone and Carbon Monoxide Design Value Calculations,'' Memorandum from Bill Laxton, Director, Technical Support Division, June 18, 1990;
2. ''Maintenance Plans for Redesignation of Ozone and Carbon Monoxide Nonattainment Areas,'' Memorandum from G. T. Helms, Chief, Ozone/Carbon Monoxide Programs Branch, April 30, 1992;
3. ''Contingency Measures for Ozone and Carbon Monoxide (CO) Redesignations,'' Memorandum from G. T. Helms, Chief, Ozone/Carbon Monoxide Programs Branch, June 1, 1992;
4. ''Procedures for Processing Requests to Redesignate Areas to Attainment,'' Memorandum from John Calcagni, Director, Air Quality Management Division, September 4, 1992 (hereafter referred to as the ''Calcagni Memorandum'');
5. ''State Implementation Plan (SIP) Actions Submitted in Response to Clean Air Act (CAA) Deadlines,'' Memorandum from John Calcagni, Director, Air Quality Management Division, October 28, 1992;
6. ''Technical Support Documents (TSDs) for Redesignation of Ozone and Carbon Monoxide (CO) Nonattainment Areas,'' Memorandum from G. T. Helms, Chief, Ozone/Carbon Monoxide Programs Branch, August 17, 1993;
7. ''State Implementation Plan (SIP) Requirements for Areas Submitting Requests for Redesignation to Attainment of the Ozone and Carbon Monoxide (CO) National Ambient Air Quality Standards (NAAQS) On or After November 15, 1992,'' Memorandum from Michael H. Shapiro, Acting Assistant Administrator for Air and Radiation, September 17, 1993;
8. ''Use of Actual Emissions in Maintenance Demonstrations for Ozone and CO Nonattainment Areas,'' Memorandum from D. Kent Berry, Acting Director, Air Quality Management Division, November 30, 1993;
9. ''Part D New Source Review (Part D NSR) Requirements for Areas Requesting Redesignation to Attainment,'' Memorandum from Mary D. Nichols, Assistant Administrator for Air and Radiation, October 14, 1994; and
10. ''Reasonable Further Progress, Attainment Demonstration, and Related Requirements for Ozone Nonattainment Areas Meeting the Ozone National Ambient Air Quality Standard,'' Memorandum from John S. Seitz, Director, Office of Air Quality Planning and Standards, May 10, 1995.

IV. Why is EPA proposing these actions?

On June 1, 2011, the State of South Carolina, through SC DHEC, requested the redesignation of the York County Area to attainment for the 1997 8-hour ozone NAAQS. EPA's evaluation indicates that the entire bi-state Charlotte Area (including the York County Area as part of the bi-State Charlotte Area) has attained the 1997 8-hour ozone NAAQS, and that the York County Area meets the requirements for redesignation set forth in section 107(d)(3)(E), including the maintenance plan requirements under section 175A of the CAA. As a result, EPA is proposing to take the two related actions summarized in section I of this notice.

V. What is EPA's analysis of the request?

As stated above, in accordance with the CAA, EPA proposes in today's action to: (1) Redesignate the York County Area (including the Catawba Indian Nation reservation lands) to attainment for the 1997 8-hour ozone NAAQS; and (2) approve the York County Area's 1997 8-hour ozone NAAQS maintenance plan, including the associated MVEB, into the South Carolina SIP. These actions are based upon EPA's preliminary determinations that the bi-state Charlotte Area (including the York County Area as part of the bi-State Charlotte Area) continues to attain the 1997 8-hour ozone NAAQS, and EPA's preliminary determination that South Carolina has met all other redesignation criteria for the York County Area. The five redesignation criteria provided under CAA section 107(d)(3)(E) are discussed in greater detail for the York County Area in the following paragraphs of this section.

Criteria (1)—The Bi-State Charlotte Area (Including the York County Area as Part of the Bi-State Charlotte Area) Has Attained the 1997 8-Hour Ozone NAAQS

For ozone, an area may be considered to be attaining the 1997 8-hour ozone NAAQS if it meets the 1997 8-hour ozone NAAQS, as determined in accordance with 40 CFR 50.10 and Appendix I of part 50, based on three complete, consecutive calendar years of quality-assured air quality monitoring data. To attain these NAAQS, the 3-year average of the fourth-highest daily maximum 8-hour average ozone concentrations measured at each monitor within an area over each year must not exceed 0.08 ppm. Based on the data handling and reporting convention described in 40 CFR part 50, Appendix I, the NAAQS are attained if the design value is 0.084 ppm or below. The data must be collected and quality-assured in accordance with 40 CFR part 58, and recorded in the EPA Air Quality System (AQS). The monitors generally should have remained at the same location for the duration of the monitoring period required for demonstrating attainment.

On November 15, 2011, at 76 FR 70656, EPA determined that the bi-state Charlotte Area was attaining the 1997 8-hour ozone NAAQS. For that action EPA reviewed ozone monitoring data from monitoring stations in the bi-state Charlotte Area for the 1997 8-hour ozone NAAQS for 2008–2010. These data have been quality-assured and are recorded in AQS. EPA has reviewed the 2009–2011 data, which indicate that the Area continues to attain the 1997 8-hour ozone NAAQS beyond the submitted 3-year attainment period of 2008–2010. The fourth-highest 8-hour ozone average for 2008, 2009 and 2010, and the 3-year average of these values (i.e., design values), are summarized in the following Table 1 of this proposed rulemaking.

TABLE 1—DESIGN VALUE CONCENTRATIONS FOR THE BI-STATE CHARLOTTE 1997 8-HOUR OZONE AREA

Location	County	Monitor ID	Annual arithmetic mean concentrations (ppm)				3-Year design values (ppm)	
			2008	2009	2010	2011	2008–2010	2009–2011
Lincoln County Replacing Iron Station.	Lincoln	37–109–0004	0.079	0.065	0.072	0.077	0.072	0.071

TABLE 1—DESIGN VALUE CONCENTRATIONS FOR THE BI-STATE CHARLOTTE 1997 8-HOUR OZONE AREA—Continued

Location	County	Monitor ID	Annual arithmetic mean concentrations (ppm)				3-Year design values (ppm)	
			2008	2009	2010	2011	2008–2010	2009–2011
Garinger High School.	Mecklenburg	37–119–0041	0.085	0.069	0.082	0.088	0.078	0.079
Westinghouse Blvd.	Mecklenburg	37–119–1005	0.073	0.068	0.078	0.082	0.073	0.076
29 N at Mecklenburg Cab Co.	Mecklenburg	37–119–1009	0.093	0.071	0.082	0.083	0.082	0.078
Rockwell	Rowan	37–159–0021	0.084	0.071	0.077	0.077	0.077	0.075
Enochville School	Rowan	37–159–0022	0.082	0.073	0.078	0.078	0.077	0.076
Monroe Middle School.	Union	37–179–0003	0.08	0.067	0.071	0.073	0.072	0.070

* An ozone monitor is located in York County, South Carolina; however, it is outside of the nonattainment area. This monitor is monitoring attainment of the 1997 8-hour ozone NAAQS.

The 3-year design value for 2008–2010 submitted by South Carolina for redesignation of the bi-state Charlotte Area is 0.082 ppm, which meets the NAAQS as described above. As mentioned above, on November 15, 2011 (76 FR 70656), EPA published a clean data determination for the bi-state Charlotte Area for the 1997 8-hour ozone NAAQS. The 2009–2011 certified data show that the bi-state Charlotte Area continues to attain the 1997 8-hour ozone NAAQS with a design value of 0.079 ppm at the Garinger High School monitor. In today's action, EPA is proposing to determine that the Area is attaining the 1997 8-hour ozone NAAQS. EPA will not go forward with the redesignation if the Area does not continue to attain until the time that EPA finalizes the redesignation. As discussed in more detail below, the State of South Carolina has committed to continue monitoring in this Area in accordance with 40 CFR part 58.

Criteria (2)—South Carolina Has a Fully Approved SIP Under Section 110(k) for the York County Area; and Criteria (5)—South Carolina Has Met All Applicable Requirements Under Section 110 and Part D of Title I of the CAA

For redesignating a nonattainment area to attainment, the CAA requires EPA to determine that the state has met all applicable requirements under section 110 and part D of title I of the CAA (CAA section 107(d)(3)(E)(v)) and that the state has a fully approved SIP under section 110(k) for the area (CAA section 107(d)(3)(E)(ii)). EPA proposes to find that South Carolina has met all applicable SIP requirements for the York County Area under section 110 of the CAA (general SIP requirements) for purposes of redesignation. Additionally, EPA proposes to find that the South Carolina SIP satisfies the criterion that it meets applicable SIP requirements for purposes of redesignation under part D of title I of the CAA (requirements specific to 1997 8-hour ozone nonattainment areas) in accordance with section 107(d)(3)(E)(v). Further, EPA proposes to determine that the SIP is fully approved with respect to all requirements applicable for purposes of redesignation in accordance with section 107(d)(3)(E)(ii). In making these proposed determinations, EPA ascertained which requirements are applicable to the Area and, if applicable, that they are fully approved under section 110(k). SIPs must be fully approved only with respect to requirements that were applicable prior to submittal of the complete redesignation request.

a. The York County Area Has Met All Applicable Requirements Under Section 110 and Part D of the CAA

General SIP requirements. Section 110(a)(2) of title I of the CAA delineates the general requirements for a SIP, which include enforceable emissions limitations and other control measures, means, or techniques; provisions for the establishment and operation of appropriate devices necessary to collect data on ambient air quality; and programs to enforce the limitations. General SIP elements and requirements are delineated in section 110(a)(2) of title I, part A of the CAA. These requirements include, but are not limited to, the following: submittal of a SIP that has been adopted by the state after reasonable public notice and hearing; provisions for establishment and operation of appropriate procedures needed to monitor ambient air quality; implementation of a source permit program; provisions for the implementation of part C requirements (Prevention of Significant Deterioration (PSD)) and provisions for the implementation of part D requirements (New Source Review (NSR) permit programs); provisions for air pollution modeling; and provisions for public and local agency participation in planning and emission control rule development.

Section 110(a)(2)(D) requires that SIPs contain certain measures to prevent sources in a state from significantly contributing to air quality problems in another state. To implement this provision, EPA has required certain states to establish programs to address the interstate transport of air pollutants (e.g., NO_X SIP Call [2] and the Clean Air Interstate Rule (CAIR) [3]). The section 110(a)(2)(D) requirements for a state are not linked with a particular nonattainment area's designation and classification in that state. EPA believes that the requirements linked with a

[2] On October 27, 1998 (63 FR 57356), EPA issued a NO_X SIP Call requiring the District of Columbia and 22 states to reduce emissions of NO_X in order to reduce the transport of ozone and ozone precursors. In compliance with EPA's NO_X SIP Call, South Carolina developed rules governing the control of NO_X emissions from electric generating units (EGU), major non-EGU industrial boilers, major cement kilns, and internal combustion engines. On June 28, 2002, EPA approved South Carolina's rules as fulfilling Phase I of the NO_X SIP Call (67 FR 43546).

[3] On May 12, 2005 (70 FR 25162), EPA promulgated CAIR, which required 28 upwind States and the District of Columbia to revise their SIPs to include control measures that would reduce emissions of SO_2 and NO_X. Various aspects of CAIR rule were petitioned in court and on December 23, 2008, the U.S. Court of Appeals for the District of Columbia Circuit remanded CAIR to EPA (*see North Carolina* v. *EPA,* 550 F.3d 1176 (DC Circuit, December 23, 2008)), which left CAIR in place to ''temporarily preserve the environmental values covered by CAIR'' until EPA replaces it with a rule consistent with the Court's ruling. In response to the court's decision, EPA issued a new rule to address interstate transport of NO_X and SO_2 in the eastern United States (i.e., the Transport Rule, also known as the Cross-State Air Pollution Rule). *See* 76 FR 48208, August 8, 2011. In a ruling on August 21, 2012, the court vacated the Transport Rule and reiterated its expectation for EPA to continue to administer CAIR until a replacement rule is in place. Therefore, CAIR is currently in effect in South Carolina.

particular nonattainment area's designation and classifications are the relevant measures to evaluate in reviewing a redesignation request. The transport SIP submittal requirements, where applicable, continue to apply to a state regardless of the designation of any one particular area in the state. Thus, EPA does not believe that the CAA's interstate transport requirements should be construed to be applicable requirements for purposes of redesignation. However, as discussed later in this notice, addressing pollutant transport from other states is an important part of an area's maintenance demonstration.

In addition, EPA believes other section 110 elements that are neither connected with nonattainment plan submissions nor linked with an area's attainment status are applicable requirements for purposes of redesignation. The area will still be subject to these requirements after the area is redesignated. The section 110 and part D requirements which are linked with a particular area's designation and classification are the relevant measures to evaluate in reviewing a redesignation request. This approach is consistent with EPA's existing policy on applicability (i.e., for redesignations) of conformity and oxygenated fuels requirements, as well as with section 184 ozone transport requirements. *See* Reading, Pennsylvania, proposed and final rulemakings (61 FR 53174–53176, October 10, 1996), (62 FR 24826, May 7, 1997); Cleveland-Akron-Loraine, Ohio, final rulemaking (61 FR 20458, May 7, 1996); and Tampa, Florida, final rulemaking at (60 FR 62748, December 7, 1995). *See also* the discussion on this issue in the Cincinnati, Ohio, redesignation (65 FR 37890, June 19, 2000), and in the Pittsburgh, Pennsylvania, redesignation (66 FR 50399, October 19, 2001).

EPA completed rulemaking on a submittal from South Carolina dated December 13, 2007, addressing ''infrastructure SIP'' elements required for the 1997 8-hour ozone NAAQS under CAA section 110(a)(2) on July 13, 2011. *See* 76 FR 41111. However, these are statewide requirements that are not a consequence of the nonattainment status of the York County Area. As stated above, EPA believes that section 110 elements not linked to an area's nonattainment status are not applicable for purposes of redesignation. Therefore, EPA believes it has approved all SIP elements under section 110 that must be approved as a prerequisite for redesignating the York County Area to attainment.

Title I, Part D, subpart 1 applicable SIP requirements. Subpart 1 of part D, found in sections 172(c)(1) through (9) and in section 176 of the CAA, sets forth the basic nonattainment requirements applicable to all nonattainment areas. A thorough discussion of the requirements contained in section 172 can be found in the General Preamble for Implementation of title I (57 FR 13498, April 16, 1992). Subpart 2 of part D, which includes section 182 of the CAA, establishes additional specific requirements depending on the area's ozone nonattainment classification. A thorough discussion of the requirements contained in section 182 can be found in the General Preamble for Implementation of Title I (57 FR 13498).

Part D Subpart 1 Section 172 Requirements and Part D, Subpart 2 Section 182 Requirements. Section 172(c)(1) requires the plans for all nonattainment areas to provide for the implementation of all RACM as expeditiously as practicable and to provide for attainment of the national primary ambient air quality standards. EPA interprets this requirement to impose a duty on all nonattainment areas to consider all available control measures and to adopt and implement such measures as are reasonably available for implementation in each area as components of the area's attainment demonstration. Under section 172, states with nonattainment areas must submit plans providing for timely attainment and meeting a variety of other requirements. Section 182 of the CAA, found in subpart 2 of part D, establishes additional specific requirements depending on the area's ozone nonattainment classification. For purposes of evaluating this redesignation request, the applicable part D, subpart 2 SIP requirements for all moderate nonattainment areas are contained in sections 182(b)(1)–(5). However, pursuant to 40 CFR 51.918, EPA's November 15, 2011, determination that the Area was attaining the 8-hour ozone NAAQS suspended South Carolina's obligation to submit most of the attainment planning requirements that would otherwise apply. Specifically, the determination of attainment suspended South Carolina's obligation to submit an attainment demonstration and planning SIPs to provide for RFP, RACM, and contingency measures under sections 172(c)(9) and 182(b)(1) of the CAA.

The General Preamble for Implementation of Title I (57 FR 13498, April 16, 1992) also discusses the evaluation of these requirements in the context of EPA's consideration of a redesignation request. The General Preamble sets forth EPA's view of applicable requirements for purposes of evaluating redesignation requests when an area is attaining a standard (General Preamble for Implementation of Title I (57 FR 13498, April 16, 1992)).

Because attainment has been reached in the bi-state Charlotte Area, no additional measures are needed to provide for attainment for the 1997 8-hour ozone NAAQS,[4] and section 172(c)(1) requirements for an attainment demonstration and RACM are no longer considered to be applicable for purposes of redesignation as long as the Area continues to attain the 1997 8-hour ozone NAAQS until redesignation. See also 40 CFR 51.918.

The RFP plan requirements under sections 172(c)(2) and 182(b)(1) are defined as progress that must be made toward attainment for the 1997 8-hour ozone NAAQS. These requirements are not relevant for purposes of redesignation because EPA has determined that the entire bi-state Charlotte Area has monitored attainment of the 1997 8-hour ozone NAAQS. *See* General Preamble, 57 FR 13564. *See* also 40 CFR 51.1004 (c). While it is not a requirement for redesignation, EPA is considering taking action on South Carolina's RFP plan for the 1997 8-hour ozone NAAQS separate from today's proposed action.

Section 172(c)(3) and section 182(b) requires submission and approval of a comprehensive, accurate, and current inventory of actual emissions. Section 182(b) references section 182(a) of the CAA which requires, in part, for states to submit a current inventory of actual emissions (182(a)(1)). As part of South Carolina's attainment demonstration for the York County Area, South Carolina submitted a 2002 base year emissions inventory. EPA approved the 2002 base year inventory on May 18, 2012, as meeting the section 172(c)(3) and section 182(a)(1) emissions inventory requirement. *See* 77 FR 29540.

Section 172(c)(4) requires the identification and quantification of emissions for major new and modified stationary sources to be allowed in an area, and section 172(c)(5) and section 182(b) require source permits for the construction and operation of new and modified major stationary sources anywhere in the nonattainment area.

[4] Effective July 20, 2012, EPA designated a portion of York County (excluding the Catawba Indian Nation reservation lands) as nonattainment for the 2008 8-hour ozone NAAQS. This rulemaking does not address requirements for the portion of York County that was designated nonattainment for the 2008 8-hour ozone NAAQS. Requirements for the portion of York County that was designated nonattainment for the 2008 8-hour ozone NAAQS will be addressed in the future.

EPA has determined that, since PSD requirements will apply after redesignation, areas being redesignated need not comply with the requirement that a NSR program be approved prior to redesignation, provided that the area demonstrates maintenance of the NAAQS without part D NSR. A more detailed rationale for this view is described in a memorandum from Mary Nichols, Assistant Administrator for Air and Radiation, dated October 14, 1994, entitled, ''Part D New Source Review Requirements for Areas Requesting Redesignation to Attainment.'' South Carolina has demonstrated that the York County Area will be able to maintain the NAAQS without part D NSR in effect, and therefore South Carolina need not have fully approved part D NSR programs prior to approval of the redesignation request. Nonetheless, South Carolina currently has a fully-approved part D NSR program in place. South Carolina's PSD program will become applicable in the York County Area upon redesignation to attainment. Section 172(c)(6) requires the SIP to contain control measures necessary to provide for attainment of the NAAQS. Because attainment has been reached, no additional measures are needed to provide for attainment.

Section 172(c)(7) requires the SIP to meet the applicable provisions of section 110(a)(2). As noted above, EPA believes the South Carolina SIP meets the requirements of section 110(a)(2) applicable for purposes of redesignation.

Section 182(b) references, in part, section 182(a)(3), which requires states to submit periodic inventories and emissions statements. Section 182(a)(3)(A) of the CAA requires states to submit a periodic inventory every 3 years. The periodic emissions inventory is discussed in more detail in Criteria (4)(e), *Verification of Continued Attainment.*

Section 182(a)(3)(B) of the CAA requires states with areas designated nonattainment for the ozone NAAQS to submit a SIP revision to require emissions statements to be submitted to the state by sources within that nonattainment area. EPA approved South Carolina's emissions statements requirement, which is part of the attainment plan submittal, on June 25, 2012. *See* 77 FR 37812. EPA believes the South Carolina SIP meets the requirements of section 182(a)(3)(B) applicable for purposes of redesignation.

Section 182(b)(2) of the CAA requires states with areas designated nonattainment for the ozone NAAQS to submit a SIP revision to require reasonably available control technology (RACT) for all major VOC and NO_X sources and for each category of VOC sources in the Area covered by a Control Techniques Guidelines (CTG) document.

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

South Carolina did a RACT analysis for major VOC and NO_X sources in the York County Area and determined that these sources met RACT. EPA approved South Carolina's RACT submittal on November 28, 2011. *See* 76 FR 72844. SC DHEC provided certifications to this effect to EPA within the original August 31, 2007, attainment demonstration and on February 23, 2009, for Group III, and on July, 9, 2009, for Group IV. On November 28, 2011, EPA approved South Carolina's SIP revisions in support of the negative declarations for Groups I, II, III and IV CTG, and concluded that the York County Area has met all the statutory and regulatory requirements for making a negative declaration regarding Groups I, II, III and IV CTG. *See* 76 FR 72844. EPA believes the South Carolina SIP meets the requirements of section 182(b)(2) applicable for purposes of redesignation.

Originally, the section 182(b)(3) Stage II requirement also applied in all moderate ozone nonattainment areas. However, under section 202(a)(6) of the CAA, 42 U.S.C. 7521(a)(6), the requirements of section 182(b)(3) no longer apply in moderate ozone nonattainment areas after EPA promulgated the onboard refueling vapor recovery standards on April 6, 1994, 59 FR 16262, codified at 40 CFR parts 86 (including 86.098–8), 88 and 600. Under implementation rules issued in 2002 for the 1997 8-hour ozone NAAQS, EPA retained the Stage II-related requirements under section 182(b)(3) as they applied for the now-revoked 1-hour ozone NAAQS. *See* 40 CFR 51.900(f)(5) and 40 CFR 51.916(a). Therefore, the York County Area is not subject to the Stage 2 vapor recovery program requirements.

Section 182(b)(4) of the CAA requires states with areas designated nonattainment for the ozone NAAQS to submit SIPs requiring inspection and maintenance of vehicles (I/M). Even though a portion of York County was designated as part of the moderate bi-state Charlotte Area for the 1997 8-hour ozone NAAQS, applicability of the I/M regulations to areas outside the Ozone Transport Region is based on the population of the urbanized area as defined by the 1990 census. As defined by the 1990 census, York County and Charlotte urbanized areas were distinct and were not contiguous. Although the Charlotte urbanized portion of the metropolitan statistical area is contiguous to the North Carolina/South Carolina border, it did not extend into South Carolina. In 1990, the York County urbanized area was totally contained within South Carolina and did not touch the State line. Therefore, the applicability level of a 1990 census population of 200,000 or more in an urbanized area (40 CFR 51.350(a)(1)) applies to each of the two urbanized areas separately. Since the York County urbanized area had a population less than 200,000, the I/M requirement in section 182(b)(4) of the CAA is not applicable to the York County Area. EPA believes the South Carolina SIP meets the requirements of section 182(b)(3) and 182(b)(4) applicable for purposes of redesignation.

Section 182(b)(5) of the CAA requires that for purposes of satisfying the general emission offset requirement, the ratio of total emission reductions to total increase emissions shall be at least 1.15 to 1. South Carolina currently requires these offsets. EPA believes the South Carolina SIP meets the requirements of section 182(b)(5) applicable for purposes of redesignation.

Section 176 Conformity Requirements. Section 176(c) of the CAA requires states to establish criteria and procedures to ensure that federally supported or funded projects conform to the air quality planning goals in the applicable SIP. The requirement to determine conformity applies to transportation plans, programs and projects that are developed, funded or approved under title 23 of the United States Code (U.S.C.) and the Federal Transit Act (transportation conformity) as well as to all other federally supported or funded projects (general conformity). State transportation conformity SIP revisions must be consistent with federal conformity regulations relating to consultation, enforcement and enforceability that EPA promulgated pursuant to its authority under the CAA.

EPA interprets the conformity SIP requirements [5] as not applying for purposes of evaluating a redesignation request under section 107(d) because state conformity rules are still required after redesignation and federal conformity rules apply where state rules have not been approved. *See Wall* v. *EPA,* 265 F.3d 426 (6th Cir. 2001) (upholding this interpretation); *see also* 60 FR 62748 (December 7, 1995) (redesignation of Tampa, Florida). Nonetheless, South Carolina has an approved conformity SIP for the York County Area. *See* 74 FR 37168, July 28, 2009. Thus, the York County Area has satisfied all applicable requirements for purposes of redesignation under section 110 and part D of title I of the CAA.

b. The York County Area Has a Fully Approved Applicable SIP Under Section 110(k) of the CAA

EPA has fully approved the applicable South Carolina SIP for the York County Area under section 110(k) of the CAA for all requirements applicable for purposes of redesignation. EPA may rely on prior SIP approvals in approving a redesignation request (*see* Calcagni Memorandum at p. 3; *Southwestern Pennsylvania Growth Alliance* v. *Browner,* 144 F.3d 984, 989–90 (6th Cir. 1998); *Wall,* 265 F.3d 426) plus any additional measures it may approve in conjunction with a redesignation action (*see* 68 FR 25426 (May 12, 2003) and citations therein). Following passage of the CAA of 1970, South Carolina has adopted and submitted, and EPA has fully approved at various times, provisions addressing the various 1997 8-hour ozone NAAQS SIP elements applicable in the York County Area (May 31, 1972, 37 FR 10842; 110(a)(1) and (2) for 1997 8-hour ozone NAAQS, July 13, 2011, 76 FR 41111; RACT, November 16, 2011, 76 FR 72884; emissions inventory, May 18, 2012, 77 FR 29540; emissions statement, June 25, 2012, 77 FR 37812).

As indicated above, EPA believes that the section 110 elements that are neither connected with nonattainment plan submissions nor linked to an area's nonattainment status are not applicable requirements for purposes of redesignation. EPA has approved all part D subpart 1 requirements applicable for purposes of this redesignation.

[5] CAA section 176(c)(4)(E) requires states to submit revisions to their SIPs to reflect certain Federal criteria and procedures for determining transportation conformity. Transportation conformity SIPs are different from the MVEBs that are established in control strategy SIPs and maintenance plans.

Criteria (3)—The Air Quality Improvement in the Bi-State Charlotte 1997 8-Hour Ozone NAAQS Nonattainment Area Is Due to Permanent and Enforceable Reductions in Emissions Resulting From Implementation of the SIP and Applicable Federal Air Pollution Control Regulations and Other Permanent and Enforceable Reductions

For redesignating a nonattainment area to attainment, the CAA requires EPA to determine that the air quality improvement in the area is due to permanent and enforceable reductions in emissions resulting from implementation of the SIP and applicable federal air pollution control regulations and other permanent and enforceable reductions (CAA section 107(d)(3)(E)(iii)). EPA has preliminarily determined that South Carolina has demonstrated that the observed air quality improvement in its portion of the bi-state Charlotte Area is due to permanent and enforceable reductions in emissions resulting from implementation of the SIP, federal measures, and other state adopted measures. EPA does not have any information to suggest that the decrease in ozone concentrations in the York County Area is due to unusually favorable meteorological conditions.

State, local and federal measures enacted in recent years have resulted in permanent emission reductions. Most of these emission reductions are enforceable through regulations. A few non-regulatory measures also result in emission reductions.

The state and local measures, some of which implement federal requirements, that have been implemented to date and relied upon by South Carolina to demonstrate attainment and/or maintenance include: NSR regulations, NO_X regulations, VOC regulations, emissions inventory, emissions statements, and RACT.

The Celanese Acetate Celriver Plant closed in 2006. This plant, which included six coal-fired boilers, the largest of which was rated at 320 million metric British thermal units per hour, was the largest stationary source of NO_X in the York County Area. As a result, South Carolina retired 2,493 tons of NO_X and 1,686 tons of VOC.

Additionally, South Carolina identified other areas of potential reductions. North Carolina has implemented measures in the North Carolina portion of the bi-state Charlotte Area, such as North Carolina's Clean Smokestacks Act (CSA), which helps to improve air quality in the Area. EPA approved the CSA into the North Carolina SIP on September 26, 2011. *See* 76 FR 59250. Closures of certain facilities have resulted in continued reductions of local NO_X and VOC emissions in the bi-state Charlotte Area.

The federal measures that have been implemented include the following:

Tier 2 vehicle standards. Implementation began in 2004 and will require all passenger vehicles in any manufacturer's fleet to meet an average standard of 0.07 grams of NO_X per mile. The Tier 2 rule also reduced the sulfur content of gasoline to 30 ppm starting in January of 2006.

Large Non-road Diesel Engines rule. EPA issued this rule in June 2004 (69 FR 38958), which applies to diesel engines used in industries, such as construction, agriculture, and mining. It is estimated that compliance with this rule will cut NO_X emissions from non-road diesel engines by up to 90 percent nationwide. The non-road diesel rule was fully implemented by 2010.

Control Technique Guidelines. South Carolina listed CTGs under federal measures implemented in the York County Area. See criteria 2(a) of section V of this action for more information.

Heavy-duty gasoline and diesel highway vehicle standards. EPA issued this rule in January 2001 (66 FR 5002). This rule includes standards limiting the sulfur content of diesel fuel, which went into effect in 2004. A second phase took effect in 2007, which further reduced the highway diesel fuel sulfur content to 15 ppm, leading to additional reductions in combustion NO_X and VOC emissions. This rule is expected to achieve a 95 percent reduction in NO_X emissions from diesel trucks and buses.

Nonroad spark-ignition engines and recreational engines standards. This rule was effective in 2003 and will reduce NO_X and hydrocarbon emissions.

NO_X SIP Call. The NO_X SIP Call created the NO_X Budget Trading Program designed to reduce the amount of ozone that crosses state lines. By the end of 2008, ozone season emissions dropped by 62 percent from 2000 at all sources subject to the NO_X SIP Call (EPA, NO_X Budget Trading Program: 2008 Highlights, October 2009, page 3, available at *http://www.epa.gov/airmarkets/progress/NBP_4/NBP_2008_Highlights.pdf).* It follows that the bi-state Charlotte nonattainment area (including the York County Area) benefited from these overall reductions, since it is part of the larger NO_X SIP Call area. The NO_X Budget Trading Program also reduced local emissions. The one source subject to the NO_X SIP Call in the York County Area, AbitibiBowater Inc.—Catawba Operations, reduced

ozone season NO_X emissions from 36 tons in 2003, the first year of the NO_X Budget Trading Program, to 14 tons in 2008, the final year of the NO_X Budget Trading Program.

EPA has considered the relationship of the York County Area's maintenance plan to the reductions currently required pursuant to CAIR. Although CAIR was remanded to EPA, the remand of CAIR does not alter the requirements of the NO_X SIP Call and the State has now demonstrated that the bi-state Charlotte Area can maintain without any additional requirements (beyond those required by the NO_X SIP Call). Therefore, EPA has made the preliminary determination that the State's demonstration of maintenance under sections 175A and 107(d)(3)(E) remains valid based on reductions from the NO_X SIP Call.

The NO_X SIP Call required states to make emissions reductions. It also provided a mechanism, the NO_X Budget Trading Program, that states could use to achieve those reductions. When EPA promulgated CAIR, it discontinued (starting in 2009) the NO_X Budget Trading Program, 40 CFR 51.121(r), but established another mechanism—the CAIR ozone season trading program—which states could use to meet their NO_X SIP Call obligations, 70 FR 25289–90. EPA notes that a number of states, when submitting SIP revisions to require sources to participate in the CAIR ozone season trading program, removed the SIP provisions that required sources to participate in the NO_X Budget Trading Program. In addition, because the provisions of CAIR including the ozone season NO_X trading program have remained in place during the remand, EPA is not currently administering the NO_X Budget Trading Program. Nonetheless, all states regardless of the current status of their regulations that previously required participation in the NO_X Budget Trading Program, will remain subject to all of the requirements in the NO_X SIP Call even if the existing CAIR ozone season trading program is withdrawn or altered. In addition, the anti-backsliding provisions of 40 CFR 51.905(f) specifically provide that the provisions of the NO_X SIP Call, including the statewide NO_X emission budgets, continue to apply after revocation of the 1-hour NAAQS. Thus, for purposes of today's action, emissions reductions associated with the NO_X SIP Call are ''permanent and enforceable.''

All NO_X SIP Call states have SIPs that currently satisfy their obligations under the NO_X SIP Call; the NO_X SIP Call reduction requirements are being met; and EPA will continue to enforce the requirements of the NO_X SIP Call even after any response to the CAIR remand. For these reasons, EPA believes that regardless of the status of the CAIR program, the NO_X SIP Call requirements can be relied upon in demonstrating maintenance. Here, the State has demonstrated maintenance based in part on those requirements.

Additionally, EPA has preliminarily determined that South Carolina has demonstrated that attainment of the 1997 8-hour ozone NAAQS will be maintained in the York County Area with or without the implementation of CAIR or the Transport Rule. In addition, modeling conducted by EPA during the Transport Rule rulemaking process also demonstrates that the portion of York County, South Carolina that is in the Charlotte NC–SC ozone nonattainment area will have ozone levels below the 1997 8-hour standard in both 2012 and 2014 without taking into account emissions reductions from CAIR or the Transport Rule. See ''Air Quality Modeling Final Rule Technical Support Document'', App. B, B–28, B–29. This modeling is available in the docket for this rulemaking. Moreover, in its August 2012 decision, the Court also ordered EPA to continue implementing CAIR. See *EME Homer Generation LP* v. *EPA,* slip op. at 60. In sum, neither the current status of CAIR nor the current status of the Transport Rule affects any of the criteria for proposed approval of this redesignation request for the South Carolina portion of the bi-state Charlotte Area.

Criteria (4)—The York County Area Has a Fully Approved Maintenance Plan Pursuant to Section 175A of the CAA

For redesignating a nonattainment area to attainment, the CAA requires EPA to determine that the area has a fully approved maintenance plan pursuant to section 175A of the CAA (CAA section 107(d)(3)(E)(iv)). In conjunction with its request to redesignate the York County Area to attainment for the 1997 8-hour ozone NAAQS, SC DHEC submitted a SIP revision to provide for the maintenance of the 1997 8-hour ozone NAAQS for at least 10 years after the effective date of redesignation to attainment. EPA has interpreted this as a showing of maintenance ''for a period of ten years following redesignation.'' (September 4, 1992 Memorandum from John Calcagni, Director, AQMD, ''Procedures for Processing Requests to Redesignate Areas to Attainment,'' p. 9) where the emissions inventory method of showing maintenance is used, its purpose is to show that emissions during the maintenance period will not increase over the attainment year inventory. Calcagni Memorandum, pp. 9–10.

As discussed in detail in the section below, the State's maintenance plan submission expressly documents that the Area's emissions inventories will remain below the attainment year inventories through 2022. In addition, for the reasons set forth below, EPA believes that the State's submission, in conjunction with additional supporting information, further demonstrates that the Area will continue to maintain the 8-hour ozone NAAQS at least through 2023. In summary, as discussed in under ''Criteria 3,'' the reductions that have been realized are due to federal, state and local control measures that are anticipated to remain in place. For example, there have been local reductions attributable to North Carolina' CSA, the NO_X SIP Call, and from local plant closures. A review of the reductions achieved and the projected emissions inventories as seen in Tables 2 and 3 below, it is not anticipated that emissions in the York County Area will significantly increase between 2022 and 2023, such that these emissions would be above the 2010 attainment level emissions. For example, mobile NO_X emissions between 2010 and 2022, are estimated to be reduced by 63 percent, and it is not expected that mobile NO emissions between 2022 and 2023 will increase by 63 percent. Likewise, mobile VOC emissions between 2010 and 2022, are estimated to be reduced by 45 percent, and it is not expected that mobile VOC emissions between 2022 and 2023 will increase by 45 percent. Thus, if EPA finalizes its proposed approval of the redesignation request and maintenance plan in 2013, it is based on a showing, in accordance with section 175A, that the State's maintenance plan provides for maintenance for at least ten years after redesignation. Therefore, EPA has made the preliminary determination that this maintenance plan meets the requirements for approval under section 175A of the CAA.

a. What is required in a maintenance plan?

Section 175A of the CAA sets forth the elements of a maintenance plan for areas seeking redesignation from nonattainment to attainment. Under section 175A, the plan must demonstrate continued attainment of the applicable NAAQS for at least 10 years after the Administrator approves a redesignation to attainment. Eight years after the redesignation, the state must submit a revised maintenance plan which demonstrates that attainment will continue to be maintained for the

remainder of the 20-year period following the initial 10-year period. To address the possibility of future NAAQS violations, the maintenance plan must contain contingency measures as EPA deems necessary to assure prompt correction of any future 1997 8-hour ozone violations. The Calcagni Memorandum provides further guidance on the content of a maintenance plan, explaining that a maintenance plan should address five requirements: the attainment emissions inventory, maintenance demonstration, monitoring, verification of continued attainment, and a contingency plan. As is discussed more fully below, EPA proposes to find that South Carolina's maintenance plan includes all the necessary components and is thus proposing to approve it as a revision to the South Carolina SIP.

b. Attainment Emissions Inventory

The bi-state Charlotte Area attained the 1997 8-hour ozone NAAQS based on monitoring data for the 3-year period from 2008–2010. South Carolina selected 2010 as the attainment emissions inventory year. The attainment inventory identifies a level of emissions in the Area that is sufficient to attain the 1997 8-hour ozone NAAQS. South Carolina began development of the attainment inventory by first generating a baseline emissions inventory for the York County Area. As noted above, the year 2010 was chosen as the base year for developing a comprehensive emissions inventory for NO_X and VOC, for which projected emissions could be developed for 2013, 2016, 2019, and 2022. All large permitted sources defined as Inventory Type A sources under EPA's Air Emissions Reporting Rule are required to report emissions annually and other title V sources are required to report every three years to SC DHEC. Additionally, EPA requires SC DHEC to submit this data to the EPA Emissions Inventory System (EIS) on the same schedule. The latest year available for the Inventory Type A point source inventory submitted to EPA is 2010. For the smaller sources that report emissions every three years, the most recent emissions inventory available (2008) was used as representative of 2010 emissions. The emissions data upon which SC DHEC's maintenance plan is based were from files maintained by the SC DHEC. In addition to comparing the final year of the plan, 2022, to the base year, 2010, South Carolina compared interim years to the baseline to demonstrate that these years are also expected to show continued maintenance of the 8-hour ozone NAAQS. As mentioned above, emissions inventory levels in 2022 are well below the attainment year inventory levels, and it is highly improbable that they will suddenly increase and exceed attainment year inventory levels in 2023.

The emissions inventory is composed of four major types of sources: point, area, on-road mobile and non-road mobile. The emissions inventory was projected to future years by utilizing EPA's Economic Growth Analysis System (E–GAS) version 5 software. There are two major data sources that are used as growth indicators in EGAS 5.0: the Department of Energy's (DOE) Annual Energy Outlook and version 6.0 of state-level economic models from Regional Economic Models, Inc. (REMI). In general, DOE data are expected to be used as growth indicators for fuel combustion/production categories, while REMI data will be used for all other source categories. The complete descriptions of how the inventories were developed are discussed in the appendices of the June 2, 2011, SIP revision, which can be found in the docket for this action. Non-road mobile emissions estimates were based on the EPA's NONROAD2008a non-road mobile model, with the exception of the railroad locomotives, commercial marine, and aircraft engine. These emissions are estimated by taking activity data, such as landings and takeoffs, and multiplying by an EGAS 5.0 emissions factor. On-road mobile source emissions were calculated using EPA's MOVES2010a mobile emission factors model. The 2010 NO_X and VOC emissions for the bi-state Charlotte Area, as well as the emissions for other years, were developed consistent with EPA guidance and are summarized in Tables 2 through 4 of the following subsection discussing the maintenance demonstration.

c. Maintenance Demonstration

The June 2, 2011, final SIP revision includes a maintenance plan for the York County Area. The maintenance plan:

(i) Shows compliance with and maintenance of the 8-hour ozone standard by providing information to support the demonstration that current and future emissions of NO_X and VOC remain at or below 2010 emissions levels.

(ii) Uses 2010 as the attainment year and includes future emissions inventory projections for 2013, 2016, 2019, 2022.

(iii) Identifies an ''out year'' at least 10 years (and beyond) after the time necessary for EPA to review and approve the maintenance plan. Per 40 CFR part 93, NO_X and VOC MVEB were established for an interim year (2013) and the last year (2022) of the maintenance plan (see section VI below).

(iv) Provides actual and projected emissions inventories, in tons per day (tpd), for the York County Area, as shown in Tables 2 through 4 below.

TABLE 2—ACTUAL AND PROJECTED ANNUAL NO_X EMISSIONS (TPD) FOR THE YORK COUNTY AREA*

Sector	2010	2013	2016	2019	2022
Point	4.54	4.64	4.91	5.19	5.48
Area	1.1733	1.2219	1.2665	1.3183	1.3641
Nonroad	3.209	2.686	2.174	1.817	1.595
Mobile	12.05	8.73	6.52	5.16	4.42
Total	20.97	17.28	14.87	13.49	12.86

* Portion of York County within the nonattainment area.

TABLE 3—ACTUAL AND PROJECTED ANNUAL VOC EMISSIONS (TPD) FOR THE YORK COUNTY AREA*

Sector	2010	2013	2016	2019	2022
Point	2.07	2.06	2.2	2.34	2.49
Area	7.1645	7.3870	7.5672	7.7027	7.8311
Nonroad	2.149	1.776	1.541	1.438	1.407

TABLE 3—ACTUAL AND PROJECTED ANNUAL VOC EMISSIONS (TPD) FOR THE YORK COUNTY AREA*—Continued

Sector	2010	2013	2016	2019	2022
Mobile	3.92	3.14	2.61	2.29	2.14
Total	15.30	14.36	13.92	13.77	13.87

* Portion of York County within the nonattainment area.

TABLE 4—EMISSION ESTIMATES FOR THE YORK COUNTY AREA

Year	VOC (tpd)	NO_X (tpd)
2010	15.30	20.97
2013	14.36	17.28
2016	13.92	14.87
2019	13.77	13.49
2022	13.87	12.86
Difference from 2010 to 2022	−1.43	−8.11

Tables 2 through 4 summarize the 2010 and future projected emissions of NO_X and VOC from York County. In situations where local emissions are the primary contributor to nonattainment, the ambient air quality standard should not be violated in the future as long as emissions from within the nonattainment area remain at or below the baseline with which attainment was achieved. South Carolina has projected emissions as described previously and determined that emissions in the York County Area will remain below those in the attainment year inventory for the duration of the maintenance plan.

As discussed in section VI of this proposed rulemaking, a safety margin is the difference between the attainment level of emissions (from all sources) and the projected level of emissions (from all sources) in the maintenance plan. The attainment level of emissions is the level of emissions during one of the years in which the area met the NAAQS. South Carolina selected 2010 as the attainment emissions inventory year for the York County Area. South Carolina calculated safety margins for years 2013 and 2022 in its submittal for years 2013, 2016, 2019, and 2022. The State has decided to allocate a safety margin to the 2013 and 2022 MVEB for the bi-state Charlotte Area. For the year 2013, the NO_X safety margin was calculated as 3,348 kilograms per day (kg/day)[6] and for VOC as 853 kg/day. For the year 2022, the safety margin was calculated as 7,357 for kg/day for NO_X and 1,297 kg/day for VOC. The State has decided to allocate the full safety margin amounts to the MVEB for these years. Therefore, no remaining safety margin will be available for VOC and NO_X for the years 2013 and 2022. The MVEB to be used for transportation conformity proposes is discussed in section VI. This allocation and the resulting available safety margin for the York County Area are discussed further in section VI of this proposed rulemaking.

d. Monitoring Network

There is currently one monitor measuring ozone in York County. However, this monitor is not located within the nonattainment area boundary. The State of South Carolina, through SC DHEC, has committed to continue operation of the monitor in York County in compliance with 40 CFR part 58 and have thus addressed the requirement for monitoring. EPA approved South Carolina's 2011 monitoring plan on October 12, 2011.

e. Verification of Continued Attainment

The State of South Carolina, through SC DHEC, has the legal authority to enforce and implement the requirements of the 1997 8-hour ozone maintenance plan for the York County Area. This includes the authority to adopt, implement and enforce any subsequent emissions control contingency measures determined to be necessary to correct future ozone attainment problems.

South Carolina will continue to update its emissions inventory at least once every three years. In addition to the emissions inventory for 2010, the emissions inventory base year, and the last year of the maintenance plan, 2022, interim years of 2013, 2016 and 2019 were selected to show a trend analysis for maintenance of the 1997 8-hour ozone NAAQS. Tracking the progress of the maintenance plan also includes performing reviews of the updated emissions inventories for the area using the latest emissions factors, models, and methodologies. For these periodic inventories, SC DHEC will review the assumptions made for the purpose of the maintenance demonstration concerning projected growth of activity levels. In addition, SC DHEC will continue to work with local stakeholders to maintain the NAAQS as required.

f. Contingency Measures in the Maintenance Plan

The contingency measures are designed to promptly correct a violation of the NAAQS that occurs after redesignation. Section 175A of the CAA requires that a maintenance plan include such contingency measures as EPA deems necessary to assure that the state will promptly correct a violation of the NAAQS that occurs after redesignation. The maintenance plan should identify the contingency measures to be adopted, a schedule and procedure for adoption and implementation, and a time limit for action by the state. A state should also identify specific indicators to be used to determine when the contingency measures need to be implemented. The maintenance plan must include a requirement that a state will implement all measures with respect to control of the pollutant that were contained in the SIP before redesignation of the area to attainment in accordance with section 175A(d).

In the June 1, 2011, SIP revision, South Carolina affirms that all programs instituted by the State and EPA will remain enforceable and that sources are prohibited from reducing emissions controls following the redesignation of the Area. The contingency plan portion of the maintenance determination was further clarified with a July 8, 2011, letter. This letter can be found in the docket for today's action using Docket ID No. EPA–R04–OAR–2012–0327.

The contingency plan included in South Carolina's June 1, 2011, SIP revision includes a triggering mechanism to determine when contingency measures are needed and a process of developing and implementing appropriate control measures. The State of South Carolina will use actual ambient monitoring data as the triggering event to determine when contingency measures should be implemented.

South Carolina has identified a primary trigger as occurring when a quality assured/quality controlled (QA/QC) design value exceeds the 1997 8-hour ozone NAAQS at any monitor in the Area. In the event that the trigger is activated, SC DHEC will verify the data through QA/QC and certification;

[6] Conversion factor from kilograms to tons is 0.0011023.

analyze the data to verify monitored ozone data, meteorology, transport, and related activities to determine the possible cause of the violation; consult with North Carolina Department of Air Quality[7] to determine which state will implement a contingency measure(s) within a time frame specified in the respective maintenance plan to bring the Area back into attainment; if necessary, select a contingency measure within three months after verification of an exceedance of the 1997 8-hour ozone NAAQS; and develop and implement necessary regulations as soon as practicable and within the in guidelines established in the South Carolina Administrative Procedures Act or no more than two years after selection of the appropriate measure. South Carolina further clarified this statement in the July 8, 2011, letter to EPA by defining the triggering event as the date of the design value violation, and not the final QA/QC date, such that appropriate measures would be implemented within 24 months of activating the primary trigger. Further, the guidelines set forth in the South Carolina Administrative Procedures Act state the selection of a measure and the development and implementation of necessary regulations would be expected to be completed within 24 months of activating the primary trigger. However, if it is determined that a longer schedule is required to implement specific contingency measures, then, upon selection of appropriate measures, SC DHEC will notify EPA, for approval, of the proposed schedule and provide sufficient information to demonstrate that the proposed measures are a prompt correction of the triggering event.

At least one of the following contingency measures will be adopted and implemented upon a primary triggering event:

- RACT for NO_X on existing stationary sources not subject to existing requirements;
- Implementation of diesel retrofit programs, including incentives for performing retrofits for fleet vehicle operations;
- Alternative fuel programs for fleet vehicle operations;
- Gas can and lawnmower replacement programs;
- Voluntary engine idling reduction programs;
- SC DHEC's *Take a Break from the Exhaust* program; and
- Other measures deemed appropriate at the time as a result of advances in control technologies.

In addition to the trigger indicated above, as a secondary trigger South Carolina will monitor periodic emissions inventory updates and compare to actual emissions. As stated in the June 1, 2011, SIP revision, and further explained in the July 8, 2011, clarification letter, if actual emissions are greater than 10 percent of the projected emissions in the maintenance plan, SC DHEC will investigate the differences and develop an appropriate strategy for addressing the differences.

EPA has concluded that the maintenance plan adequately addresses the five basic components of a maintenance plan: attainment inventory, monitoring network, verification of continued attainment, and a contingency plan. Therefore, the maintenance plan SIP revision submitted by the State of South Carolina for the York County Area meets the requirements of section 175A of the CAA, and thus EPA is proposing approval of the plan.

VI. What is EPA's analysis of South Carolina's proposed NO_X and VOC MVEB for the York County area?

Under section 176(c) of the CAA, new transportation plans, programs, and projects, such as the construction of new highways, must ''conform'' to (i.e., be consistent with) the part of the state's air quality plan that addresses pollution from cars and trucks. Conformity to the SIP means that transportation activities will not cause new air quality violations, worsen existing violations, or delay timely attainment of the NAAQS or any interim milestones. If a transportation plan does not conform, most new projects that would expand the capacity of roadways cannot go forward. Regulations at 40 CFR part 93 set forth EPA policy, criteria, and procedures for demonstrating and assuring conformity of such transportation activities to a SIP. The regional emissions analysis is one, but not the only, requirement for implementing transportation conformity. Transportation conformity is a requirement for nonattainment and maintenance areas. Maintenance areas are areas that were previously nonattainment for a particular NAAQS but have since been redesignated to attainment with an approved maintenance plan for that NAAQS.

Under the CAA, states are required to submit, at various times, control strategy SIPs and maintenance plans for nonattainment areas. These control strategy SIPs (including RFP and attainment demonstration) and maintenance plans create MVEB for criteria pollutants and/or their precursors to address pollution from cars and trucks. Per 40 CFR part 93, a MVEB must be established for the last year of the maintenance plan. A state may adopt MVEB for other years as well. The MVEB is the portion of the total allowable emissions in the maintenance demonstration that is allocated to highway and transit vehicle use and emissions. *See* 40 CFR 93.101. The MVEB serves as a ceiling on emissions from an area's planned transportation system. The MVEB concept is further explained in the preamble to the November 24, 1993, Transportation Conformity Rule (58 FR 62188). The preamble also describes how to establish the MVEB in the SIP and how to revise the MVEB.

After interagency consultation with the transportation partners for the York County Area, South Carolina has developed MVEB for NO_X and VOC for the York County Area. South Carolina is developing these MVEB, as required, for the last year of its maintenance plan, 2022. Through the interagency consultation process, MVEB were also set for the interim year 2013. The MVEB reflect the total on-road emissions for 2013 and 2022, plus an allocation from the available NO_X and VOC safety margin. Under 40 CFR 93.101, the term ''safety margin'' is the difference between the attainment level (from all sources) and the projected level of emissions (from all sources) in the maintenance plan. The safety margin can be allocated to the transportation sector; however, the total emissions must remain below the attainment level. The NO_X and VOC MVEB and allocation from the safety margin were developed in consultation with the transportation partners and were added to account for uncertainties in population growth, changes in model vehicle miles traveled and new emission factor models. The NO_X and VOC MVEB for the York County Area are defined in Table 5 below.

[7] As stated earlier, there is currently one monitor measuring ozone in York County. This monitor is not located in the bi-state Charlotte Area.

TABLE 5—YORK COUNTY PORTION OF THE BI-STATE CHARLOTTE AREA$_X$ AND VOC MVEB (KG/DAY)

	2013	2022
NO_X Emissions		
Base Emissions	7,924	4,011
Safety Margin Allocated to MVEB	3,348	7,357
NO_X Conformity MVEB	11,272	11,368
VOC Emissions		
Base Emissions	2,846	1,939
Safety Margin Allocated to MVEB	853	1,297
VOC Conformity MVEB	3,699	3,236

As mentioned above, South Carolina has chosen to allocate a portion of the available safety margin to the NO_X and VOC MVEB for 2013 and 2022 for the York County Area. This allocation is 3,348 kg/day and 853 kg/day for NO_X and VOC, respectively for 2013 and 7,357 kg/day and 1,297 kg/day for NO_X and VOC, respectively for 2022. Thus, the remaining safety margins for 2013 and 2022 are 0 kg/day for NO_X and VOC.

Through this rulemaking, EPA is proposing to approve the MVEB for NO_X and VOC for 2013 and 2022 for the York County Area because EPA has preliminarily determined that the Area maintains the 1997 8-hour ozone NAAQS with the emissions at the levels of the budgets. Once the MVEB for the York County Area are approved or found adequate (whichever is completed first), they must be used for future conformity determinations. After thorough review, EPA has preliminarily determined that the budgets meet the adequacy criteria, as outlined in 40 CFR 93.118(e)(4), and is proposing to approve the budgets because they are consistent with maintenance of the 1997 8-hour ozone NAAQS through 2022. As discussed in section V, EPA is proposing that if this approval is finalized in 2013, the Area will continue to maintain the 1997 8-hour ozone NAAQS through at least 2023. Consistent with this proposal, EPA is proposing to approve the MVEB submitted by the State in its June 1, 2011, maintenance plan for the York County Area. EPA is proposing that the submitted MVEB are consistent with maintenance of the 1997 8-hour ozone NAAQS through 2023.

VII. What is the status of EPA's adequacy determination for the proposed NO_X and VOC MVEB for 2013 and 2022 for the York County area?

When reviewing submitted ''control strategy'' SIPs or maintenance plans containing MVEB, EPA may affirmatively find the MVEB contained therein adequate for use in determining transportation conformity. Once EPA affirmatively finds the submitted MVEB is adequate for transportation conformity purposes, that MVEB must be used by state and federal agencies in determining whether proposed transportation projects conform to the SIP as required by section 176(c) of the CAA.

EPA's substantive criteria for determining adequacy of a MVEB are set out in 40 CFR 93.118(e)(4). The process for determining adequacy consists of three basic steps: public notification of a SIP submission, a public comment period, and EPA's adequacy determination. This process for determining the adequacy of submitted MVEB for transportation conformity purposes was initially outlined in EPA's May 14, 1999, guidance, ''Conformity Guidance on Implementation of March 2, 1999, Conformity Court Decision.'' EPA adopted regulations to codify the adequacy process in the Transportation Conformity Rule Amendments for the ''New 8-Hour Ozone and $PM_{2.5}$ National Ambient Air Quality Standards and Miscellaneous Revisions for Existing Areas; Transportation Conformity Rule Amendments—Response to Court Decision and Additional Rule Change,'' on July 1, 2004 (69 FR 40004). Additional information on the adequacy process for transportation conformity purposes is available in the proposed rule entitled, ''Transportation Conformity Rule Amendments: Response to Court Decision and Additional Rule Changes,'' 68 FR 38974, 38984 (June 30, 2003).

As discussed earlier, South Carolina's maintenance plan submission includes NO_x and VOC MVEB for the York County Area for 2013, an interim year of the maintenance plan, and 2022, the last year of the maintenance plan. EPA reviewed the NO_x and VOC MVEB through the adequacy process. The South Carolina SIP submission, including the bi-state Charlotte Area NO_x and VOC MVEB, was open for public comment on EPA's adequacy Web site on October 28, 2011, found at: *http://www.epa.gov/otaq/stateresources/transconf/currsips.htm.* The EPA public comment period on adequacy for the MVEB for 2013 and 2022 for the York County Area closed on November 28, 2011. No comments, adverse or otherwise, were received during EPA's adequacy process for the MVEB associated with South Carolina's 1997 8-hour ozone maintenance plan.

The 2013 and 2022 NO_x and VOC MVEB must be used for future transportation conformity determinations. For required regional emissions analysis years that involve 2013 through 2021, the applicable 2013 MVEB will be used and for 2022 and beyond, the applicable budgets will be the 2022 MVEB established in the maintenance plan, as defined in section VI of this proposed rulemaking.

VIII. What is the effect of EPA's proposed actions?

EPA's proposed actions establish the basis upon which EPA may take final action on the issues being proposed for approval today. Approval of South Carolina's redesignation request would change the legal designation of the designated portion of York County in South Carolina (including the Catawba Indian Nation reservation lands) for the 1997 8-hour ozone NAAQS, found at 40 CFR part 81, from nonattainment to attainment.[8] Approval of South Carolina's request would also incorporate a plan for maintaining the 1997 8-hour ozone NAAQS in the York County Area through 2022 into the South Carolina SIP. This maintenance plan includes contingency measures to remedy any future violations of the 1997 8-hour ozone NAAQS and procedures for evaluation of potential violations. The maintenance plan also establishes

[8] This proposed action does not proposed to change the Area's designation for the 2008 8-hour ozone NAAQS.

NO_x and VOC MVEB for the York County Area. The NO_x MVEB for 2013 and 2022 for the York County Area are 11,272 kg/day and 11,368 kg/day, respectively. The VOC MVEB for 2013 and 2022 for the York County Area are 3,699 kg/day and 3,236 kg/day, respectively. Additionally, EPA is notifying the public of the status of EPA's adequacy determination for the newly-established NO_x and VOC MVEB for 2013 and 2022 for the York County Area, and is notifying the public that the 2022 MVEB are consistent with maintenance in the Area through 2023 as well.

IX. Proposed Actions on the Redesignation Request and Maintenance Plan SIP Revisions Including Approval of the NO_x and VOC MVEB for 2013 and 2022 for the York County Area

EPA previously determined that the entire bi-state Charlotte Area (including the portion of York County that is a part of this Area) was attaining the 1997 8-hour ozone NAAQS on November 15, 2011, at 76 FR 70656. EPA is now proposing to take two separate but related actions regarding the York County Area's redesignation and maintenance of the 1997 8-hour ozone NAAQS.

First, EPA is proposing to determine, based on complete, quality-assured and certified monitoring data for the 2009–2011 monitoring period that the entire bi-state Charlotte Area (including the portion of York County that is a part of this Area) is attaining the 1997 8-hour ozone NAAQS. EPA is proposing to determine that South Carolina has met the criteria under CAA section 107(d)(3)(E) for the York County Area for redesignation from nonattainment to attainment for the 1997 8-hour ozone NAAQS. On this basis, EPA is proposing to approve South Carolina's redesignation request for the 1997 8-hour ozone NAAQS for the York County Area.

Second, EPA is proposing to approve the maintenance plan for the York County Area, including the NO_x and VOC MVEB for 2013 and 2022, into the South Carolina SIP (under CAA section 175A). The maintenance plan demonstrates that the Area will continue to maintain the 1997 8-hour ozone NAAQS, and the budgets meet all of the adequacy criteria contained in 40 CFR 93.118(e)(4) and (5). Further, as part of today's action, EPA is describing the status of its adequacy determination for the NO_x and VOC MVEB for 2013 and 2022 in accordance with 40 CFR 93.118(f)(1). On September 24, 2012, at 77 FR 58829, EPA announced the adequacy of the MVEB would take effect on October 9, 2012. Within 24 months from this effective date, the transportation partners will need to demonstrate conformity to the new NO_x and VOC MVEB pursuant to 40 CFR 93.104(e).

As discussed in section V, EPA is proposing that if this approval is finalized in 2013 the area will continue to maintain the 1997 8-hour ozone NAAQS through at least 2023. Consistent with this proposal, EPA is proposing to approve the MVEB submitted by the State in its June 1, 2011, maintenance plan for the York County Area. EPA is proposing that the submitted MVEB are consistent with maintenance of the 1997 8-hour ozone NAAQS through 2023.

If finalized, approval of the redesignation request would change the official designation of the nonattainment portion of York County (including the Catawba Indian Nation reservation lands) in the Area for the 1997 8-hour ozone NAAQS, found at 40 CFR part 81, from nonattainment to attainment.

X. Statutory and Executive Order Reviews

Under the CAA, 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 CAA 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 CAA. Accordingly, these proposed actions merely approve state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For this reason, these proposed actions:

- Are not ''significant regulatory action[s]'' 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 economically significant regulatory actions based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Are not significant regulatory actions 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 CAA; 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, the redesignation for the York County Area does have Tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because it may have substantial direct effects on the Catawba Indian Nation as the Tribe's reservation lands are within the York County Area for the 1997 8-hour ozone NAAQS. As such, today's proposal to redesignate the York County Area to attainment for the 1997 8-hour ozone NAAQS includes the Catawba Indian Nation reservation lands. Accordingly, EPA and the Catawba Indian Nation consulted on this redesignation prior to today's proposed action. EPA's consultation on this and other ozone SIP matters for the York County Area with the Catawba Indian Nation commenced on October 14, 2011, and concluded on October 31, 2012. EPA further notes that today's action is not anticipated to impose substantial direct costs on Tribal governments or preempt Tribal law.

List of Subjects

40 CFR Part 52

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

40 CFR Part 81

Environmental protection, Air pollution control.

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

Dated: November 6, 2012.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

[FR Doc. 2012–27807 Filed 11–14–12; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register

Vol. 77, No. 221

Thursday, November 15, 2012

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.

ARCTIC RESEARCH COMMISSION

Programs and Research Projects Affecting the Arctic; 99th Meeting

Notice is hereby given that the U.S. Arctic Research Commission will hold its 99th meeting in Vancouver, British Columbia, Canada, on December 10–11, 2012. The business sessions, open to the public, will convene at 9 a.m. on December 10 and December 11. An afternoon meeting on December 10 from 2:15–5:30 p.m. will be closed to the public.

The Agenda items include:

(1) Call to order and approval of the agenda

(2) Approval of the minutes from the 98th meeting

(3) Commissioners and staff reports

(4) Discussion and presentations concerning Arctic research activities

The focus of the meeting will be reports and updates on programs and research projects affecting the Arctic.

If you plan to attend this meeting, please notify us via the contact information below. Any person planning to attend who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission of those needs in advance of the meeting.

CONTACT PERSON FOR FURTHER INFORMATION: John Farrell, Executive Director, U.S. Arctic Research Commission, 703–525–0111 or TDD 703–306–0090.

John Farrell,

Executive Director.

[FR Doc. 2012–27531 Filed 11–14–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: Bureau of Industry and Security (BIS).

Title: License Transfer and Duplicate License Services.

OMB Control Number: 0694–0126.

Form Number(s): N/A.

Type of Request: Regular submission (extension of a currently approved information collection).

Burden Hours: 38.

Number of Respondents: 110.

Average Hours per Response: 16 to 66 minutes.

Needs and Uses: This collection is needed to provide services to exporters who have either lost their original license and require a duplicate, or who wish to transfer their ownership of an approved license to another party.

Affected Public: Business and other for-profit organizations

Frequency: On occasion.

Respondent's Obligation: Required to obtain benefits.

OMB Desk Officer: Jasmeet Seehra, (202) 395–3123.

Copies of the above information collection proposal can be obtained by calling or writing Jennifer Jessup, Departmental Paperwork Clearance Officer, (202) 482–0336, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *jjessup@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to Jasmeet Seehra, OMB Desk Officer, Fax no. (202) 395–5167 or via email to *Jasmeet_K._Seehra@omb.eop.gov.*

Dated: November 8, 2012.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2012–27711 Filed 11–14–12; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–81–2012]

Foreign-Trade Zone 163—Ponce, PR; Application for Subzone; Zimmer Manufacturing BV; Ponce, PR

An application has been submitted to the Foreign-Trade Zones Board (the Board) by CODEZOL, C.D., grantee of FTZ 163, requesting special-purpose subzone status for the facility of Zimmer Manufacturing BV located in Ponce, Puerto Rico. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally docketed on November 8, 2012.

The proposed subzone (14.34 acres) is located at State Road 1 Km 123.4, Mercedita Ward, Ponce, Puerto Rico. A notification of proposed production activity has been submitted and will be published separately for public comment.

In accordance with the Board's regulations, Camille Evans of the FTZ Staff is designated examiner to review the application and make recommendations to the Board.

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is December 26, 2012. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to January 9, 2013.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the ''Reading Room'' section of the Board's Web site, which is accessible via *www.trade.gov/ftz.* For further information, contact Camille Evans at *Camille.Evans@trade.gov* or (202) 482–2350.

Dated: November 8, 2012.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2012–27780 Filed 11–14–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–80–2012]

Foreign-Trade Zone 163—Ponce, PR; Notification of Proposed Production Activity; Zimmer Manufacturing BV (Medical Devices); Ponce, PR

CODEZOL, C.D., grantee of FTZ 163, submitted a notification of proposed production activity on behalf of Zimmer Manufacturing BV (Zimmer), located in Ponce, Puerto Rico. The notification conforming to the requirements of the regulations of the Board (15 CFR 400.22) was received on November 1, 2012.

A separate application for subzone status at the Zimmer facility was submitted and will be processed under Section 400.31 of the Board's regulations. The facility is used for the production, warehousing and distribution of orthopedic implants for knee and hip reconstruction as well as trauma devices. Production under FTZ procedures could exempt Zimmer from customs duty payments on the foreign status components used in export production. On its domestic sales, Zimmer would be able to choose the duty rates during customs entry procedures that apply to the finished products (duty-free) for the foreign status inputs noted below. Customs duties also could possibly be deferred or reduced on foreign status production equipment.

Components and materials sourced from abroad include: polymers of ethylene in primary forms; acrylic polymers in primary forms; silicones in primary forms; self-adhesive shapes of plastics; other shapes of plastics; packaging; bars, rods, angles shapes and sections of stainless steel; articles of iron or steel; and, artificial joints, parts and accessories (duty rate ranges from duty-free to 6.5%).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is December 26, 2012.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the ''Reading Room'' section of the Board's Web site, which is accessible via *www.trade.gov/ftz.*

For further information, contact Elizabeth Whiteman at *Elizabeth.Whiteman@trade.gov* or (202) 482–0473.

Dated: November 5, 2012.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2012–27776 Filed 11–14–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

Michigan State University, et al.; Notice of Decision on Applications for Duty-Free Entry of Scientific Instruments

This is a decision pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, as amended by Pub. .106–36; 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 a.m. and 5:00 p.m. in Room 3720, U.S. Department of Commerce, 14th and Constitution Avenue NW., Washington, DC.

Docket Number: 12–036. *Applicant:* Michigan State University, 2555 Engineering Building, Department of Mechanical Engineering, East Lansing, MI 48824–1226. *Instrument:* Diode Pumped High speed Nd:YAG laser system. *Manufacturer:* Edgewave GmbH, Germany. *Intended Use:* See notice at 77 FR 61739, October 11, 2012. *Comments:* None received. *Decision:* Approved. We know of no instruments of equivalent scientific value to the foreign instruments described below, for such purposes as this is intended to be used, that was being manufactured in the United States at the time of its order. *Reasons:* The instrument will be used as a diagnostics equipment to study high temperature combustion occurring in a laboratory combustor with highly turbulent flows, specifically to detect chemical species of combustion in conditions that are similar to actual engine operating conditions. The system will be used to pump a dye laser to generate ultra-violet light which can be used to rack chemical species during combustion, such as hydroxyl (OH) radicals. The hydroxyl which is excited using ultraviolet light (283 nm) will then fluoresce and can be detected using an intensified CCD camera. The key requirements that this system fulfills are the beam profile of $M^2<2$, to ability to perform sub 10 ns pulses with all the different specifications, and the crystals inside are all temperature controlled to phase match regardless of the outside temperature fluctuations.

Dated: November 8, 2012.

Gregory W. Campbell,

Director, Subsidies Enforcement Office, Import Administration.

[FR Doc. 2012–27782 Filed 11–14–12; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

National Construction Safety Team Advisory Committee Meeting

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice of open meeting.

SUMMARY: The National Construction Safety Team (NCST) Advisory Committee (Committee) will meet on Monday, December 10, 2012 from 8:30 to 5:00 p.m. Eastern time. The primary purpose of this meeting is to update the Committee on the status of the National Institute of Standards and Technology (NIST) Disaster and Failure Studies Program, receive NIST's response to the Committee's 2011 annual report recommendations, update the Committee on the progress of the NIST Technical Investigation of the May 22, 2011 Tornado in Joplin, MO, and gather information for the Committee's 2012 Annual Report to Congress. The agenda may change to accommodate Committee business. The final agenda will be posted on the NIST Web site at *http://www.nist.gov/el/disasterstudies/ncst/.*

DATES: The NCST Advisory Committee will meet on Monday, December 10, 2012 from 8:30 a.m. until 5:00 p.m. Eastern time. The meeting will be open to the public.

ADDRESSES: The meeting will be held in Lecture Room B, Administration Building, National Institute of Standards and Technology (NIST), 100 Bureau Drive, Gaithersburg, Maryland 20899. Please note admittance instructions under the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Eric Letvin, Director, Disaster and Failure Studies Program, 100 Bureau Drive, Mail Stop 8600, Gaithersburg, Maryland 20899–8600. Mr. Letvin's email address is *eric.letvin@nist.gov* and his phone number is (301) 975–5412.

SUPPLEMENTARY INFORMATION: The Committee was established pursuant to Section 11 of the NCST Act (15 U.S.C. 7310). The Committee is composed of ten members, appointed by the Director of NIST, who were selected for their technical expertise and experience,

established records of distinguished professional service, and their knowledge of issues affecting teams established under the NCST Act. The Committee will advise the Director of NIST on carrying out studies of building failures conducted under the authorities of the NCST Act and will review the procedures developed to implement the NCST Act and reports issued under section 8 of the NCST Act (15 U.S.C. 7307). Background information on the NCST Act and information on the NCST Advisory Committee is available at *http://www.nist.gov/el/disasterstudies/ncst/.*

Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. App., notice is hereby given that the NCST Advisory Committee will meet on Monday, December 10, 2012 at 8:30 a.m. and will adjourn at 5:00 p.m. Eastern time. The meeting will be open to the public.

The primary purpose of this meeting is to update the Committee on the status of the National Institute of Standards and Technology (NIST) Disaster and Failure Studies Program, receive NIST's response to the Committee's 2011 annual report recommendations, update the Committee on the progress of the NIST Technical Investigation of the May 22, 2011 Tornado in Joplin, MO, and gather information for the Committee's 2012 Annual Report to Congress. The final agenda will be posted on the NIST Web site at *http://www.nist.gov/el/disasterstudies/ncst/.*

Individuals and representatives of organizations who would like to offer comments and suggestions related to items on the Committee's agenda for this meeting are invited to request a place on the agenda. Approximately fifteen minutes will be reserved for public comments, and speaking times will be assigned on a first-come, first-served basis. The amount of time per speaker will be determined by the number of requests received, but is likely to be 5 minutes each. Questions from the public will not be considered during this period. Speakers who wish to expand upon their oral statements, those who had wished to speak but could not be accommodated on the agenda, and those who were unable to attend in person are invited to submit written statements to the National Construction Safety Team Advisory Committee, National Institute of Standards and Technology, 100 Bureau Drive, MS 8600, Gaithersburg, Maryland 20899–8600, via fax at (301) 975–4032, or electronically by email to *ncstac@nist.gov.*

All those wishing to speak must submit their request by email to the attention of Mr. Eric Letvin, *eric.letvin@nist.gov* by 5:00 p.m. Eastern time, Monday, December 3, 2012.

All visitors to the NIST site are required to pre-register to be admitted. Anyone wishing to attend this meeting must register by 5:00 p.m. Eastern time, Monday, December 3, 2012, in order to attend. Please submit your full name, email address, and phone number to Michelle Harman. Non-U.S. citizens must also submit their country of citizenship, title, and employer/sponsor. Mrs. Harman's email address is *michelle.harman@nist.gov,* and her phone number is (301) 975–5324.

Dated: November 7, 2012.

Willie E. May,

Associate Director for Laboratory Programs.

[FR Doc. 2012–27689 Filed 11–14–12; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Socio-Economic Profile of Small-Scale Commercial Fisheries in the U.S. Caribbean

AGENCY: National Oceanic and Atmospheric Administration (NOAA).

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before January 14, 2013.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Dr. Juan J. Agar, (305) 361–4218 or *Juan.Agar@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for a new information collection.

The National Marine Fisheries Service (NMFS) proposes to collect socio-economic data about small scale fishermen and seafood dealers operating in the U.S. Caribbean. The survey intends to collect information on demographics, fishing practices, costs and earnings (revenues, variable and fixed costs), market and distribution channels, capital investment, attitudes and perceptions about the performance management actions and the health of local fisheries, including the impact of invasive species. The data gathered will be used to describe U.S. Caribbean fisheries, assess socio-economic performance of small-scale fleets, and evaluate the socio-economic impacts of Federal regulatory actions. In addition, the information will be used to strengthen and improve fishery management decision-making, satisfy legal mandates under Executive Order 12866, the Magnuson-Stevens Fishery Conservation and Management Act (U.S.C. 1801 *et seq.*), the Regulatory Flexibility Act, the Endangered Species Act, and the National Environmental Policy Act, and other pertinent statues.

II. Method of Collection

The socio-economic information sought will be collected via in-person, telephone and mail surveys.

III. Data

OMB Control Number: None.

Form Number: None.

Type of Review: Regular submission (request for a new information collection).

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 2,000.

Estimated Time per Response: 1 hr.

Estimated Total Annual Burden Hours: 2,000.

Estimated Total Annual Cost to Public: $ 0 in recordkeeping/reporting costs.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: November 8, 2012.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2012–27707 Filed 11–14–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Fisheries of the Caribbean; Southeast Data, Assessment, and Review (SEDAR); Public Meetings

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

ACTION: Notice of cancellation for SEDAR Review Workshop for Caribbean blue tang and queen triggerfish.

SUMMARY: The SEDAR assessments of the Caribbean stocks of blue tang and queen triggerfish will no longer have an in-person Review Workshop. See **SUPPLEMENTARY INFORMATION**.

DATES: The Review Workshop originally scheduled for February 4–7, 2013 has been cancelled. See **SUPPLEMENTARY INFORMATION**.

SUPPLEMENTARY INFORMATION: The original notice published in the **Federal Register** on May 7, 2012 (77 FR 26746).

The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions, have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR includes three workshops: (1) Data Workshop; (2) Stock Assessment Workshop; and (3) Review Workshop. The product of the Data Workshop is a data report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Stock Assessment Workshop is a stock assessment report which describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Consensus Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and the NOAA Fisheries Southeast Regional Office and Southeast Fisheries Science Center. Participants include: data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and non-governmental organizations (NGOs); international experts; and staff of Councils, Commissions, and state and federal agencies.

February 4–7, 2013; SEDAR 30 Review Workshop—CANCELLED

The in-person Review Workshop, scheduled for 4–7 February 2013 to review the 2012 assessments of blue tang and queen triggerfish, has been cancelled. At the Assessment workshop, held October 16–17, 2012 in Miami, FL, the Assessment Panel decided not to move forward with the blue tang assessment due to data issues and determined that little could be accomplished for queen triggerfish beyond what had been completed to date.

Given the reduced scope of assessment products in need of review, the in-person workshop is being cancelled in favor of a Desk Review. The Desk Review would still utilize Center for Independent Experts (CIE) Reviewers. The Reviewers would be provided the assessment reports of each species, review them according to the Terms of Reference (TOR), and provide an individual independent review report. Those reports would be made available to the analysts, as well as to the Scientific and Statistical Committee (SSC), for their review and discussion before the SSC makes any management recommendations. The timing of the Desk Review would be similar to the timing already in place for the project, with the plan to have the material imparted to the SSC by early March 2013.

All other previously-published information remains unchanged.

Dated: November 8, 2012.

Tracey L. Thompson,

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

[FR Doc. 2012–27682 Filed 11–14–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration (NOAA)

Marine Protected Areas Federal Advisory Committee; Public Meeting

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of open meeting.

SUMMARY: Notice is hereby given of a meeting of the Marine Protected Areas Federal Advisory Committee (Committee) in Santa Cruz, California.

DATES: The meeting will be held Tuesday, December 5, 2012, from 9 a.m. to 5 p.m., Wednesday, December 6, from 8:30 a.m. to 4:30 p.m., and Thursday, December 7, from 8:30 a.m. to 2 p.m. These times and the agenda topics described below are subject to change. Refer to the web page listed below for the most up-to-date meeting agenda.

ADDRESSES: The meeting will be held at the Hotel Paradox, 611 Ocean Street, Santa Cruz, CA, 95060.

FOR FURTHER INFORMATION CONTACT: Kara Yeager, Designated Federal Officer, MPA FAC, National Marine Protected Areas Center, 1305 East West Highway, Silver Spring, Maryland 20910. (Phone: 301–713–7242, Fax: 301–713–3110); email: *kara.yeager@noaa.gov;* or visit the National MPA Center Web site at *http://www.mpa.gov*).

SUPPLEMENTARY INFORMATION: The Committee, composed of external, knowledgeable representatives of stakeholder groups, was established by the Department of Commerce (DOC) to provide advice to the Secretaries of Commerce and the Interior on implementation of Section 4 of Executive Order 13158, which calls for the development of a National System of Marine Protected Areas (MPAs). The National System aims to strengthen existing MPAs and MPA programs through national and regional coordination, capacity building, science and analysis. The meeting is open to the public, and public comment will be accepted from 4:15 p.m. to 5 p.m. on Tuesday, November 15, 2011. In general, each individual or group will be limited to a total time of five (5) minutes. If members of the public wish to submit written statements, they should be submitted to the Designated Federal Official by November 30, 2012.

Matters to be Considered: The focus of the Committee's meeting will be the development of workplans by the Subcommittees (Jobs, Recreation and

Tourism Subcommittee and Stakeholder Engagement Subcommittee) to address the Committee's charge. The Committee will also hear from two panels of experts: One on successful ocean engagement initiatives, and one from MPA managers on engaging with the travel, recreation and tourism industries. On Wednesday, December 5, the Committee will meet with representatives from National Marine Sanctuary Advisory Councils to discuss fostering links between MPAs and the recreation, travel and tourism industries. The agenda is subject to change. The latest version will be posted at *http://www.mpa.gov.*

Dated: November 8, 2012.

Daniel J. Basta,

Director, Office of National Marine Sanctuaries, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2012–27735 Filed 11–14–12; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC352

Second 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 (NOAA), Department of Commerce.

ACTION: Notice of reduction payment tender and industry fee collection system effective date.

SUMMARY: The FY 2005 Appropriations Act (the Appropriations Act) authorized a capacity reduction program for the Longline Catcher Processor Subsector of the Bering Sea and Aleutian Islands non-pollock groundfish fishery (Reduction Fishery). Pursuant to this authorization, the Freezer Longline Conservation Cooperative (FLCC) conducted the bid selection process and submitted a reduction plan to NMFS to purchase a single latent permit within the Reduction Fishery. On September 24, 2012, the National Marine Fisheries Service published regulations for the second fishing capacity reduction program for this Reduction Fishery. NMFS conducted a successful referendum approving the reduction loan repayment fees of $2,700,000 which post-reduction harvesters will repay over a 30-year period. Accordingly, NMFS is preparing to tender a reduction payment to the accepted bidder and implement an industry fee collection system to repay the loan.

DATES: The public has until December 17, 2012 to inform NMFS of any holding, owning, or retaining claims that conflict with the representations of bids as presented by the FLCC. Fee collection will begin on January 1, 2013.

ADDRESSES: Send comments about this notice to Paul Marx, Chief, Financial Services Division, NMFS, Attn: Second Non-Pollock Groundfish Longline Catcher Processor Buyback, 1315 East-West Highway, Silver Spring, MD 20910 (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Michael A. Sturtevant at (301) 427–8799, fax (301) 713–1306, or *michael.a.sturtevant@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In 2007, NMFS approved and implemented a $35.7 million fishing capacity reduction loan program for the Longline Catcher Processor Subsector, which represented the full amount authorized for that subsector of the $75 million authorized for the entire BSAI non-pollock groundfish fishery. The initial program removed three fishing vessels and 12 fishing licenses and permits for a loan amount of $35 million. All long-line catcher processors harvesting non-pollock groundfish were required to pay and forward a fee to NMFS to repay the loan. The original fee assessment was $0.02 per pound caught with payment and collection beginning on October 24, 2007. That rate has since been reduced to $0.0145 per pound.

None of the other BSAI non-pollock groundfish subsectors have expressed an interest in implementing a capacity reduction program for their subsector. A provision in the Appropriations Act permits the Secretary of Commerce to make available any of the unused loan amounts, originally allocated for each subsector, for capacity reduction programs in any of the subsectors after January 1, 2009.

Members of the BSAI Longline Catcher Processor Subsector informed NMFS that they wished to access the remaining loan amounts to undertake a second buyback. To implement this next buyback, the FLCC on behalf of the Reduction Fishery was required by the Appropriations Act to draft and submit a Reduction Plan to NMFS. On August 27, 2010, the FLCC submitted a Reduction Plan to access $2.7 million of the total remaining $39,105,450 funds to purchase a single latent permit.

NMFS published proposed program regulations on July 30, 2012 (77 FR 44572), and final program regulations on September 24, 2012 (77 FR 58775), to implement the second reduction program. Interested persons should review these for further program details.

II. Present Status

NMFS conducted a referendum to determine the industry's willingness to repay a fishing capacity reduction loan to purchase the permit identified in the reduction plan. NMFS mailed ballots to 37 holders of record of LLP licenses in the fishery who were eligible to vote in the referendum. The voting period opened on October 24, 2012, and closed on November 7, 2012. NMFS received 32 timely and valid votes; all 32 of the votes approved the fees. This exceeded majority of permit holders (19) required for industry fee system approval. Consequently, the referendum was successful and permit holders approved the industry fee system. Accordingly, the reduction contract is in full force and effect and NMFS is preparing to tender and disburse a reduction payment to the selected bidder.

III. Reduction Payment Tender

NMFS publishes this notice to inform the public before tendering the reduction payment to Permit Holding LLC (the selected bidder), for LLP license LLG2085 with area endorsements for Bering Sea Catcher/Processor Hook and Longline and Aleutian Islands Catcher/Processor Hook and Longline. NMFS will tender the reduction payment on or about December 17, 2012. When NMFS tenders the reduction payment to Permit Holding LLC, the selected bidder must permanently stop all further fishing with the reduction permit it has relinquished. The selected bidder, in accordance with section 5 of the relinquishment contract, must notify all creditors or other parties with security interests in the reduction permit.

This notice provides the public (including creditors or other parties) 30 days from publication of this notice to advise NMFS in writing of any holding, owning, or retaining claims that conflict with the representations of the bid as presented by the FLCC.

IV. Fee System Effective Date

This notice also establishes the reduction loan repayment fee's effective date in accordance with subpart M to 50 CFR 600.1108. The second BSAI non-pollock groundfish longline catcher processor program fee payment and

collection will begin on January 1, 2013. Starting on this date, additional fees will be assessed and collected on all harvested Pacific cod, including that used for bait or discarded, on all members of this subsector. The initial fee applicable to this second loan in the BSAI longline program's reduction fishery is $0.001 per pound. Subsector members must pay and collect the fee in the manner set out in 50 CFR 600.1108 and the framework rule. Consequently, all subsector members may wish to read subpart L to 50 CFR 600.1013 to understand how fish harvesters must pay and fish buyers must collect the fee.

Dated: November 9, 2012.

Dana Flowerlake,

Acting Deputy Director, Office of Management and Budget, National Marine Fisheries Service.

[FR Doc. 2012–27820 Filed 11–14–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC153

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Rocky Intertidal Monitoring Surveys on the South Farallon Islands, CA

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

ACTION: Notice; issuance of an incidental harassment authorization.

SUMMARY: In accordance with the Marine Mammal Protection Act (MMPA) regulations, notification is hereby given that NMFS has issued an Incidental Harassment Authorization (IHA) to the National Ocean Service's Office of National Marine Sanctuaries Gulf of the Farallones National Marine Sanctuary (GFNMS) to take marine mammals, by harassment, incidental to rocky intertidal monitoring work and searching for black abalone, components of the Sanctuary Ecosystem Assessment Surveys.

DATES: Effective November 8, 2012, through November 7, 2013.

ADDRESSES: A copy of the authorization, application, and associated Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) and Biological Opinion may be obtained by writing to Michael Payne, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910, telephoning the contact listed below (see **FOR FURTHER INFORMATION CONTACT**), or visiting the Internet at: *http://www.nmfs.noaa.gov/pr/permits/incidental.htm.* Documents cited in this notice may also be viewed, by appointment, during regular business hours, at the aforementioned address.

FOR FURTHER INFORMATION CONTACT: Candace Nachman, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking, other means of effecting the least practicable impact on the species or stock and its habitat, and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''* * * an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.''

Section 101(a)(5)(D) of the MMPA established an expedited process by which citizens of the United States can apply for an authorization to incidentally take small numbers of marine mammals by harassment. Section 101(a)(5)(D) establishes a 45-day time limit for NMFS review of an application followed by a 30-day public notice and comment period on any proposed authorizations for the incidental harassment of marine mammals. Within 45 days of the close of the comment period, NMFS must either issue or deny the authorization. Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: ''any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].''

Summary of Request

On May 13, 2012, NMFS received an application from GFNMS for the taking of marine mammals incidental to rocky intertidal monitoring work and searching for black abalone. NMFS determined that the application was adequate and complete on July 20, 2012. On August 23, 2012, we published a notice in the **Federal Register** of our proposal to issue an IHA with preliminary determinations and explained the basis for the proposal and preliminary determinations (77 FR 50990). The notice initiated a 30-day public comment period. Responses are discussed below.

GFNMS proposes to continue rocky intertidal monitoring work and the search for black abalone in areas previously unexplored for black abalone for periods of 4–8 days in November 2012 and February 2013. All work will be done only during daylight minus low tides. This is a long-term study that began in 1992 and at present is anticipated to continue beyond November 2013. This IHA is only effective for a 12-month period. In future years (depending on funding), survey activities may occur in February, August, and November. For purposes of the present request, four sites will be sampled during both November and February, with two additional sites to be sampled in February only. The following specific aspects of the activities are likely to result in the take of marine mammals: presence of survey personnel near pinniped haulout sites and approach of survey personnel towards hauled out pinnipeds. Take, by Level B harassment only, of individuals of five species of marine mammals is anticipated to result from the specified activity.

Description of the Specified Activity and Specified Geographic Region

Since the listing of black abalone as ''endangered'' under the U.S. Endangered Species Act (ESA; 16 U.S.C. 1531 *et seq.*), NMFS has requested that GFNMS explore as much of the shoreline as possible, as well as document and map the location of quality habitat for black abalone and the location of known animals. This listing

prompted the need to expand the search for black abalone into other areas on the South Farallon Islands (beyond those that have been studied since 1992) to gain a better understanding of the abundance and health of the black abalone population in this remote and isolated location. The monitoring is planned to remain ongoing, and efforts to assess the status and health of the black abalone population on the South Farallon Islands may take several years, and perhaps decades, because black abalone tend to be very cryptic and difficult to find, especially when they are sparse and infrequent in occurrence. In order for the assessment of black abalone to be more comprehensive, GFNMS needs to expand shore searches in areas beyond the proximity of their quantitative quadrat sampling areas and also into new areas on Southeast Farallon and Maintop (West End) Islands. Additional information regarding the purpose of the research is contained in the Notice of Proposed IHA (77 FR 50990, August 23, 2012).

Routine shore activity will continue to involve the use of only non-destructive sampling methods to monitor rocky intertidal algal and invertebrate species abundances (see Figure 2 in GFNMS' application). The sampling, photographic documentation, and shore walks for the period of this IHA have been scheduled to occur in November 2012 and February 2013. (In future years, surveys conducted under separate IHA(s) may occur 3 times annually: February, August, and November, based on funding.) Each survey will last for approximately 4 to 8 days. All work will be done only during daylight minus, low tides. Each location (as listed in Tables 2 and 3 in GFNMS' application) will be visited/sampled by three to four biologists, for a duration of 3–4 hours, one to two times each minus tide cycle, during November and February. The Notice of Proposed IHA contains additional information on the survey methodology (77 FR 50990, August 23, 2012). That information has not changed and is therefore not repeated here.

PRBO Conservation Science (PRBO) continues its year round pinniped and seabird research and monitoring efforts on the South Farallon Islands, which began in 1968, under MMPA scientific research permits and IHAs. GFNMS biologists will gain access to the sites via boats operated by PRBO, with disturbance and incidental take authorized via IHAs issued to PRBO. For this reason, GFNMS has not requested authorization for take from disturbance by boat, as incidental take from that activity is authorized in a separate IHA.

Specified Geographic Location and Activity Timeframe

The Farallon Islands consists of a chain of seven islands located approximately 48 km (30 mi) west of San Francisco, near the edge of the continental shelf and in the geographic center of the GFNMS (see Figure 1 in GFNMS' application). The nearshore and offshore waters are foraging areas for pinniped species discussed in this document. The two largest islands of the seven islands are the Southeast Farallon and Maintop (aka West End) Islands. These and several smaller rocks are collectively referred to as the South Farallon Islands and are the subject of this IHA.

Current areas that are sampled during November and February are: Blow Hole Peninsula; Mussel Flat; Dead Sea Lion Flat; and Low Arch (see Figure 2 in GFNMS' application). Current areas that are sampled only during February are: Raven's Cliff and Drunk Uncle Islet. Areas to be added for intensive black abalone assessment and habitat mapping sampling during November and February include: East Landing; North Landing; Fisherman's Bay; and Weather Service Peninsula on Southeast Farallon Island. Areas to be added for intensive black abalone assessment and habitat mapping during February only include: Ravens' Cliff; Indian Head; Shell Beach; and Drunk Uncle Islet (see Figure 2 in GFNMS' application). Specific dates of sampling in February and November of each year will vary, as in the past, dependent on tide conditions, boat logistics to the island, staff schedules, island housing availability, seabird breeding cycles, and at the discretion of Refuge management. Each visit will last approximately 4–8 days in November 2012 and February 2013. Additional information on the specified geographic location is contained in the Notice of Proposed IHA (77 FR 50990, August 23, 2012).

Accessing portions of the intertidal habitat may cause incidental Level B (behavioral) harassment of pinnipeds through some unavoidable approaches if pinnipeds are hauled out directly in the study plots or while biologists walk from one location to another. No motorized equipment is involved in conducting these surveys. The species for which Level B harassment is requested are: California sea lions (*Zalophus californianus californianus*); harbor seals (*Phoca vitulina richardii*); northern elephant seals (*Mirounga angustirostris*); Stellar sea lions (*Eumetopias jubatus*); and northern fur seals (*Callorhinus ursinus*).

Comments and Responses

A Notice of Proposed IHA was published in the **Federal Register** on August 23, 2012 (77 FR 50990) for public comment. During the 30-day public comment period, NMFS received one letter from the Marine Mammal Commission. No other organizations or private citizens provided comments on the proposed issuance of an IHA for this activity. The Marine Mammal Commission recommended that NMFS issue the IHA, subject to inclusion of the proposed mitigation and monitoring measures. NMFS has included all of the mitigation and monitoring measures proposed in the Notice of Proposed IHA (77 FR 50990, August 23, 2012) in the issued IHA.

Description of Marine Mammals in the Area of the Specified Activity

Many of the shores of the two South Farallon Islands provide resting, molting, and breeding habitat for pinniped species: northern elephant seals; harbor seals; California sea lions; northern fur seals; and Steller sea lions. California sea lion is the species anticipated to be encountered most frequently during the specified activity. The other four species are only anticipated to be encountered at some of the sites. Tables 2 and 3 in GFNMS' application outline the average and maximum expected occurrences of each species at each sampling location in November and February, respectively. Numbers are based on weekly surveys conducted by PRBO. The data in these tables are from counts conducted in February and November 2010 and 2011. Figures 3, 4, and 5 in GFNMS' application depict the overlap between pinniped haulouts and abalone sampling sites. Of the five species noted here, only the eastern stock of Stellar sea lion (which is the stock found in the activity area) is listed as threatened under the ESA and as depleted under the MMPA.

We refer the public to Carretta *et al.,* (2011) for general information on these species. The publication is available on the Internet at: *http://www.nmfs.noaa.gov/pr/pdfs/sars/po2011.pdf.* Additional information on the status, distribution, seasonal distribution, and life history can also be found in GFNMS' application and NMFS' Notice of Proposed IHA (77 FR 50990, August 23, 2012). The information has not changed and is therefore not repeated here.

California (southern) sea otters (*Enhydra lutris nereis*), listed as

threatened under the ESA and categorized as depleted under the MMPA, usually range in coastal waters within 2 km (1.2 mi) of shore. PRBO has not encountered California sea otters on Southeast Farallon Island during the course of seabird or pinniped research activities over the past five years. This species is managed by the USFWS and is not considered further in this notice.

Potential Effects of the Specified Activity on Marine Mammals

The appearance of researchers may have the potential to cause Level B harassment of any pinnipeds hauled out on Southeast Farallon and Maintop (West End) Islands. Although marine mammals are never deliberately approached by abalone survey personnel, approach may be unavoidable if pinnipeds are hauled out in the immediate vicinity of the permanent abalone study plots. Disturbance may result in reactions ranging from an animal simply becoming alert to the presence of researchers (e.g., turning the head, assuming a more upright posture) to flushing from the haul-out site into the water. NMFS does not consider the lesser reactions to constitute behavioral harassment, or Level B harassment takes, but rather assumes that pinnipeds that move greater than 1 m (3.3 ft) or change the speed or direction of their movement in response to the presence of researchers are behaviorally harassed, and thus subject to Level B taking. Animals that respond to the presence of researchers by becoming alert, but do not move or change the nature of locomotion as described, are not considered to have been subject to behavioral harassment. NMFS' Notice of Proposed IHA (77 FR 50990, August 23, 2012) contains information regarding potential impacts to marine mammals from the specified activity. The information has not changed and is therefore not repeated here.

Typically, even those reactions constituting Level B harassment would result at most in temporary, short-term disturbance. In any given study season (i.e., November 2012 and February 2013), the researchers will visit the islands for a total of 4–8 days each of the two months, and each site is not visited during both months. Visits to each site are thus separated by several months. Each site visit typically lasts 3–4 hours. Therefore, disturbance of pinnipeds resulting from the presence of researchers lasts only for short periods of time and is separated by significant amounts of time in which no disturbance occurs. Because such disturbance is sporadic, rather than chronic, and of low intensity, individual marine mammals are unlikely to incur any detrimental impacts to vital rates or ability to forage and, thus, loss of fitness. Correspondingly, even local populations, much less the overall stocks of animals, are extremely unlikely to accrue any significantly detrimental impacts.

NMFS does not anticipate that the activities would result in the injury, serious injury, or mortality of pinnipeds because (1) the timing of research visits would preclude separation of mothers and pups for four of the pinniped species, as activities occur outside of the pupping/breeding season and (2) elephant seals are generally not susceptible to disturbance as a result of researchers' presence. In addition, researchers will exercise appropriate caution approaching sites, especially when pups are present and will redirect activities when pups are present.

Anticipated Effects on Marine Mammal Habitat

The only habitat modification associated with the activity is the quadrat locations being marked with marine epoxy. The plot corners are marked with a 3x3 cm (1.2x1.2 in) patch of marine epoxy glued to the benchrock for relocating the quadrat sites. Markers have been in place since 1993, and pinniped populations have increased throughout the islands during this time. Maintenance is sometimes required, which consists of replenishing worn markers with fresh epoxy or replacing markers that have become dislodged. No gas power tools are used, so there is no potential for noise or accidental fuel spills disturbing animals and impacting habitats. Thus, the activity is not expected to have any habitat-related effects, including to marine mammal prey species, that could cause significant or long-term consequences for individual marine mammals or their populations.

Mitigation

In order to issue an incidental take authorization (ITA) under Section 101(a)(5)(D) of the MMPA, NMFS must, where applicable, set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses (where relevant).

GFNMS shall implement several mitigation measures to reduce potential take by Level B (behavioral disturbance) harassment. Measures include: (1) Coordinating sampling efforts with other permitted activities (i.e., PRBO and USFWS); (2) conducting slow movements and staying close to the ground to prevent or minimize stampeding; (3) avoiding loud noises (i.e., using hushed voices); (4) vacating the area as soon as sampling of the site is completed; (5) monitoring the offshore area for predators (such as killer whales and white sharks) and avoid flushing of pinnipeds when predators are observed in nearshore waters; (6) using binoculars to detect pinnipeds before close approach to avoid being seen by animals; and (7) rescheduling work at sites where pups are present, unless other means to accomplishing the work can be done without causing disturbance to mothers and dependent pups.

The methodologies and actions noted in this section will be utilized and are included as mitigation measures in the IHA to ensure that impacts to marine mammals are mitigated to the lowest level practicable. The primary method of mitigating the risk of disturbance to pinnipeds, which will be in use at all times, is the selection of judicious routes of approach to abalone study sites, avoiding close contact with pinnipeds hauled out on shore, and the use of extreme caution upon approach. In no case will marine mammals be deliberately approached by abalone survey personnel, and in all cases every possible measure will be taken to select a pathway of approach to study sites that minimizes the number of marine mammals potentially harassed. In general, researchers will stay inshore of pinnipeds whenever possible to allow maximum escape to the ocean. Each visit to a given study site will last for approximately 4 hours, after which the site is vacated and can be re-occupied by any marine mammals that may have been disturbed by the presence of abalone researchers. By arriving before low tide, worker presence will tend to encourage pinnipeds to move to other areas for the day before they haul out and settle onto rocks at low tide.

The following measures will be implemented to avoid disturbances to elephant seal pups. Disturbances to females with dependent pups can be mitigated to the greatest extent practicable by avoiding visits to those intertidal sites with pinnipeds that are actively nursing, with the exception of northern elephant seals. The time of year when GFNMS plans to sample avoids disturbance to young, dependent pups, with the exception of northern elephant seals. Thus, early February and

November, at minimum, are preferable for the intertidal survey work in order to minimize the risk of harassment. Harassment of nursing northern elephant seal pups may occur but only to a limited extent. Disruption of nursing to northern elephant seal pups will occur only as biologists pass by the area. No flushing of nursing northern elephant seal pups is anticipated, and no disturbance to newborn northern elephant seals (pups less than 1 week old) is anticipated. Moreover, elephant seals have a much higher tolerance of nearby human activity than sea lions or harbor seals. In the event of finding pinnipeds breeding and nursing, the intertidal monitoring activities will be re-directed to sites where these activities and behaviors are not occurring. This mitigation measure will reduce the possibility of takes by harassment and further reduce the remote possibility of serious injury or mortality of dependent pups.

GFNMS will suspend sampling and monitoring operations immediately if an injured marine mammal is found in the vicinity of the project area and the abalone site sampling activities could aggravate its condition.

NMFS has carefully evaluated GFNMS' proposed mitigation measures and considered a range of other measures in the context of ensuring that NMFS prescribes the means of effecting the least practicable impact on the affected marine mammal species and stocks and their habitat. Our evaluation of potential measures included consideration of the following factors in relation to one another:

- The manner in which, and the degree to which, the successful implementation of the measure is expected to minimize adverse impacts to marine mammals;
- The proven or likely efficacy of the specific measure to minimize adverse impacts as planned; and
- The practicability of the measure for applicant implementation.

Based on our evaluation of the final mitigation measures, NMFS has determined that they provide the means of effecting the least practicable impact on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Monitoring and Reporting

In order to issue an ITA for an activity, Section 101(a)(5)(D) of the MMPA states that NMFS must, where applicable, set forth ''requirements pertaining to the monitoring and reporting of such taking''. The MMPA implementing regulations at 50 CFR 216.104 (a)(13) indicate that requests for ITAs must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the action area.

Currently many aspects of pinniped research are being conducted by PRBO scientists on the Farallon Islands, which includes elephant seal pup tagging and behavior observations with special notice to tagged animals. Additional observations are always desired, such as observations of pinniped carcasses bearing tags, as well as any rare or unusual marine mammal occurrences. GFNMS' observations and reporting will add to the observational database and on-going marine mammal assessments on the Farallon Islands.

GFNMS can add to the knowledge of pinnipeds on the South Farallon Islands by noting observations of: (1) Unusual behaviors, numbers, or distributions of pinnipeds, such that any potential follow-up research can be conducted by the appropriate personnel; (2) tag-bearing carcasses of pinnipeds, allowing transmittal of the information to appropriate agencies and personnel; and (3) rare or unusual species of marine mammals for agency follow-up.

Monitoring requirements in relation to GFNMS' abalone research surveys include observations made by the applicant. Information recorded will include species counts (with numbers of pups/juveniles), numbers of observed disturbances, and descriptions of the disturbance behaviors during the abalone surveys. Observations of unusual behaviors, numbers, or distributions of pinnipeds on the South Farallon Islands will be reported to NMFS and PRBO so that any potential follow-up observations can be conducted by the appropriate personnel. In addition, observations of tag-bearing pinniped carcasses as well as any rare or unusual species of marine mammals will be reported to NMFS and PRBO.

If at any time injury, serious injury, or mortality of the species for which take is authorized should occur, or if take of any kind of any other marine mammal occurs, and such action may be a result of the abalone research, GFNMS will suspend research activities and contact NMFS immediately to determine how best to proceed to ensure that another injury or death does not occur and to ensure that the applicant remains in compliance with the MMPA.

A draft final report must be submitted to NMFS Office of Protected Resources within 60 days after the conclusion of the 2012–2013 field season or 60 days prior to the start of the next field season if a new IHA will be requested. The report will include a summary of the information gathered pursuant to the monitoring requirements set forth in the IHA. A final report must be submitted to the Director of the NMFS Office of Protected Resources and to the NMFS Southwest Office Regional Administrator within 30 days after receiving comments from NMFS on the draft final report. If no comments are received from NMFS, the draft final report will be considered to be the final report.

Estimated Take by Incidental Harassment

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].

All anticipated takes would be by Level B harassment, involving temporary changes in behavior. The mitigation and monitoring measures are expected to minimize the possibility of injurious or lethal takes such that take by injury, serious injury, or mortality is considered remote. Animals hauled out close to the actual survey sites may be disturbed by the presence of biologists and may alter their behavior or attempt to move away from the researchers. No motorized equipment is involved in conducting the abalone monitoring surveys.

As discussed earlier, NMFS considers an animal to have been harassed if it moved greater than 1 m (3.3 ft) in response to the researcher's presence or if the animal was already moving and changed direction and/or speed, or if the animal flushed into the water. Animals that became alert without such movements were not considered harassed. The distribution of pinnipeds hauled out on beaches is not consistent throughout the year. The number of marine mammals disturbed will vary by month and location. PRBO obtains weekly counts of pinnipeds on the South Farallon Islands, dating back to the early 1970s. GFNMS used data collected by PRBO in February and November 2010 and 2011 (since those are the months they propose to conduct their abalone monitoring in 2012 and

2013) to estimate the number of pinnipeds that may potentially be taken by Level B (behavioral) harassment. Table 3 in GFNMS' IHA application and Table 1 here present the maximum numbers of California sea lions, harbor seals, northern elephant seals, northern fur seals, and Steller sea lions that may be present at the various sampling sites in November and February. As indicated in the table, some sites will be sampled in both months and others only in one of the two survey months. Based on this information, NMFS has authorized the take, by Level B harassment only, of 6,850 California sea lions, 175 harbor seals, 225 northern elephant seals, 20 northern fur seals, and 95 Steller sea lions. These numbers are considered to be maximum take estimates; therefore, actual take may be slightly less if animals decide to haul out at a different location for the day or animals are out foraging at the time of the survey activities.

Negligible Impact and Small Numbers Analysis and Determination

NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''* * * an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.'' In making a negligible impact determination, NMFS considers a variety of factors, including but not limited to: (1) The number of anticipated mortalities; (2) the number and nature of anticipated injuries; (3) the number, nature, intensity, and duration of Level B harassment; and (4) the context in which the take occurs.

No injuries, serious injuries, or mortalities are anticipated to occur as a result of GFNMS' rocky intertidal monitoring surveys, and none are authorized. The behavioral harassments that could occur would be of limited duration, as researchers only conduct sampling two times per year for a total of 4–8 days each time. Additionally, each site is sampled for approximately 3–4 hours before moving to the next sampling site. Therefore, disturbance will be limited to a short duration, allowing pinnipeds to reoccupy the sites within a short amount of time.

Some of the pinniped species use the islands to conduct pupping and/or breeding. However, with the exception of northern elephant seals, GFNMS will conduct its abalone site sampling outside of the pupping/breeding seasons. GFNMS will implement measures to minimize impacts to northern elephant seals nursing or tending to dependent pups. Such measures will likely avoid mother/pup separation or trampling of pups.

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Table 1. Estimated number of animals to be disturbed at each sampling site during each month of surveys based on maximum daily counts of pinnipeds estimated from PRBO monitoring data and the total proposed number of Level B harassment takes to be authorized for each species.

	East Landing & Blowhole Peninsula	North Landing & Fisherman's Bay	Dead Sea Lion Flat	Mussel Flat	Low Arch	Weather Service Peninsula**	Raven's Cliff**	Indian Head**	Shell Beach**	Drunk Uncle Islet & Pelican Bowl**	Proposed Level B Take
CA Sea Lion November	5	520	880	180	575	120	NA	NA	NA	NA	
CA Sea Lion February	50	35	850	110	280	215	260	775	1420	575	
Total	55	555	1730	290	855	335	260	775	1420	575	**6850**
Harbor Seal November	10	10	5	50	-	5	NA	NA	NA	NA	
Harbor Seal February	10	20	10	55	-	-	-	-	-	-	
	20	30	15	105	0	5	0	0	0	0	**175**
N. Elephant Seal November	-	40	25	60	45	-	NA	NA	NA	NA	
N. Elephant Seal February	-	5	5	5	5	-	-	25	10	-	
Total	0	45	30	65	50	-	0	25	10	0	**225**
N. Fur Seal November	-	-	-	-	-	-	NA	NA	NA	NA	
N. Fur Seal February	-	-	-	-	-	-	-	20	-	-	
Total	0	0	0	0	0	0	0	20	0	0	**20**
Steller Sea Lion November	-	-	10	-	-	-	NA	NA	NA	NA	
Steller Sea Lion February	-	-	15	15	5	5	5	20	20	-	
Total	0	0	25	15	5	5	5	20	20	0	**95**

* Estimates above are based on the SEAS team sampling each area once in each month indicated.
NA: Not applicable.
**These areas on Maintop Island (West End Island) will not be sampled in November to minimize disturbance to seabirds and marine mammals.

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Of the five marine mammal species anticipated to occur in the activity areas, only the Steller sea lion is listed as threatened under the ESA. The species is also designated as depleted under the MMPA. Table 2 in this document presents the abundance of each species or stock, the authorized take estimates, and the percentage of the affected populations or stocks that may be taken by harassment. Based on these estimates, GFNMS would take less than 1% of each species or stock, with the exception of the California sea lion, which would result in an estimated take of 2.3% of the stock. Because these are maximum estimates, actual take numbers are likely to be lower, as some animals may select other haulout sites the day the researchers are present.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the required mitigation and monitoring measures, NMFS finds that the rocky intertidal monitoring program will result in the incidental take of small numbers of marine mammals, by Level B harassment only, and that the total taking from the rocky intertidal monitoring program will have a negligible impact on the affected species or stocks.

TABLE 2—POPULATION ABUNDANCE ESTIMATES, TOTAL AUTHORIZED LEVEL B TAKE, AND PERCENTAGE OF POPULATION THAT MAY BE TAKEN FOR THE POTENTIALLY AFFECTED SPECIES DURING THE PROPOSED ROCKY INTERTIDAL MONITORING PROGRAM

Species	Abundance*	Total authorized level B take	Percentage of stock or population
Harbor Seal	30,196	175	0.6
California Sea Lion	296,750	6,850	2.3
Northern Elephant Seal	124,000	225	0.2
Steller Sea Lion	58,334–72,223	95	0.1–0.2
Northern Fur Seal	9,968	20	0.2

* Abundance estimates are taken from the 2011 U.S. Pacific Marine Mammal Stock Assessments (Carretta *et al.,* 2012).

Impact on Availability of Affected Species or Stock for Taking for Subsistence Uses

There are no relevant subsistence uses of marine mammals implicated by this action. Therefore, NMFS has determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Endangered Species Act (ESA)

There is one marine mammal species listed as threatened under the ESA with confirmed or possible occurrence in the project area: the eastern U.S. stock of Steller sea lion. NMFS' Permits and Conservation Division conducted consultation with NMFS' Endangered Species Division, Southwest Regional Office, under section 7 of the ESA on the issuance of an IHA to GFNMS under section 101(a)(5)(D) of the MMPA for this activity. In October 2012, NMFS finished conducting its section 7 consultation and issued a Biological Opinion, and concluded that the issuance of the IHA associated with GFNMS' rocky intertidal monitoring program is not likely to jeopardize the continued existence of the threatened eastern U.S. stock of Steller sea lion or result in the destruction or adverse modification of critical habitat for the species. The mitigation measures included in the final IHA have also been included in the Incidental Take Statement provided with the Biological Opinion.

National Environmental Policy Act (NEPA)

NMFS has prepared an EA that includes an analysis of potential environmental effects associated with NMFS' issuance of an IHA to GFNMS to take marine mammals incidental to conducting rocky intertidal monitoring surveys on the South Farallon Islands, California. NMFS has finalized the EA and prepared a FONSI for this action. Therefore, preparation of an Environmental Impact Statement is not necessary.

Authorization

As a result of these determinations, NMFS has authorized the take of marine mammals incidental to GFNMS' rocky intertidal and black abalone monitoring research activities, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated.

Dated: November 8, 2012.

Helen M. Golde,

Acting Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2012–27817 Filed 11–14–12; 8:45 am]

BILLING CODE 3510–22–P

COMMISSION OF FINE ARTS

Notice of Meeting

The next meeting of the U.S. Commission of Fine Arts is scheduled for 15 November 2012, at 9:00 a.m. in the Commission offices at the National Building Museum, Suite 312, Judiciary Square, 401 F Street NW., Washington DC, 20001–2728. Items of discussion may include buildings, parks, and memorials.

Draft agendas and additional information regarding the Commission are available on our Web site: *www.cfa.gov.* Inquiries regarding the agenda and requests to submit written or oral statements should be addressed to Thomas Luebke, Secretary, U.S. Commission of Fine Arts, at the above address; by emailing *CFAStaff@cfa.gov;* or by calling 202–504–2200. Individuals requiring sign language interpretation for the hearing impaired should contact the Secretary at least 10 days before the meeting date.

Dated: October 31, 2012, in Washington DC.

Thomas Luebke, AIA,

Secretary.

[FR Doc. 2012–27532 Filed 11–14–12; 8:45 am]

BILLING CODE 6331–01–M

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Intent To Prepare a Supplement to the 2008 Environmental Impact Statement for Introduction of the P–8A Multi-Mission Maritime Aircraft Into the U.S. Navy Fleet

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: Pursuant to Section 102(2)(c) of the National Environmental Policy Act of 1969 and regulations implemented by the Council on Environmental Quality (40 Code of Federal Regulations parts 1500–1508), the Department of the Navy (DoN) announces its intent to prepare a Supplement to the Environmental Impact Statement (EIS) for the Introduction of the P–8A Multi-Mission Maritime Aircraft (MMA) to the U.S. Navy Fleet. The Supplemental EIS will address the potential environmental impacts of new homebasing alternatives and updated P–8A MMA program information.

SUPPLEMENTARY INFORMATION: In September 2008, the DoN completed the Final EIS for the Introduction of the P–8A MMA into the U.S. Navy Fleet, which evaluated the environmental impacts of homebasing 12 P–8A MMA fleet squadrons (72 aircraft) and one Fleet Replacement Squadron (FRS) (12 aircraft) at established maritime patrol homebases. The Final EIS analyzed transitioning personnel, new construction or renovation of structures, and all airfield operations necessary to accommodate the P–8A MMA as the DoN phases the P–3C Orion out of service.

The Assistant Secretary of the Navy for Installations and Environment reviewed the Final EIS, and after carefully weighing the operational, social, and environmental impacts of the proposed action, determined the DoN would homebase five fleet squadrons and the FRS at Naval Air

Station (NAS) Jacksonville, four fleet squadrons at NAS Whidbey Island, and three fleet squadrons at Marine Corps Base (MCB) Hawaii Kaneohe Bay, with periodic squadron detachments at NAS North Island (Alternative 5). A notice of the Record of Decision (ROD) was published in the **Federal Register** on January 2, 2009 (74 FR 100). At the time, Alternative 5 was considered to best meet mission requirements because it optimized operational efficiencies related to training and contractor logistics support functions at the three established maritime patrol homebase locations.

To meet the DoN's current and future requirements and maximize the efficiency of support facilities, simulation training equipment, and on-site support personnel, the DoN proposes to analyze additional alternatives for P–8A aircraft homebasing. The DoN has determined that a dual-siting alternative, rather than homebasing the aircraft at three locations, now best meets current requirements. The two potential homebase locations for the P–8A MMA are NAS Jacksonville, located in Duval County, Florida, and NAS Whidbey Island, located in Island County, Washington.

Homebasing the P–8A MMA at two locations would result in differences in numbers of aircraft and personnel, as well as associated facility requirements at several Naval installations when compared to the 2008 ROD. For NAS Jacksonville, this would mean an increase in P–8A MMA aircraft and personnel permanently assigned, but would require no new facilities. For NAS Whidbey Island, this would mean an increase in P–8A MMA aircraft and personnel permanent assigned, as well as an expanded facility footprint. For MCB Hawaii Kaneohe Bay, the proposed dual-siting would result in the new assignment of two rotating P–8A MMA detachments, the elimination of permanently assigned P–8A MMA aircraft and personnel, and a reduced facility footprint. For NAS North Island, there would be no change in P–8A MMA aircraft, personnel or facility requirements from the 2008 ROD.

The environmental analysis in the Supplemental EIS will focus on several aspects of the proposed action: facility and infrastructure renovation and construction, personnel changes, and aircraft operations at the homebase airfields. Resource areas to be addressed in the Supplemental EIS will include, but not be limited to: air quality, noise environment, land use, socioeconomic, infrastructure and community services, natural resources, biological resources, cultural resources, safety and environmental hazards. The analysis will evaluate direct and indirect impacts, and will account for cumulative impacts from other relevant activities near the installations. Relevant and reasonable measures that could avoid or mitigate environmental effects will also be analyzed. Additionally, the DoN will undertake any consultation applicable by law and regulation. No decision will be made to implement any alternative for homebasing the P–8A aircraft until the Supplemental EIS process is completed and a new ROD is signed by the DoN.

During the 45-day public comment and agency review period following release of the Draft Supplemental EIS, anticipated in Summer 2013, the DoN will schedule public meetings to discuss findings of the Draft Supplemental EIS and to receive public comments. The public meetings will be held near each of the homebasing locations. Dates, locations, and times for the public meetings will be announced in the **Federal Register** and local media at the appropriate time.

FOR FURTHER INFORMATION CONTACT: The DoN has established a public Web site for the Supplemental EIS: *http://www.mmaseis.com.* This public web site includes up-to-date information on the project and schedule, as well as related documents associated with the Supplemental EIS and 2008 Final EIS. To be included on the DoN's mailing list for the Supplemental EIS (or to receive a copy of the Draft Supplemental EIS), submit an electronic request through the project Web site under ''mailing list'' or a written request to: P–8A MMA EIS Project Manager (Code EV21/CZ); Naval Facilities Engineering Command (NAVFAC) Atlantic, 6506 Hampton Blvd., Norfolk, VA 23508.

Dated: November 8, 2012.

S.F. Thompson,

Captain, Office of the Judge Advocate General, U.S. Navy, Alternate Federal Register Liaison Officer.

[FR Doc. 2012–27762 Filed 11–14–12; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Extension of Comment Period for the Draft Environmental Impact Statement for Military Training Activities at the Naval Weapons Systems Training Facility Boardman, OR

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: A notice of availability was published by the U.S. Environmental Protection Agency (EPA) in the **Federal Register** (77 FR 55213) on September 7, 2012 for Draft Environmental Impact Statement (EIS) for Military Training Activities at the Naval Weapons Systems Training Facility. The public comment period ended on November 6, 2012. This notice confirms a 30 day extension of the public comment period until December 6, 2012 as announced by EPA in the **Federal Register** on November 9, 2012.

FOR FURTHER INFORMATION CONTACT: Mrs. Amy Burt, Naval Facilities Engineering Command Northwest, 1101 Tautog Circle Suite 203, Silverdale, Washington, 98315–1101, Attn: NWSTF Boardman Project Manager; or *http://www.NWSTFBoardmanEIS.com.*

SUPPLEMENTARY INFORMATION: The public comment period on the NWSTF Boardman EIS will be extended until December 6, 2012. Comments may be submitted in writing to Naval Facilities Engineering Command Northwest, Attention: Mrs. Amy Burt, NWSTF Boardman EIS Project Manager, 1101 Tautog Circle Suite 203, Silverdale, Washington, 98315–1101. In addition, comments may be submitted online at *http://www.NWSTFBoardmanEIS.com* during the comment period. All written comments must be postmarked by December 6, 2012, to ensure they become part of the official record. All written comments will be addressed in the Final EIS.

Copies of the Draft EIS are available for public review at the following libraries:

1. Multnomah County Library—Central Library, 801 Southwest 10th Avenue, Portland, Oregon.

2. Oregon Trail Library District—Boardman Library, 200 South Main Street, Boardman, Oregon.

3. Oregon Trail Library District—Heppner Branch, 444 North Main Street, Heppner, Oregon.

4. Salem Public Library—Central Branch, 585 Liberty Street Southeast, Salem, Oregon.

5. Salem Public Library—West Salem Branch, 395 Glen Creek Road Northwest, Salem, Oregon.

6. Stafford Hansell Government Center, 915 Southeast Columbia Drive, Hermiston, Oregon.

Copies of the Draft EIS are available for electronic viewing at *http://www.NWSTFBoardmanEIS.com.*

Dated: November 8, 2012.

S.F. Thompson,

Captain, Office of the Judge Advocate General, U.S. Navy, Alternate Federal Register Liaison Officer.

[FR Doc. 2012–27764 Filed 11–14–12; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. CP13–14–000; PF12–10–000]

Millennium Pipeline Company, L.L.C.; Notice of Application

Take notice that on November 1, 2012, Millennium Pipeline Company, L.L.C. (Millennium), One Blue Hill Plaza, Seventh Floor, P.O. Box 1565, Pearl River, New York 10965, filed an application pursuant to Section 7 of the Natural Gas Act (NGA) and Part 157 of the Commission's regulations, for authorization to construct, own, and operate the Hancock Compressor Station and related facilities (Project) located in the Town of Hancock, Delaware County, New York. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, call (866) 208–3676 or TTY, (202) 502–8659.

The Project will consist of a new 15,900 horsepower gas-fired turbine compressor and related facilities located on a 35.8 acre parcel of land (Millennium owns 10.8 acres and has an option to purchase the remaining 25 acres). The purpose of the Project is to provide 107,500 dekatherms per day (Dth/d) of firm transportation service on Millennium's system to the existing interconnection with Algonquin Gas Transmission, L.L.C. in Ramapo, New York and points further east. In addition, depending upon election of primary receipt points by Millennium's shippers, up to an additional 115,000 Dth/d of firm transportation service could be created between a recently completed interconnection with Laser Gathering and an existing interconnection with Columbia Gas Transmission, L.L.C. at Wagoner in Deerpark, New York. Millennium estimates that the project facilities will cost approximately $45.8 million and proposes to charge its existing system rates as recourse rates for the project. However, Millennium specifically does not seek a pre-determination of rolled-in rate treatment for the project's costs. The expansion shippers have elected to pay negotiated rates for the service.

Any questions regarding this application should be directed to Gary A. Kruse, Vice President—General Counsel & Secretary, Millennium Pipeline Company, L.L.C., One Blue Hill Plaza, Seventh Floor, P.O. Box 1565, Pearl River, New York 10965, by telephone at (845) 620–1300, by facsimile at (845) 620–1320, or by email at *kruse@millenniumpipeline.com,* or Jessica Fore, Baker Botts L.L.P., 1299 Pennsylvania Avenue NW., Washington, DC 20004–2400, by telephone at (202) 639–7727, by facsimile at (202) 585–1080, or by email at *Jessica.fore@bakerbotts.com.*

On May 1, 2012, the Commission staff granted Millennium's request to use the pre-filing process and assigned Docket No. PF12–10–000 to staff activities involving the Project. Now, as of the filing of this application on November 1, 2012, the NEPA Pre-Filing Process for this project has ended. From this time forward, this proceeding will be conducted in Docket No. CP13–14–000, as noted in the caption of this Notice.

Pursuant to Section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding, or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

Motions to intervene, protests and comments may be filed electronically via the internet in lieu of paper; see, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

Comment Date: November 29, 2012.

Dated: November 8, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–27734 Filed 11–14–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 6952–008]

Water Wheel Ranch; Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene, Protests, Recommendations, and Terms and Conditions

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Amendment of Exemption.

b. *Project No.:* 6952–008.

c. *Date filed:* December 12, 2011, and supplemented on October 8, 2012.

d. *Applicant:* Water Wheel Ranch.

e. *Name of Project:* Water Wheel Ranch Hydroelectric Project.

f. *Location:* The Water Wheel Ranch Hydroelectric Project would be located on the North Fork Little Cow Creek in Shasta County, California. The land on which all the project structures are located is owned by the applicant.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791a—825r.

h. *Applicant Contact:* Mr. Finley McMillan, P.O. Box 130, Round Mountain, CA 96084. Phone (530) 337–6581.

i. *FERC Contact:* Robert Bell, (202) 502–6062, *robert.bell@ferc.gov.*

j. *Status of Environmental Analysis:* This application is ready for environmental analysis at this time, and the Commission is requesting comments, reply comments, recommendations, terms and conditions, and prescriptions.

k. *Deadline for filing responsive documents:* All comments, motions to intervene, protests, recommendations, terms and conditions, and prescriptions due within *30 days* from the issuance date of this notice. All reply comments filed in response to comments submitted by any resource agency, Indian tribe, or person, must be filed with the Commission within 15 days from the issuance date of this notice.

Comments, protests, and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at *http://www.ferc.gov/docs-filing/efiling.asp.* The Commission strongly encourages electronic filings.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

l. *Description of the project:* The amended Water Wheel Ranch Hydroelectric Project would consist of: (1) Relocating powerhouse No. 2, which was destroyed by a forest fire, 850 feet closer to the dam, up the existing penstock, (2) installing a new 100-foot-long tailrace which would discharge into Cedar Creek, 1,400 feet upstream of the current discharge location and (3) appurtenant facilities. The applicant states there would be no change in project capacity.

m. This filing is available for review and reproduction at the Commission in the Public Reference Room, Room 2A, 888 First Street NE., Washington, DC 20426. The filing may also be viewed on the web at *http://www.ferc.gov/docs-filing/elibrary.asp* using the ''eLibrary'' link. Enter the docket number, P–6952, in the docket number field to access the document. For assistance, call toll-free 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov.* For TTY, call (202) 502–8659. A copy is also available for review and reproduction at the address in item h above.

n. Protests or Motions to Intervene—Anyone may submit a protest or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, and 385.214. In determining the appropriate action to take, the Commission will consider all protests filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any protests or motions to intervene must be received on or before the specified deadline date for the particular application.

q. All filings must (1) bear in all capital letters the title ''PROTEST'', ''MOTION TO INTERVENE'', ''COMMENTS'', ''REPLY COMMENTS,'' ''RECOMMENDATIONS,'' ''TERMS AND CONDITIONS,'' or ''PRESCRIPTIONS;'' (2) set forth in the heading, the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. Any of these documents must be filed by providing the original and seven copies to: The Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Office of Energy Projects, Federal Energy Regulatory Commission, at the above address. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Dated: November 8, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–27731 Filed 11–14–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PR13–5–000]

TEAK Texana Transmission Company, LP; Notice of Petition for Rate Approval

Take notice that on November 2, 2012, TEAK Texana Transmission Company, LP (TEAK) filed a Petition for Rate Approval pursuant to 284.123(b)(2) of the Commissions regulations for firm and interruptible natural gas transportation services, as more fully detailed in the petition.

Any person desiring to participate in this rate filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the date as indicated below. Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest

date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 7 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on Friday, November 16, 2012.

Dated: November 8, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–27730 Filed 11–14–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL13–18–000]

Electric Transmission Texas, LLC; Notice of Petition for Declaratory Order

Take notice that on November 6, 2012, pursuant to section 207(a)(2) of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure 18 CFR 385.207(a)(2), Electric Transmission Texas, LLC (ETT) filed a petition for declaratory order requesting that the Commission disclaim Federal Power Act (FPA) jurisdiction over (1) the transmission lines that ETT, an electric utility in the Electric Reliability Council of Texas (ERCOT) region that is not a public utility, will own and operate within ERCOT, (2) transmission service over those transmission facilities, and (3) sales of electric energy over the lines by companies that are not public utility companies under the FPA.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on November 27, 2012.

Dated: November 7, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–27708 Filed 11–14–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL13–17–000]

Blue Summit Wind, LLC; Notice of Petition for Declaratory Order

Take notice that on November 6, 2012, pursuant to section 207(a)(2) of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure 18 CFR 385.207(a)(2), Blue Summit Wind, LLC (Blue Summit) filed a petition for declaratory order requesting that the Commission disclaim jurisdiction over (1) interconnection facilities that deliver power from the Blue Summit's wind energy generator (Blue Summit Facility) located within the Southwest Power Pool region to an interconnection point on the transmission system of American Electric Power Company, Inc. and Electric Transmission Texas, LLC, within the Electric Reliability Council of Texas (ERCOT) region, (2) transmission and sales of energy over these interconnection facilities, and (3) the electric utilities in ERCOT that are not public utilities under the Federal Power Act as a result of the interconnection of Blue Summit.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on November 27, 2012.

Dated: November 7, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–27710 Filed 11–14–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PR13–4–000]

TexStar Transmission, LP; Notice of Petition for Rate Approval

Take notice that on November 2, 2012, TexStar Transmission, LP (TexStar) filed a Petition for Rate Approval pursuant to 284.123(b)(2) of the Commissions regulations for firm and interruptible natural gas transportation services, as more fully detailed in the petition.

Any person desiring to participate in this rate filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the date as indicated below. Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 7 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on Friday, November 16, 2012.

Dated: November 8, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–27733 Filed 11–14–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13314–001]

Corral Creek South Hydro, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On April 3, 2012, Corral Creek South Hydro, LLC filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Corral Creek South Pumped Storage Project (project) to be located near Twin Falls in Twin Falls County, Idaho. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The Commission issued a notice on May 11, 2012, accepting the application and soliciting comments, motions to intervene, and competing applications within a 60-day period. On July 10, 2012, the U.S. Department of the Interior filed a comment letter with the Commission stating the Shoshone-Paiute Tribe was not identified in the preliminary permit application as an Indian tribe that may be affected by the project (section 4.32(a)(2)). This notice is extending to the Shoshone-Paiute Tribe a 30-day period for filing comments, motions to intervene, and competing applications.

The proposed project would consist of: (1) A 180-foot-high, 8,400-foot-long upper earthen dam; (2) an upper reservoir with surface area of 118 acres, storage capacity of 9,120 acre-feet, and maximum pool elevation of 6,620 feet mean sea level (msl); (3) a 200-foot-high, 4,140-foot-long lower earthen dam; (4) a lower reservoir with surface area of 113 acres, storage capacity of 10,880 acre-feet, and maximum pool elevation of 5,500 feet msl; (5) a 30-foot-diameter, 4,710-foot-long steel penstock; (6) a powerhouse containing 4 pump/turbine units with a total installed capacity of 1,100 megawatts; (7) a 10.6-mile-long, 500-kilovolt transmission line; and (8) appurtenant facilities. The estimated annual generation of the project would be 3,212 gigawatt-hours.

Applicant Contact: Mr. Brent L. Smith, COO, Symbiotics LLC, 811 SW Naito Parkway Ste. 120, Portland, OR 97204; phone: (503) 235–3424.

FERC Contact: Kelly Wolcott (202) 502–6480, or by email at *kelly.wolcott@ferc.gov.*

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 30 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36. Comments, motions to intervene, notices of intent, and competing applications may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

More information about this project, including a copy of the application, can be viewed or printed on the ''eLibrary'' link of Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–13314–001) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: November 8, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–27732 Filed 11–14–12; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2012–0532; FRL–9524–3]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; NSPS for Beverage Can Surface Coating (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 et seq.), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. The ICR which is abstracted below describes the nature of the collection and the estimated burden and cost.

DATES: Additional comments may be submitted on or before December 17, 2012.

ADDRESSES: Submit your comments, referencing docket ID number EPA–HQ–OECA–2012–0532, to: (1) EPA online, using *www.regulations.gov* (our preferred method), or by email to: *docket.oeca@epa.gov,* or by mail to: EPA Docket Center (EPA/DC), Environmental Protection Agency, Enforcement and Compliance Docket and Information Center, mail code 28221T, 1200 Pennsylvania Avenue NW., Washington, DC 20460; and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Learia Williams, Compliance Assessment and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number: (202) 564–4113; fax number: (202) 564–0050; email address: *williams.learia@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On August 9, 2012 (77 FR 47631), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments. Any additional comments on this ICR should be submitted to both EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under docket ID number EPA–HQ–OECA–2012–0532, which is available for either public viewing online at *http://www.regulations.gov,* or in person viewing at the Enforcement and Compliance Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Avenue NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Enforcement and Compliance Docket is (202) 566–1752.

Use EPA's electronic docket and comment system at *http://www.regulations.gov,* either to submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. Once in the system, select ''docket search,'' then key in the docket ID number identified above. Please note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at *http://www.regulations.gov* as EPA receives them and without change, unless the comment contains copyrighted material, Confidentiality of Business Information (CBI), or other information whose public disclosure is restricted by statute. For further information about the electronic docket, go to *www.regulations.gov.*

Title: NSPS for Beverage Can Surface Coating (Renewal).

ICR Numbers: EPA ICR Number 0663.11, OMB Control Number 2060–0001.

ICR Status: This ICR is scheduled to expire on December 31, 2012. Under OMB regulations, the Agency may continue to either conduct or sponsor the collection of information while this submission is pending at OMB.

Abstract: The affected entities are subject to the General Provisions of the NSPS at 40 CFR part 60, subpart A and any changes, or additions to the Provisions specified at 40 CFR part 60, subpart WW. Owners or operators of the affected facilities must make an initial notification, performance tests, periodic reports, and maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. Reports are also required semiannually.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 43 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.

Respondents/Affected Entities: Owners or operators of beverage can surface coating facilities.

Estimated Number of Respondents: 48.

Frequency of Response: Initially, occasionally, and semiannually.

Estimated Total Annual Hour Burden: 5,134.

Estimated Total Annual Cost: $597,892, which includes $497,092 in labor costs, no capital/startup costs, and $100,800 in operation and maintenance (O&M) costs.

Changes in the Estimates: There is no change in labor hours in this ICR compared to the previous ICR. This is due to two considerations: (1) The regulations have not changed over the past three years and are not anticipated to change over the next three years; and (2) the growth rate for the industry is very low, negative or non-existent, so there is no significant change in the overall burden. However, there is an increase in the total labor and Agency costs as currently identified in the OMB Inventory of Approved Burdens. This increase is not due to any program changes. The change in cost estimates reflects updated labors rates available from the Bureau of Labor Statistics.

John Moses,

Director, Collection Strategies Division.

[FR Doc. 2012–27787 Filed 11–14–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–RCRA–2011–0280; FRL–9524–2]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; 2013 Hazardous Waste Report, Notification of Regulated Waste Activity, and Part A Hazardous Waste Permit Application and Modification (Revision)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), ''2013 Hazardous Waste Report, Notification of Regulated Waste Activity, and Part A Hazardous Waste Permit Application and Modification (Revision)''. (EPA ICR No. 0976.16, OMB Control No. 2050–0024) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This is a proposed amendment of the ICR, which is currently approved through December 31, 2014. Public comments were previously requested via the **Federal Register** (77 FR 31005) on May 24, 2012 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. 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.

DATES: Additional comments may be submitted on or before December 17, 2012.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–RCRA–2011–0280, to (1) EPA, either online using *www.regulations.gov* (our preferred method), or by email to *rcra-docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Avenue NW., Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

FOR FURTHER INFORMATION CONTACT: Peggy Vyas, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: 703–308–5477; fax number: 703–308–8433; email address: *vyas.peggy@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: The Hazardous Waste Report Instructions and Forms booklet is updated every two years, to comply with the statutory mandate that EPA conduct a survey of hazardous waste generation at least every two years. The report, known as the ''Biennial Report,'' has been conducted since 1989, every odd-numbered year, known as the data collection year. The even-numbered years are known as the reporting years. The ICR has been renewed every data collection year, and the forms have been made available to respondents at the beginning of the reporting year. However, EPA is amending the current ICR this year so that the booklet for the next cycle, the 2013 cycle, will be available at the beginning of the data collection year. This change is in response to many requests by States.

The proposed changes to the 2013 booklet include: (1) Some management method codes will be consolidated in order to ease reporting, (2) the waste minimization codes will be revised in order to assist filers with reporting their waste minimization activities, and (3) editorial changes will be made to the description of some source codes in order to improve clarity for filers.

This amendment will not affect the Notification booklet or the Part A Permit Application booklet, which are both part of this ICR.

Form Numbers: 8700–13 A/B.

Respondents/affected entities: Business or other for-profit as well as State, Local, or Tribal governments.

Respondent's obligation to respond: mandatory (RCRA sections 3002 and 3004).

Estimated number of respondents: 56,672.

Frequency of response: Biennially.

Total estimated burden: 432,903 hours per year. Burden is defined at 5 CFR 1320.03(b).

T*otal estimated cost:* $18,404,963 (per year), includes $18,153,496 annualized labor and $251,467 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is a decrease of 7,341 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This decrease is due to changes in the waste minimization data reported in Form GM (i.e., use of a revised set of waste minimization codes for which the requirement to submit comments is optional).

John Moses,

Director, Collection Strategies Division.

[FR Doc. 2012–27788 Filed 11–14–12; 8:45 am]

BILLING CODE 6560–50–P

EXPORT-IMPORT BANK

[Public Notice 2012–0540]

Application for Final Commitment for a Long-Term Loan or Financial Guarantee in Excess of $100 Million; 25 Day Comment Period

AGENCY: Export-Import Bank of the United States.

ACTION: Notice of 25 day comment period regarding an application for final commitment for a long-term loan or financial guarantee in excess of $100 million.

Reason for Notice: This Notice is to inform the public, in accordance with Section 3(c)(10) of the Charter of the Export-Import Bank of the United States (''Ex-Im Bank''), that Ex-Im Bank has received an application for final commitment for a long-term loan or financial guarantee in excess of $100 million (as calculated in accordance with Section 3(c)(10) of the Charter). Comments received within the comment period specified below will be presented to the Ex-Im Bank Board of Directors prior to final action on this Transaction.

Reference: AP087225XX.

Purpose and Use: Brief description of the purpose of the transaction:

To support the export of goods and design, engineering and construction services utilized in the rehabilitation and expansion of a hospital in Ghana.

Brief non-proprietary description of the anticipated use of the items being exported:

Goods and services will be utilized for the rehabilitation and expansion of a hospital in Ghana.

To the extent that Ex-Im Bank is reasonably aware, the item(s) being exported are not expected to produce exports or provide services in competition with the exportation of goods or provision of services by a United States industry.

Parties: Principal Supplier: Americaribe Inc., USA.

Obligor: Republic of Ghana acting through its Ministry of Finance and Economic Planning.

Guarantor: N/A.

Description of Items Being Exported: Design, engineering and construction services and related equipment for the rehabilitation and expansion of a hospital.

Information on Decision: Information on the final decision for this transaction will be available in the ''Summary Minutes of Meetings of Board of Directors'' on *http://www.exim.gov/articles.cfm/board%20minute*

Confidential Information: Please note that this notice does not include confidential or proprietary business information; information which, if disclosed, would violate the Trade Secrets Act; or information which would jeopardize jobs in the United States by supplying information that competitors could use to compete with companies in the United States.

DATES: Comments must be received on or before December 10, 2012 to be assured of consideration before final consideration of the transaction by the Board of Directors of Ex-Im Bank.

ADDRESSES: Comments may be submitted through *www.regulations.gov.*

Sharon A. Whitt,

Agency Clearance Officer.

[FR Doc. 2012–27736 Filed 11–14–12; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Sunshine Act Meeting

Pursuant to the provisions of the ''Government in the Sunshine Act'' (5 U.S.C. 552b), notice is hereby given that at 10:01 a.m. on Tuesday, November 13, 2012, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters related to the Corporation's supervision, corporate, and resolution activities.

In calling the meeting, the Board determined, on motion of Director Richard Cordray (Director, Consumer Financial Protection Bureau), seconded by Director Thomas M. Hoenig (Appointive), concurred in by Director Jeremiah O. Norton (Appointive), Director Thomas J. Curry (Comptroller of the Currency), and Acting Chairman Martin J. Gruenberg, that Corporation business required its consideration of the matters which were to be the subject of this meeting on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10) of the ''Government in the Sunshine Act'' (5 U.S.C. 552b(c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10)).

The meeting was held in the Board Room of the FDIC Building located at 550-17th Street NW., Washington, DC.

Dated: November 13, 2012.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2012–27926 Filed 11–13–12; 4:15 pm]

BILLING CODE P

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 (*www.fmc.gov*) or by contacting the Office of Agreements at (202)–523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 011275–034.

Title: Australia and New Zealand-United States Discussion Agreement.

Parties: ANL Singapore Pte Ltd.; CMA CGM, S.A.; Hamburg-Süd KG; Hapag-Lloyd AG; and Mediterranean Shipping Company S.A.

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Connor LLP; 1627 I Street NW.; Suite 1100; Washington, DC 20006–4007.

Synopsis: The amendment would add A.P. Moller-Maersk AS, trading under the name Maersk Line, as a party to the agreement.

Agreement No.: 012185.

Title: Priority/Marine Express Space Charter, Sailing and Cooperative Working Agreement.

Parties: Priority RoRo Services, LLC and Marine Express, Inc.

Filing Party: Carlos E. Bayron; Bayron Law Offices, P.S.C.; P.O. Box 6461, Mayaguez, PR 00681.

Synopsis: The agreement would authorize the parties to share vessels and charter space to each other in the trade between Puerto Rico and the Dominican Republic.

Agreement No.: 012186.

Title: Crowley/Priority Ro/Ro Space Charter and Sailing Agreement.

Parties: Crowley Latin America Services, LLC and Priority Ro/Ro Services, Inc.

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Connor; 1627 I Street NW., Suite 1100; Washington, DC 20006–4007.

Synopsis: The agreement authorizes Priority to charter space to Crowley in the trade between Puerto Rico and the Dominican Republic for cargo originating in Puerto Rico as well as for cargo being transshipped in Puerto Rico.

By Order of the Federal Maritime Commission.

Dated: November 9, 2012.

Rachel E. Dickon,

Assistant Secretary.

[FR Doc. 2012–27833 Filed 11–14–12; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than November 29, 2012.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *The Selken Family (Teresa L. Selken Revocable Trust #2, Teresa L. Selken, Keystone, Iowa, Trustee; William D. Selken and Teresa A. Selken, both of Keystone, Iowa; Ronald J. Selken, Council Bluffs, Iowa; Ryan J. Selken, Keystone, Iowa; and Renae C. McKay, Iowa City, Iowa)* together as a group, to gain control of Keystone Community Bancorporation, Keystone, Iowa, and thereby indirectly control Keystone Savings Bank, Keystone, Iowa.

Board of Governors of the Federal Reserve System, November 9, 2012.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2012–27744 Filed 11–14–12; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Savings and Loan Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Home Owners' Loan Act (12 U.S.C. 1461 *et seq.*) (HOLA), Regulation LL (12 CFR part 238), and Regulation MM (12 CFR part 239), and all other applicable statutes and regulations to become a savings and loan holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a savings association and nonbanking companies owned by the savings and loan holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the HOLA (12 U.S.C. 1467a(e)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 10(c)(4)(B) of the HOLA (12 U.S.C. 1467a(c)(4)(B)). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 10, 2012.

A. Federal Reserve Bank of Minneapolis (Jacqueline G. King, Community Affairs Officer) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *The Miller Family 2012 Trust U/A Dated December 21, 2012, St. Cloud, Minnesota;* to become a savings and loan holding company and acquire 31.14 percent of Liberty Financial Services of Saint Cloud, Inc., Saint Cloud, MN, and thereby indirectly acquire control of Liberty Savings Bank, FSB, Saint Cloud, Minnesota.

Board of Governors of the Federal Reserve System, November 9, 2012.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2012–27745 Filed 11–14–12; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier HHS–OS–17883–30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for a new collection. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before December 17, 2012.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.Collection Clearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the Information Collection Request Title and document identifier HHS–OS–17883–30D for reference.

Information Collection Request Title: Teen Pregnancy Prevention Replication Evaluation Study: Follow-up Data Collection.

Abstract: The Office of Adolescent Health (OAH), Office of the Assistant Secretary for Health (OASH), Office of the Secretary (OS), U.S. Department of Health and Human Services (HHS), is overseeing and coordinating adolescent pregnancy prevention evaluation efforts as part of the Teen Pregnancy Prevention Initiative. OAH is working collaboratively with the Office of the Assistant Secretary for Planning and Evaluation (ASPE), the Centers for Disease Control and Prevention (CDC), and the Administration for Children and Families (ACF) on adolescent pregnancy prevention evaluation activities.

OAH will jointly oversee with ASPE the Teen Pregnancy Prevention Replication Evaluation Study (TPP Replication Study). The TPP Replication Study will be a random assignment evaluation which will determine the extent to which evidence-based program models that have been shown to be effective in an earlier trial, demonstrate effects on adolescent sexual risk behavior and teenage pregnancy when they are replicated with different populations.

OAH and ASPE are proposing follow-up data collection activity as part of the TPP Replication Evaluation. Specifically, there will be two follow-up data collection points: (1) Short-term follow-up data collection 6 to 12 months post-baseline; and (2) longer-term follow-up data collection 18–24 months post-baseline. Respondents will be asked to answer carefully selected questions about risk and protective factors related to teen pregnancy, intermediate outcomes, and behavioral outcomes.

The survey data will be collected through private, self-administered questionnaires completed by study participants, i.e. adolescents assigned to a select school or community teen pregnancy prevention program or a control group. Surveys will be distributed and collected by trained professional staff.

Need and Proposed Use of the Information: Information from this data collection will be used to perform meaningful analysis to determine significant program effects. The findings from this evaluation will be of interest to the general public, to policy-makers, and to organizations interested in teen pregnancy prevention.

Likely Respondents: Adolescents, either assigned to teen pregnancy preview programs or part of a control group.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review

the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Safer Sex Intervention	Sexually active youth	1,900	2	0.5	1,900
Reducing the Risk	Sexually active youth	1,900	2	0.5	1,900
Reducing the Risk	Sexually inexperienced youth	1,900	2	0.5	1,900
Total		5,700			5,700

Keith A. Tucker,

Information Collection Clearance Officer.

[FR Doc. 2012–27770 Filed 11–14–12; 8:45 am]

BILLING CODE 4168–11–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Privacy Act of 1974; System of Records Notice

AGENCY: Office of Minority Health (OMH), Office of the Assistant Secretary for Health (OASH), Office of the Secretary (OS), Department of Health and Human Services (HHS).

ACTION: Notice to establish a new Privacy Act system of records notice (SORN).

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, the Office of Minority Health, Office of the Assistant Secretary for Health, Office of the Secretary of Health and Human Services (HHS/OS/OASH/OMH) is establishing a new system of records, ''Think Cultural Health,'' to support its Think Cultural Health Web site Program. The system will provide educational information, training, best practices, and tools to health professionals as one initiative to help them accomplish cultural competency in accordance with national Culturally and Linguistically Appropriate Services (CLAS) Standards. The CLAS standards were originally promulgated by OMH in 2001 and are being revised and enhanced in order to guide health and health care organizations in the provision of culturally and linguistically appropriate services that will improve the health care of all Americans.

The system will maintain registration and training records containing personally identifiable information (PII) about individual health professionals who are registrants/users of the Think Cultural Health Web site. The program and the system of records are more thoroughly described in the **SUPPLEMENTARY INFORMATION** section and System of Records Notice (SORN) below.

DATES: *Effective Dates:* Effective 30 days after publication. Written comments should be submitted on or before the effective date. HHS/OS/OASH/OMH may publish an amended SORN in light of any comments received.

ADDRESSES: The public should address written comments to Mr. Guadalupe Pacheco, Senior Health Advisor to the Director, Office of Minority Health, by mail or email, at 1101 Wootton Parkway, Suite 600, Rockville, MD 20852 or *guadalupe.pacheco@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. Guadalupe Pacheco, Senior Health Advisor to the Director, Office of Minority Health, 1101 Wootton Parkway, Suite 600, Rockville, MD 20852. He can be reached by telephone at (240) 453–6174 or via email at *guadalupe.pacheco@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. The Think Cultural Health Web Site Program

The Think Cultural Health Web site Program was created in recognition of the effectiveness of on-line distance learning. It supports the HHS/OS/OASH/OMH in complying with the cultural competency requirements of the Affordable Care Act of 2010 (Pub. L. 111–148), as well as the HHS Action Plan to Reduce Racial and Ethnic Health Disparities, the National Stakeholder Strategy for Achieving Health Equity, Healthy People 2020, the Secretary's Strategic Plan priorities, and the Assistant Secretary for Health's Public Health Quality Agenda. The program will use a Web site to post information such as cultural competency, language access and health disparities articles, and notices of health disparities conferences for viewing by any visitors to the site. Other resources, consisting of training and newsletters, will be available through the Web site to health professionals who register to use those resources. The Think Cultural Health system will not collect PII about visitors, but will collect PII about registrants/users. Use of the resources offered on the site is voluntary, but registration information is required to determine if the site is used by variety of health professionals, representing different disciplines, skill sets, and demographic locations. The provision of data concerning the registrant's gender and race is optional. Additionally, training and test records are needed for reports to accrediting bodies.

II. The Privacy Act

The Privacy Act (5 U.S.C. 552a) governs the means by which the United States Government collects, maintains, and uses PII in a system of records. A ''system of records'' is a group of any records under the control of a Federal agency from which information about individuals is retrieved by name or other personal identifier. The Privacy Act requires each agency to publish in the **Federal Register** a SORN identifying and describing each system of records the agency maintains, including the purposes for which the agency uses PII in the system, the routine uses for which the agency discloses such information outside the agency, and how individual record subjects can exercise their rights under the Privacy Act (e.g., to determine if the system contains information about them).

SYSTEM NUMBER:

09–90–1202

SYSTEM NAME:

Think Cultural Health

SECURITY CLASSIFICATION:

Unclassified

SYSTEM LOCATION:

Servers: The servers hosting the system will be housed at Equinix Data Center 2, Ashburn, VA. Portals: This

system will be accessed via the Internet at *www.ThinkCulturalHealth.hhs.gov.* System Software: System software is maintained by Astute Technology in Reston, Virginia.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The system will contain PII about individual health professionals who register to receive a monthly newsletter distributed via email through the site or to take training offered on the site.

CATEGORIES OF RECORDS IN THE SYSTEM:

The system will contain the following categories of records and PII data elements:

• *Newsletter registration records and E-learning registration records,* including registrant's first and last name, email address, User ID number, user name, street address, degree, certificate type, gender, age, race/ethnicity, practice setting, level of seniority, primary role, years in profession, notification information, and current and future contact information.

• *E-learning training and test records,* including registrant's first and last name, evaluation data, pretest and posttest scores, and E-learning registration information.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The statutory authority for maintenance of the system is Section 5307 of the Affordable Care Act of 2010, Public Law 111–148, codified at 42 U.S.C. 293e and 42 U.S.C. 296e–1.

PURPOSE(S) OF THE SYSTEM:

HHS/OS/OASH/OMH personnel will use PII in the system, on a ''need to know'' basis, for the following purposes:

• To identify individuals who request to receive the Think Cultural Health newsletter;

• To identify individuals who enroll in the Think Cultural Health E-learning program and receive continuing education credits;

• To report the fulfillment of continuing education credits to the accrediting bodies; and

• To evaluate statistics showing how, where, and by whom the program is utilized; for HHS research, marketing, and quality improvement purposes directed at ensuring the site is used by individuals representing a variety of skills and backgrounds.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The system may disclose records containing PII to parties outside HHS for the following routine uses:

1. Certain E-learning test records, consisting of the registrant's name, evaluation data, pretest and posttest scores, and registration information, will be disclosed to accrediting bodies (such as Cine-Med and Indian Health Services), for their use in reporting continuing education credits for health professionals who complete all or part of the training program.

2. Records may be disclosed to agency contractors, consultants, or HHS grantees who have been engaged by the agency to assist in accomplishment of an HHS function relating to the purposes of this system of records and who need to have access to the records in order to assist HHS.

3. Records may be disclosed to the Department of Justice (DOJ), a court, or an adjudicatory body when:

• The agency or any component thereof; or

• Any employee of the agency in his or her official capacity, or

• Any employee of the agency in his or her individual capacity where DOJ has agreed to represent the employee, or

• The United States Government,

is a party to litigation or has an interest in such litigation and, by careful review, HHS determines that the records are both relevant and necessary to the litigation and that the use of such records by the DOJ, court, or adjudicatory body is compatible with the purpose for which the agency collected the records.

4. Records may be disclosed to another Federal agency or an instrumentality of any governmental jurisdiction within or under the control of the United States (including any State or local governmental agency) that administers, or that has the authority to investigate potential fraud, waste, or abuse in federally funded programs, when disclosure is deemed reasonably necessary by HHS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste or abuse in such programs.

5. Records may be disclosed to appropriate Federal agencies and Department contractors that have a need to know the information for the purpose of assisting the Department's efforts to respond to a suspected or confirmed breach of the security or confidentiality of information maintained in this system of records, when the information disclosed is relevant and necessary for that assistance.

6. Records may become accessible to U.S. Department of Homeland Security (DHS) cyber security personnel, if captured in an intrusion detection system used by HHS and DHS pursuant to the Einstein 2 program. Under Einstein 2, DHS uses intrusion detection systems to monitor Internet traffic to and from federal computer networks to prevent malicious computer code from reaching the networks. According to DHS' Privacy Impact Assessment for Einstein 2 (available on the DHS Cybersecurity privacy Web site, *http://www.dhs.gov/files/publications/editorial_0514.shtm#4*), only PII that is directly related to a malicious code security incident is captured and accessible to DHS, and DHS does not access any captured PII; however, accessibility alone may constitute a disclosure under the Privacy Act.

The system may also disclose PII data for any of the uses authorized directly in the Privacy Act at 5 U.S.C. 552a(b)(2) and (b)(4)–(11).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM

STORAGE:

Information will be collected via email, web form, or telephone. Electronic records are stored in databases on magnetic tape, on magnetic disk and in secure electronic files at the contractor's location (Astute Technology, Reston, VA), the data center (Equinix, Ashburn, VA) and at the tape storage facility (GRM, Capital Heights, MD).

RETRIEVABILITY:

Registration and training records will be retrieved by registrant/user name, email address, or User ID number.

SAFEGUARDS:

Access to the records in the Think Cultural Health database will be limited to agency contractors, consultants, or HHS grantees who have been engaged by the agency to assist in accomplishment of an HHS function utilizing password security, encryption, firewalls and secured operating system.

RETENTION AND DISPOSAL:

Information about newsletter recipients will be maintained until requested to be removed by the individual on whom the information is maintained. Information about training registrants will be maintained for a minimum of six years after the contract is no longer funded.

SYSTEM MANAGER AND ADDRESS:

Guadalupe Pacheco, Senior Health Advisor to the Director, Office of Minority Health, 1101 Wootton Parkway, Suite 600, Rockville, MD 20852.

NOTIFICATION PROCEDURE:

Individuals wishing to know if this system contains records about them should write to the System Manager and include the email address used for registration.

RECORD ACCESS PROCEDURE:

Individuals seeking access to records about them in this system should follow the same instructions indicated under ''Notification Procedure'' and indicate the record(s) to which access is sought (e.g., newsletter registration, E-learning registration, or training record).

CONTESTING RECORD PROCEDURES:

Individuals seeking to contest the content of information about them in this system should follow the same instructions indicated under ''Notification Procedure.'' The request should reasonably identify the record, specify the information contested, state the corrective action sought, and provide the reasons for the correction, with supporting justification.

RECORD SOURCE CATEGORIES:

All information will be collected directly from the Web site registrants/users themselves when they complete one or more than one of the following information collection forms:

- Center for Linguistic and Cultural Competency in Health Care (CLCCHC) Registration Form
- A Physician's Practical Guide to Culturally Competent Care Registration Form
- Culturally Competent Nursing Care: A Cornerstone of Caring Registration Form
- Cultural Competency Curriculum for Disaster Preparedness and Crisis Response Registration Form
- Health Care Language Services Implementation Guide Registration Form

EXEMPTIONS CLAIMED FOR THIS SYSTEM:

None

Dated: May 15, 2012.

J. Nadine Gracia,

Deputy Assistant Secretary for Minority Health (Acting), Office of Minority Health, U.S. Department of Health and Human Services.

[FR Doc. 2012–27699 Filed 11–14–12; 8:45 am]

BILLING CODE 4150–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

Statement of Organization, Functions, and Delegations of Authority

Part J (Agency for Toxic Substances and Disease Registry) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (50 FR 25129–25130, dated June 17, 1985, as amended most recently at 75 FR 70276, dated November 17, 2010) is amended to reflect the reorganization of the Agency for Toxic Substances and Disease Registry (ATSDR).

Section T–B, Organization and Functions, is hereby amended as follows:

Delete in their entirety the titles and functional statements for the Division of Regional Operations (JAAB), Division of Health Assessment and Consultation (JAAC), Division of Health Studies (JAAE), and the Division of Toxicology and Environmental Medicine (JAAG), and insert the following:

Division of Community Health Investigations (JAAM). (1) Conducts public health assessments, health consultations, and other related public health activities to determine the health implications of releases or threatened releases of toxic substances into the environment; in particular, such activities are conducted for Superfund and Resource Conservation and Recovery Act (RCRA) sites, petition requests, and other sites or instances where communities have been or may have been exposed to toxic substances in the environment; (2) plans, manages, directs, and conducts the regional operations of the Agency; (3) provides liaison, technical advice, and consultation to the Environmental Protection Agency, other federal, tribal, state, and local agencies, private organizations, community groups, and individuals on eliminating or mitigating public health problems resulting from the release of hazardous substances into the environment; (4) conducts and evaluates exposure pathways analyses and other exposure screening analyses to identify impacted communities, to include exposure investigations (biologic sampling, personal monitoring, etc.), exposure-dose reconstruction, and related environmental assessments, as appropriate; (5) identifies appropriate interventions for impacted communities to prevent exposures and/or adverse health effects; (6) issues public health advisories when a release or threatened release of a toxic substance poses an imminent health hazard; (7) plans, prepares, and executes appropriate community involvement and health educational strategies/activities/programs for communities affected or potentially affected by toxic substances released into the environment; (8) manages the ATSDR-mandated program for conducting site-specific activities at petitioned sites; (9) manages and implements ATSDR's Site-Specific Cooperative Agreement Program; (10) coordinates the Agency's environmental public health training program; (11) provides technical support and field presence for routine emergency and disaster response as appropriate; and (12) engages with regional partners to accomplish special programs that promote environmental health (i.e., brownfields/land reuse activities and environmental justice).

Office of the Director (JAAM1). (1) Provides overall leadership in directing, coordinating, evaluating, and managing all programmatic and administrative operations of the division; (2) develops programmatic goals and objectives and provides leadership, policy formation, and guidance in program planning, development, and evaluation; (3) coordinates division activities with other components of ATSDR and other federal, tribal, state and local agencies; (4) provides overall leadership and management of division activities pertaining to federal facilities response, petition coordination, special environmental public health programs (i.e., brownfields/land reuse), and community involvement/health education; (5) ensures regional offices have support for timely responses to regional partners; (6) ensures support for regional emergency response activities; (7) works with the Washington, D.C. regional office to ensure coordination with the Environmental Protection Agency at the national level; (8) assesses the need and develops training for public health professionals conducting site-specific activities, and coordinates the delivery of these courses for the training of federal staff, American Indian/Alaska Native tribal members, and state partners; (9) plans, directs, coordinates, and manages ATSDR's Site-Specific Cooperative Agreement Program; (10) reviews and evaluates the scientific accuracy and clarity of public health assessments, health consultations, and community outreach and health education materials; (11) ensures the quality and consistency in the science and format used in the development of

divisional products and materials; (12) develops outreach messages following the procedures and policies of the Agency's Office of Communication; (13) provides timely responses to policy activities (i.e., Freedom of Information Act (FOIA), congressional inquiries, budget formulation, and briefings); and (14) develops measures of divisional productivity and reports to the Agency and CDC director.

Eastern Branch (JAAMB). The branch serves regions 1–3 by performing the following: (1) Manages a wide range of public health assessment requests, including private-sector petitions and regional-led activities, that are assigned based on branch staff expertise; (2) monitors the progress of work plan activities, and reviews and evaluates the scientific accuracy and clarity of public health assessments, health consultations, and related materials; (3) plans, directs, coordinates, evaluates, conducts, and manages operations and activities at National Priorities List sites, federal sites, and RCRA sites; (4) issues public health assessments, health consultations, public health advisories, and provides technical assistance; (5) establishes working relationships with regional partners to ensure hazardous chemical exposures are addressed regionally; (6) operates regional offices providing liaison, technical advice, and consultation to the Environmental Protection Agency, other federal, tribal, state, and local agencies, private organizations, community groups, and individuals on eliminating or mitigating public health problems resulting from the release of hazardous substances into the environment; (7) ensures regional offices have adequate support to provide timely responses to external partners; (8) ensures regional offices have continued support for emergency response and removal activities; (9) participates in regional initiatives to ensure prevention and reduction of hazardous waste exposures; (10) plans, coordinates, implements, and evaluates ATSDR's health promotion, health education, and community involvement site-specific programs; (11) communicates the agency's roles, responsibilities, and public health information to public and professional audiences to mitigate health effects from potential and actual exposures to toxic substances; (12) advocates for the public health needs of communities affected by environmental hazards; (13) links members of the public in communities affected by hazardous waste with technical and scientific staff and resources, where appropriate; (14) collaborates with other ATSDR program areas and partners to ensure cultural awareness and respect are observed and practiced in all activities that involve communities, American Indian/Alaska Native tribes, tribal governments and tribal organizations; (15) develops programmatic goals and objectives, and contributes to policy formation and guidance in program planning, development and evaluation; and (16) provides health physics expertise for all division public health assessment activities and serves as the division's liaison to radiation disaster response teams.

Central Branch (JAAMC). The branch serves regions 4–6 by performing the following: (1) Manages a wide range of public health assessment requests, including private-sector petitions and regional-led activities, that are assigned based on branch staff expertise; (2) monitors the progress of work plan activities, and reviews and evaluates the scientific accuracy and clarity of public health assessments, health consultations, and related materials; (3) plans, directs, coordinates, evaluates, conducts, and manages operations and activities at National Priorities List sites, federal sites, and RCRA sites; (4) issues public health assessments, health consultations, public health advisories, and provides technical assistance; (5) establishes working relationships with regional partners to ensure hazardous chemical exposures are addressed regionally; (6) operates regional offices providing liaison, technical advice, and consultation to the Environmental Protection Agency, other federal, tribal, state, and local agencies, private organizations, community groups, and individuals on eliminating or mitigating public health problems resulting from the release of hazardous substances into the environment; (7) ensures regional offices have adequate support to provide timely responses to external partners; (8) ensures regional offices have continued support for emergency response and removal activities; (9) participates in regional initiatives to ensure prevention and reduction of hazardous waste exposures; (10) plans, coordinates, implements, and evaluates ATSDR's health promotion, health education, and community involvement site-specific programs; (11) communicates the agency's roles, responsibilities, and public health information to public and professional audiences to mitigate health effects from potential and actual exposures to toxic substances; (12) advocates for the public health needs of communities affected by environmental hazards; (13) links members of the public in communities affected by hazardous waste with technical and scientific staff and resources, where appropriate; (14) collaborates with other ATSDR program areas and partners to ensure cultural awareness and respect are observed and practiced in all activities that involve communities, American Indian/Alaska Native tribes, tribal governments and tribal organizations; (15) develops programmatic goals and objectives, and contributes to policy formation and guidance in program planning, development and evaluation; and (16) provides health physics expertise for all division public health assessment activities and serves as the division's liaison to radiation disaster response teams.

Western Branch (JAAMD). The branch serves regions 7–10 by performing the following: (1) Manages a wide range of public health assessment requests, including private-sector petitions and regional-led activities, that are assigned based on branch staff expertise; (2) monitors the progress of work plan activities, and reviews and evaluates the scientific accuracy and clarity of public health assessments, health consultations, and related materials; (3) plans, directs, coordinates, evaluates, conducts, and manages operations and activities at National Priorities List sites, federal sites, and RCRA sites; (4) issues public health assessments, health consultations, public health advisories, and provides technical assistance; (5) establishes working relationships with regional partners to ensure hazardous chemical exposures are addressed regionally; (6) operates regional offices providing liaison, technical advice, and consultation to the Environmental Protection Agency, other federal, tribal, state, and local agencies, private organizations, community groups, and individuals on eliminating or mitigating public health problems resulting from the release of hazardous substances into the environment; (7) ensures regional offices have adequate support to provide timely responses to external partners; (8) ensures regional offices have continued support for emergency response and removal activities; (9) participates in regional initiatives to ensure prevention and reduction of hazardous waste exposures; (10) plans, coordinates, implements, and evaluates ATSDR's health promotion, health education, and community involvement site-specific programs; (11) communicates the agency's roles, responsibilities, and public health information to public and professional audiences to mitigate health effects from potential and actual exposures to toxic

substances; (12) advocates for the public health needs of communities affected by environmental hazards; (13) links members of the public in communities affected by hazardous waste with technical and scientific staff and resources, where appropriate; (14) collaborates with other ATSDR program areas and partners to ensure cultural awareness and respect are observed and practiced in all activities that involve communities, American Indian/Alaska Native tribes, tribal governments and tribal organizations; (15) develops programmatic goals and objectives, and contributes to policy formation and guidance in program planning, development and evaluation; and (16) provides health physics expertise for all division public health assessment activities and serves as the division's liaison to radiation disaster response teams.

Science Support Branch (JAAME). (1) Serves as the lead branch for planning, directing, coordinating, evaluating, conducting, and managing the division's operations and activities for exposure investigations, exposure-dose reconstruction, and modeling; (2) coordinates within and across branch and divisional units to provide technical expertise for a wide-range of activities that support the division and agency's public health mandates and priorities; and (3) provides modeling and other analytic expertise to analyze the impact of exposures.

Division of Toxicology and Human Health Sciences (JAAN). The Division of Toxicology and Human Health Sciences develops and coordinates a research agenda and program that integrates epidemiology and environmental medicine with toxicology. This includes investigating the relationships between exposures to hazardous substances and adverse health effects. In order to do this, the division: (1) coordinates all activities associated with human health studies, surveillance activities, and registries; (2) provides epidemiologic, toxicologic, geospatial, and biostatistical assistance and consultation to site-specific activities across ATSDR including chemical-specific consultations as needed; (3) coordinates all activities associated with toxicological profiles including associated research; (4) develops and applies science-based health education tools, methods and strategies to deliver messages, education, and training; and (5) provides technical expertise and site specific support in addressing the health issues presented by emergency or acute release events and threatened releases of hazardous materials.

Office of the Director (JAAN1). (1) Plans, directs, coordinates, and manages the operations of the division; (2) provides leadership in the development of goals and objectives, policy formulation, and program planning, development and evaluation; (3) facilitates the science, including analytic support, of the division and undertakes special scientific activities; (4) coordinates division activities with other components of ATSDR, CDC, and other federal agencies; (5) ensures the quality and consistency in the science and format used in the development of divisional products and materials; (6) develops outreach messages following the procedures and policies of the Agency's Office of Communication; (7) provides timely responses to policy activities (i.e., FOIA inquiries, congressional inquiries, budget formulation, and briefings); and (8) develops measures of divisional productivity and reports to the Agency and CDC director.

Geospatial Research, Analysis and Services Program (JAAN12). (1) Researches and analyzes geospatial trends and patterns relevant to environmental health and emergency preparedness and response; (2) promotes and integrates the use of geospatial science and systems with data and technology; and (3) collaborates with scientists at CDC/ATSDR and public health partners on geospatial research and service needs.

Emergency Response Program (JAAN13). (1) Provides technical expertise and site-specific support in addressing the health issues presented by emergency or acute release events and threatened releases of hazardous materials; (2) provides remote and on-site support during chemical emergencies to federal, tribal, state, and local agencies, and the general public, with emphasis on preparing for and preventing emergency events; (3) develops information resources and guidance for first responders and health care providers for use in responding to unplanned releases and spills; and (4) works with the National Response Program and CDC guidelines to collaborate with other federal, tribal, state, and local agencies during emergency response situations.

Environmental Epidemiology Branch (JAANB). (1) Provides scientific expertise in environmental epidemiology; (2) designs and conducts human health, including epidemiologic, studies to evaluate the association between exposure to hazardous substances and adverse health effects; (3) provides expert medical and environmental epidemiologic consultation; and (4) implements extramural research programs that involve human health investigations.

Environmental Health Surveillance Branch (JAANC). (1) Provides scientific expertise in surveillance of hazardous substances; (2) designs and conducts surveillance and registry programs to evaluate the adverse health effects on persons exposed to hazardous substances; (3) conducts health follow-up activities resulting from surveillance and registries; and (4) implements extramural research programs that involve surveillance and registries.

Environmental Medicine Branch (JAAND). (1) Provides scientific expertise for environmental medicine and health education; (2) develops, disseminates, and applies science-based health education strategies, services, and tools to deliver key messages, education, and training to state and other public health partners; and (3) provides leadership in development, implementation, and evaluation of internal and external professional health education and environmental medicine activities.

Environmental Toxicology Branch (JAANE). (1) Provides scientific expertise for the development and dissemination of toxicological information; (2) develops and disseminates toxicological profiles; (3) develops, implements, and coordinates a program of research designed to identify priority data needs and associated health effects for various hazardous substances; (4) coordinates toxicological information and research activities with the Environmental Protection Agency, the National Toxicology Program, the Interagency Testing Committee, other appropriate federal, tribal, state, and local programs and other public and private concerns; and (5) develops and applies, through consultations, a program of computational toxicology research to enhance traditionally based approaches using modeling tools and techniques.

Dated: October 29, 2012.

Sherri A. Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2012–27533 Filed 11–14–12; 8:45 am]

BILLING CODE 4160–70–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1106]

Agency Information Collection Activities; Proposed Collection; Comment Request; Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors With Interest in Exporting to Chile

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of the guidance document entitled ''Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors With Interest in Exporting to Chile.''

DATES: Submit either electronic or written comments on the collection of information by January 14, 2013.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400T, Rockville, MD 20850, *domini.bean@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors With Interest in Exporting to Chile (OMB Control Number 0910–0509)—Extension

As a direct result of discussions that have been adjunct to the U.S./Chile Free Trade Agreement, Chile has recognized FDA as the competent U.S. food safety authority and has accepted the U.S. regulatory system for dairy inspections. Chile has concluded that it will not require individual inspections of U.S. firms by Chile as a prerequisite for trade, but will accept firms identified by FDA as eligible to export to Chile. Therefore, in the **Federal Register** of June 22, 2005 (70 FR 36190), FDA announced the availability of a revised guidance document entitled ''Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors With Interest in Exporting to Chile.'' The guidance can be found at *http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ImportsExports/ucm078936.htm.* The guidance document explains that FDA has established a list that is provided to the government of Chile and posted on *http://www.fda.gov/Food/InternationalActivities/Exports/ucm120245.htm,* which identifies U.S. dairy product manufacturers/processors that have expressed interest to FDA in exporting dairy products to Chile, are subject to FDA jurisdiction, and are not the subject of a pending judicial enforcement action (i.e., an injunction or seizure) or a pending warning letter. The term ''dairy products,'' for purposes of this list, is not intended to cover the raw agricultural commodity raw milk. Application for inclusion on the list is voluntary. However, Chile has advised that dairy products from firms not on this list could be delayed or prevented by Chilean authorities from entering commerce in Chile. The guidance explains what information firms should submit to FDA in order to be considered for inclusion on the list and what criteria FDA intends to use to determine eligibility for placement on the list. The document also explains how FDA intends to update the list and how FDA intends to communicate any new information to Chile. Finally, the guidance notes that FDA considers the information on this list, which is provided voluntarily with the understanding that it will be posted on FDA's Web site and communicated to, and possibly further disseminated by, Chile, to be information that is not protected from disclosure under 5 U.S.C. 552(b)(4). Under the guidance, FDA recommends that U.S. firms that want to be placed on the list send the following information to FDA: Name and address of the firm and the manufacturing plant; name, telephone number, and email address (if available) of the contact person; a list of products presently shipped and expected to be shipped in the next 3 years; identities of agencies that inspect the plant and the date of last inspection; plant number and copy of last inspection notice; and, if other than an FDA inspection, copy of last inspection report. FDA requests that this information be updated every 2 years.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
New written requests to be placed on the list	25	1	25	1.5	38
Biannual update	88	1	88	1.0	88
Occasional updates	25	1	25	0.5	13
Total					139

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate of the number of firms that will submit new written requests to be placed on the list, biannual updates, and occasional updates is based on FDA's experience maintaining the list over the past 7 years. The estimate of the number of hours that it will take a firm to gather the information needed to be placed on the list or update its information is based on FDA's experience with firms submitting similar requests. FDA believes that the information to be submitted will be readily available to the firms.

On average, over the last 3 years, the list contained approximately 176 firms. FDA estimates that, each year, approximately 25 new firms will apply to be added to the list. In any given year, some firms choose not to resubmit their information. These firms are removed from the list quarterly. This occurrence results in the number of firms to remain at approximately 176. We estimate that a firm will require 1.5 hours to read the guidance, gather the information needed, and to prepare a communication to FDA that contains the information and requests that the firm be placed on the list for a total of 37.5 hours, rounded to 38. Under the guidance, every 2 years each producer on the list must provide updated information in order to remain on the list. FDA estimates that each year approximately half of the firms on the list, 88 firms ($176 \times 0.5 = 88$), will resubmit the information to remain on the list. We estimate that a firm already on the list will require 1.0 hours to biannually update and resubmit the information to FDA, including time reviewing the information and corresponding with FDA, for a total of 88 hours. In addition, FDA expects that, each year, approximately 25 firms will need to submit an occasional update and each firm will require 0.5 hours to prepare a communication to FDA reporting the change, for a total of 12.5 hours, rounded to 13.

Dated: November 8, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–27723 Filed 11–14–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1108]

Agency Information Collection Activities; Proposed Collection; Comment Request; Comment Request; Interstate Shellfish Dealer's Certificate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of the Interstate Shellfish Dealer's Certificate.

DATES: Submit either electronic or written comments on the collection of information by January 14, 2013.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400T, Rockville, MD 20850, *domini.bean@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Interstate Shellfish Dealer's Certificate (OMB Control Number 0910–0021)—Extension

Under 42 U.S.C. 243, FDA is required to cooperate with and aid State and local authorities in the enforcement of their health regulations and is authorized to assist States in the prevention and suppression of communicable diseases. Under this authority, FDA participates with State regulatory agencies, some foreign nations, and the molluscan shellfish industry in the National Shellfish Sanitation Program (NSSP).

NSSP is a voluntary, cooperative program to promote the safety of molluscan shellfish by providing for the classification and patrol of shellfish growing waters and for the inspection and certification of shellfish processors. Each participating State and foreign nation monitors its molluscan shellfish processors and issues certificates for those that meet the State or foreign shellfish control authority's criteria. Each participating State and nation provides a certificate of its certified shellfish processors to FDA on Form FDA 3038, ''Interstate Shellfish Dealer's Certificate.'' FDA uses this information to publish the ''Interstate Certified Shellfish Shippers List,'' a monthly comprehensive listing of all molluscan shellfish processors certified under the cooperative program. If FDA did not collect the information necessary to compile this list, participating States would not be able to identify and keep out shellfish processed by uncertified processors in other States and foreign nations. Consequently, NSSP would not be able to control the distribution of uncertified and possibly unsafe shellfish in interstate commerce, and its effectiveness would be nullified.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of Interstate Shellfish Dealer's Certificate	3038	40	57	2,280	0.10	228

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that 40 respondents will submit 2,280 Interstate Shellfish Dealer's Certificates annually, for a total burden of 228 hours (2,280 submissions × 0.10 hours = 228 hours). This estimate is based on FDA's experience and the number of certificates received in the past 3 years.

Dated: November 8, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–27722 Filed 11–14–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1105]

Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary Hazard Analysis and Critical Control Point Manuals for Operators and Regulators of Retail and Food Service Establishments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection associated with FDA's technical assistance reference manuals provided to State, local, territorial, and tribal jurisdictions, and other Federal Agencies to interpret and promote the application of Hazard Analysis and Critical Control Point (HACCP) principles to reduce the risk of foodborne illness in the operation of retail and food service establishments.

DATES: Submit either electronic or written comments on the collection of information by January 14, 2013.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400T, Rockville, MD 20850, *domini.bean@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the

collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Voluntary Hazard Analysis and Critical Control Point Manuals for Operators and Regulators of Retail and Food Service Establishments (OMB Control Number 0910–0578)—Extension

HACCP principles are designed to reduce the occurrence of foodborne illness risk factors through preventive controls. FDA has developed two technical assistance reference manuals that interpret and promote the application of HACCP principles to reduce the risk of foodborne illness in the operation of retail and food service establishments.

The responsibility and authority for regulating retail and food service establishments lie primarily with State and local governments. Officials in State, local, territorial, and tribal agencies inspect these food facilities, license establishments, issue permits, and enforce their State or local government's laws and regulations. FDA's Retail Food Protection Program provides assistance to the more than 3,000 State and local government agencies that regulate the retail food industry nationally. The primary objective of the Retail Food Protection Program is to prevent foodborne illness at the retail level of the food industry by directing activities toward promotion of effective State and local regulatory programs. FDA provides assistance to State, local, territorial, and tribal regulatory jurisdictions through multiple means including, but not limited to, training and technical assistance. Authority for providing such assistance is derived from section 311 of the Public Health Service Act (42 U.S.C. 243). In addition, FDA's mission under section 903(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 393(b)(2)(A)) includes ensuring that foods are safe, wholesome, and sanitary, and section 903(b)(4) of the FD&C Act directs FDA to cooperate with food retailers, among others, in carrying out this part of its mission.

The first manual, entitled ''Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments'' (Operator's Manual) (available at *http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ManagingFoodSafetyHACCPPrinciples/Operators/default.htm*), provides operators of retail and food service establishments a roadmap for developing a food safety management system based on HACCP principles. Food safety management systems allow establishment operators to take a proactive role in ensuring that the food served or sold in their establishment is safe. Rather than responding to a foodborne illness when it occurs, they can prevent it by taking active steps to eliminate, prevent, or reduce to an acceptable level food safety hazards that may cause someone to become sick or injured.

The second manual, entitled ''Managing Food Safety: A Regulator's Manual for Applying HACCP Principles to Risk-based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems'' (Regulator's Manual) (available at *http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ManagingFoodSafetyHACCPPrinciples/Regulators/default.htm*), provides State, local, territorial, and tribal regulatory authorities with a model for prioritizing inspections using a risk-based approach. The Regulator's Manual provides a roadmap for evaluating retail and food service establishments based on the application of HACCP principles.

FDA developed the manuals as technical assistance reference resources for regulators and operators to help reduce the risk of foodborne illness. There is no Federal requirement that retail and food service establishments implement food safety management systems based on HACCP principles. State, local, territorial, and tribal regulatory authorities decide whether to require food safety management systems in the operation of retail and food service establishments. Regulators and operators will not submit information to FDA based on these manuals.

Regulators and retail and food service operators use the manuals as technical assistance reference resources. The Regulator's Manual contains information, recommendations and model documents for State, local, territorial, and tribal regulators who wish to develop practices for risk-based inspections of retail and food service establishments based on the application of HACCP principles. The Operator's Manual contains information, recommendations and model documents for operators of retail and food service establishments who wish to develop and/or validate the practices used in a food safety management system based on HACCP principles.

Description of Respondents: The respondents are State, local, territorial, and tribal regulatory jurisdictions and operators of retail and food service establishments in the United States. Respondents are from both the public sector (State, local, territorial, and tribal governments) and the private sector (for-profit businesses).

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
Reference of Technical Assistance Manuals by Operators	25,000	1	25,000	0.2 (12 minutes)	5,000
Reference of Technical Assistance Manuals by Regulators	1,500	1	1,500	0.25 (15 minutes)	375
Total					5,375

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The number of operator recordkeepers estimated in column 2 of Table 1 is based on FDA's goal to have 50,000 (½ of 1 percent) of the approximately one million U.S. retail and food service operators implement the recommendations outlined in the two manuals, as estimated in 2009 (73 FR 77721, at 77722). FDA's estimate of the total number of retail and food service establishments is based on numbers obtained from the two major trade organizations representing these industries, the Food Marketing Institute and the National Restaurant Association. Gathering reference material to develop and/or validate food safety management system practices is a one-time burden. We assume that those 50,000 operators have utilized FDA's technical assistance manuals to the

degree that they chose to do so over the past 3 years and over the next 3 years will only need to reference these manuals on an as-needed basis. FDA estimates that, annually, approximately one half of the operators, 25,000, will choose to reference FDA's information, recommendations or model documents.

The number of regulator recordkeepers estimated in column 2 of Table 1 is based on FDA's estimate that there are approximately 3,000 State, local, territorial, and tribal regulatory jurisdictions. Gathering and reviewing reference material to develop practices for risk-based inspections of retail and food service establishments based on HACCP principles is a one-time burden. We assume that those 3,000 regulatory jurisdictions have utilized FDA's technical assistance manuals to the degree that they chose to do so over the past 3 years and over the next 3 years will only need to reference these manuals on an as-needed basis. FDA estimates that, annually, approximately one half of the regulatory jurisdictions (1,500) will choose to reference FDA's information, recommendations or model documents.

The hours per record estimated in column 2 of Table 1 are based on FDA's experience with similar technical assistance materials offered by the Agency. FDA estimates that over the next 3 years regulators and operators will only need to reference these manuals on an as needed basis. We estimate that it will take an operator with a specific need for information approximately 12 minutes (0.2 hour) to gather and record the data from the manuals. We estimate that it will take a regulator with a specific need for information approximately 15 minutes (0.25 hour) to gather and record the data from the manuals.

The total recordkeeping burden of the technical assistance manuals is 5,375 hours, as shown in Table 1.

Dated: November 8, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–27721 Filed 11–14–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1995–N–0031; (formerly Docket No. 1995N–0205)]

Compliance Guidance for Small Business Entities on Labeling for Bronchodilators: Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a compliance guidance for small business entities entitled ''Labeling for Bronchodilators: Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Small Entity Compliance Guide.'' This guidance is intended to help small businesses understand and comply with the requirements of the final rule that provides new labeling applicable to all over-the-counter (OTC) bronchodilator drug products marketed without an approved application. The guidance describes the bronchodilator labeling requirements in plain language and provides answers to common questions on how to comply with the rule. This guidance was prepared in accordance with the Small Business Regulatory Fairness Act.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Elaine Abraham, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 22, Rm. 5410, Silver Spring, MD 20993–0002, 301–796–2090.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a compliance guidance for small business entities entitled ''Labeling for Bronchodilators: Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Small Entity Compliance Guide.'' This small entity compliance guide applies to OTC bronchodilator drug products used to treat asthma that are marketed without an approved application (i.e., under the OTC bronchodilator monograph) (21 CFR part 341). OTC bronchodilators are those that contain any of the ephedrine ingredients (i.e., ephedrine, ephedrine hydrochloride, ephedrine sulfate, and racephedrine hydrochloride) or epinephrine ingredients (i.e., epinephrine, epinephrine bitartrate, and racepinephrine hydrochloride) listed under 21 CFR 341.16.

This guidance summarizes the July 26, 2011, final rule (76 FR 44475) regarding OTC bronchodilator drug products, which makes the following changes to the OTC regulations:

- Sets forth a new use statement, warnings (including an Asthma Alert warning), and directions that are required in the labeling of OTC bronchodilator drug products under 21 CFR 341.76.
- Revises labeling requirements for OTC bronchodilator drug products to ensure consistency with the standardized Drug Facts content and formatting requirements set forth in 21 CFR 201.66.

Manufacturers must be in compliance with the rule beginning on January 23, 2012.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on labeling for OTC bronchodilator drug products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* It is only necessary to send one set of comments. Identify comments with the docket

number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: November 8, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–27724 Filed 11–14–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0799]

Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples From Donors of Whole Blood and Blood Components, Including Source Plasma, To Reduce the Risk of Transmission of Hepatitis B Virus; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples from Donors of Whole Blood and Blood Components, including Source Plasma, to Reduce the Risk of Transmission of Hepatitis B Virus,'' dated October 2012. The guidance document provides recommendations on the use of FDA-licensed nucleic acid tests (NAT) to screen blood donors for hepatitis B virus (HBV) deoxyribonucleic acid (DNA) and recommendations for product testing and disposition, donor management, methods for donor requalification, and product labeling. In addition, the guidance provides notification that FDA considers the use of an FDA-licensed HBV NAT to be necessary to reduce adequately and appropriately the risk of transmission of HBV. The guidance is intended for blood establishments that collect Whole Blood and blood components for transfusion or for further manufacture, including recovered plasma, Source Plasma and Source Leukocytes. The guidance announced in this notice finalizes the draft guidance of the same title, dated November 2011. The guidance also supplements previous memoranda and guidance from FDA concerning the testing of donations for hepatitis B surface antigen (HBsAg) and antibody to hepatitis B core antigen (anti-HBc) and the management of donors and donations mentioned in those documents.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paul E. Levine, Jr., Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples from Donors of Whole Blood and Blood Components, including Source Plasma, to Reduce the Risk of Transmission of Hepatitis B Virus,'' dated October 2012. FDA is providing blood establishments that collect Whole Blood and blood components for transfusion or for further manufacture, including recovered plasma, Source Plasma and Source Leukocytes, with recommendations concerning the use of FDA-licensed NAT to screen blood donors for HBV DNA. FDA is also providing these blood establishments with recommendations for product testing and disposition, donor management, methods for donor requalification, and product labeling.

In addition, FDA is notifying those blood establishments that FDA considers the use of an FDA-licensed HBV NAT to be necessary to reduce adequately and appropriately the risk of transmission of HBV. FDA-licensed HBV NAT can detect evidence of infection at an earlier stage than is possible using previously approved HBsAg and anti-HBc tests. Therefore, FDA is recommending the use FDA-licensed HBV NAT, in accordance with the requirements under Title 21 Code of Federal Regulations, 610.40(a) and (b) (21 CFR 610.40(a) and (b)).

The guidance supplements previous memoranda and guidance from FDA to blood establishments concerning the testing of donations for HBsAg and anti-HBc, and the management of donors and donations mentioned in those documents. Note that testing Whole Blood and blood components for transfusion and Source Leukocytes for further manufacture for HBsAg and anti-HBc, and Source Plasma for HBsAg, should continue when a blood establishment implements HBV NAT. FDA may consider advancements in technology for testing blood donations, as well as data obtained following the implementation of HBV NAT, to make future recommendations on adequate and appropriate testing for HBV.

In the **Federal Register** of November 28, 2011 (76 FR 72950), FDA announced the availability of the draft guidance of the same title, dated November 2011. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. In addition to minor editorial changes made to improve clarity, changes to the draft guidance include revised labeling recommendations and an extension of the time for implementation of the guidance to 6 months after publication of the final guidance. The guidance announced in this notice finalizes the draft guidance dated November 2011.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These

collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in § 601.12 and in §§ 606.121 and 610.40 have been approved under OMB control numbers 0910–0338 and 0910–0116, respectively.

III. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: November 7, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–27783 Filed 11–14–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request (30-day): National Institute of Nursing Research (NINR) Summer Genetics Institute Alumni Survey

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This information collection was previously published in the **Federal Register** on June 29, 2012, page 38840 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Amanda Greene, Office of Science Policy and Public Liaison, NINR, NIH, Democracy One, 6701 Democracy Blvd., Suite 700, Bethesda, MD 20892 or call non-toll-free number (301) 496–9601 or Email your request, including your address to: *amanda.greene@nih.gov.*

Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Proposed Collection: National Institute of Nursing Research (NINR) Summer Genetics Institute Alumni Survey, –0925–New

Need and Use of Information Collection: The NINR Summer Genetics Institute Alumni Survey will obtain information on the long-term outcomes of the NINR Summer Genetics Institute training program for nurse scientists and faculty. Target participants are alumni of this training institute which began in 2000. The survey inquires about career activities, including research, clinical, teaching and educational activities, since completion of the NINR Summer Genetics Institute. This is a 39-item survey that takes an average of 30 minutes to complete. The findings will provide valuable information on the influence of the Institute in developing genetics research capability among Institute alumni, and development and expansion of clinical practice in genetics among alumni who are nurse clinicians.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 75.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Frequency of response	Average time per response (in hours)	Total burden hours
Researchers	150	1	30/60	75

Dated: November 2, 2012.

Amanda Greene,

Project Clearance Liaison, NINR, National Institutes of Health.

[FR Doc. 2012–27578 Filed 11–14–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Interagency Autism Coordinating Committee (IACC) Subcommittee for Services Research and Policy.

The IACC Subcommittee for Services Research and Policy will be having a webinar/conference call on Tuesday, November 27, 2012. The Subcommittee will discuss and vote on draft Updates for Chapters 5 and 6 of the 2012 IACC Strategic Plan, which include services and lifespan issues. These Updates will describe recent progress that has been made in the autism field as well as any new gap areas in research that have emerged since the previously released 2011 Strategic Plan. The meeting will be open to the public and accessible by webinar and conference call.

Name of Committee: Interagency Autism Coordinating Committee (IACC).

Type of meeting: Subcommittee for Services Research and Policy.

Date: November 27, 2012.

Time: 11:00 a.m. to 2:00 p.m. Eastern Time.

Agenda: The Subcommittee will discuss and vote on 2012 IACC Strategic Plan Updates for Chapters 5 and 6 that will describe recent progress that has been made in the autism field and identify new gap areas in research that have emerged.

Webinar: https://www2.gotomeeting.com/register/949976034.

Conference Call: Dial: 888–390–0854, Access code: 9876377.

Cost: The conference call and webinar is free.

Contact Person: Ms. Lina Perez, Office of Autism Research Coordination, National Institute of Mental Health, NIH, 6001 Executive Boulevard, NSC, Room 6182A, Rockville, MD 20852, Phone: 301–443–6040, Email: *IACCPublicInquiries@mail.nih.gov.*

Please Note:

The webinar and conference call will be open to the public. Members of the public who participate using the conference call phone number will be able to listen to the meeting but will not be heard. If you experience any technical problems with the conference call, please email *iacchelpdesk2012@gmail.com.*

If you experience any technical problems with the web presentation tool, please contact GoToWebinar at (800) 263–6317. To access the web presentation tool on the Internet the following computer capabilities are required: (A) Internet Explorer 5.0 or later, Netscape Navigator 6.0 or later or Mozilla Firefox 1.0 or later; (B) Windows® 2000, XP Home, XP Pro, 2003 Server or Vista; (C) Stable 56k, cable modem, ISDN, DSL or better Internet connection; (D) Minimum of Pentium 400 with 256 MB of RAM (Recommended); (E) Java Virtual Machine enabled (Recommended).

Individuals who participate by using this electronic service and who need special assistance such as captioning or other reasonable accommodations should submit a request to the Contact Person listed on this notice at least 5 days prior to the meeting.

This notice is being published less than 15 days prior to the meeting due to the urgent need for the Subcommittee to discuss the update of the IACC Strategic Plan prior to the IACC meeting scheduled for December 18, 2012.

Schedule is subject to change.

Information about the IACC and a registration link for this meeting are available on the Web site: *http://www.iacc.hhs.gov.*

Dated: November 8, 2012.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–27685 Filed 11–14–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Interagency Autism Coordinating Committee (IACC) Subcommittee for Basic and Translational Research.

The IACC Subcommittee for Basic and Translational Research will be having a webinar/conference call on Monday, November 26, 2012. The Subcommittee will discuss and vote on draft Updates for Chapters 1, 2, 3, 4 and 7 of the 2012 IACC Strategic Plan, which include the diagnosis, underlying biology, risk factors, treatments and interventions, and infrastructure and surveillance needs and advances in autism research. These Updates will describe recent progress that has been made in the autism field as well as any new gap areas in research that have emerged since the previously released 2011 Strategic Plan. The meeting will be open to the public and accessible by webinar and conference call.

Name of Committee: Interagency Autism Coordinating Committee (IACC).

Type of meeting: Subcommittee for Basic and Translational Research.

Date: November 26, 2012.

Time: 12:00 p.m. to 3:00 p.m. Eastern Time.

Agenda: The Subcommittee will discuss and vote on 2012 IACC Strategic Plan Updates for Chapters 1, 2, 3, 4, and 7 that will describe recent progress that has been made in the autism field and identify new gap areas in research that have emerged.

Webinar: https://www2.gotomeeting.com/register/425502082.

Conference Call: Dial: 888–790–1866, Access code: 1503040.

Cost: The conference call and webinar is free.

Contact Person: Ms. Lina Perez, Office of Autism Research Coordination, National Institute of Mental Health, NIH, 6001 Executive Boulevard, NSC, Room 6182A, Rockville, MD 20852, Phone: 301–443–6040, Email: *IACCPublicInquiries@mail.nih.gov.*

Please Note:

The webinar and conference call will be open to the public. Members of the public who participate using the conference call phone number will be able to listen to the meeting but will not be heard. If you experience any technical problems with the conference call, please email *iacchelpdesk2012@gmail.com.*

If you experience any technical problems with the web presentation tool, please contact GoToWebinar at (800) 263–6317. To access the web presentation tool on the Internet the following computer capabilities are required: (A) Internet Explorer 5.0 or later, Netscape Navigator 6.0 or later or Mozilla Firefox 1.0 or later; (B) Windows® 2000, XP Home, XP Pro, 2003 Server or Vista; (C) Stable 56k, cable modem, ISDN, DSL or better Internet connection; (D) Minimum of Pentium 400 with 256 MB of RAM (Recommended); (E) Java Virtual Machine enabled (Recommended).

Individuals who participate by using this electronic service and who need special assistance such as captioning or other reasonable accommodations should submit a request to the Contact Person listed on this notice at least 5 days prior to the meeting.

This notice is being published less than 15 days prior to the meeting due to the urgent need for the Subcommittee to discuss the update of the IACC Strategic Plan prior to the IACC meeting scheduled for December 18, 2012.

Schedule is subject to change.

Information about the IACC and a registration link for this meeting are available on the Web site: *http://www.iacc.hhs.gov.*

Dated: November 8, 2012.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–27686 Filed 11–14–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council on Alcohol Abuse and Alcoholism.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Alcohol Abuse and Alcoholism.

Date: February 6–7, 2013.

Closed: February 6, 2013, 5:30 p.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, T–508, Rockville, MD 20852.

Closed: February 7, 2013, 8:00 to 8:45 a.m.

Agenda: Presentation of the IC Intramural Program Evaluation to Council.

Place: National Institutes of Health, 5635 Fishers Lane, T–508, Rockville, MD 20852.

Open: February 7, 2013, 9:00 a.m. to 1:00 p.m.

Agenda: Presentations and other business of the council.

Place: National Institutes of Health, 5635 Fishers Lane, T–508, Rockville, MD 20852.

Contact Person: Abraham P. Bautista, Ph.D., Executive Secretary, National Institute on Alcohol Abuse & Alcoholism National Institutes of Health, 5635 Fishers Lane, Room 2085, Rockville, MD 20852, 301–443–9737, *bautista@mail.nih.gov.*

Information is also available on the Institute's/Center's home page: *http://www.niaaa.nih.gov/Pages/default.aspx,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.273, Alcohol Research Programs, National Institutes of Health, HHS)

Dated: November 2, 2012.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–27688 Filed 11–14–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute Amended; Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Advisory Board, November 28, 2012, 6:30 p.m. to November 29, 2012, 5:00 p.m., National Institutes of Health, Building 31C, Wing C, Conference Room 10, 31 Center Drive, Bethesda, MD 20892 which was published in the **Federal Register** on October 22, 2012, 77FR64526.

This notice is being amended to add the NCAB ad hoc Subcommittee on Global Cancer Research Meeting on November 28, 2012, 5:00 p.m. to 6:30 p.m. at the Hyatt Regency Bethesda Hotel, Old Georgetown Room, One Metro Center, Bethesda, MD 20814. The NCAB ad hoc Subcommittee on Communications will convene at the same location on November 28, 2012, however, the start and end times have been changed to 7:00 p.m. to 8:30 p.m.

Dated: November 8, 2012.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–27729 Filed 11–14–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIH Support for Conferences and Scientific Meetings.

Date: December 11–13, 2012.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 3254, 6700–B Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Nancy Lewis Ernst, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–451–7383, *nancy.ernst@nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Leadership Group for a Clinical Research Network on Antibacterial Resistance (UM1).

Date: January 17–18, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, Roosevelt Room, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Annie Walker-Abbey, Ph.D., Scientific Review Officer, Scientific Review Program, NIAID/NIH/DHHS, 6700B Rockledge Drive, RM 3126, MSC–7616, Bethesda, MD 20892–7616, 301–451–2671, *aabbey@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 8, 2012.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–27728 Filed 11–14–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors, National Institute of Dental and Craniofacial Research.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Dental & Craniofacial Research, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Institute of Dental and Craniofacial Research.

Date: November 26–28, 2012.

Time: 7:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 30, Bethesda, MD 20892.

Contact Person: Alicia J. Dombroski, Ph.D., Director, Division of Extramural Activities, National Institute of Dental and Craniofacial Research, National Institutes of Health, Bethesda, MD 20892.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the intramural research review cycle.

Information is also available on the Institute's/Center's home page: *http://www.nidcr.nih.gov/about/Council Committees.asp,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: November 8, 2012.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–27727 Filed 11–14–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel NIDDK Look Ahead Ancillary Study Applications

Date: December 5, 2012.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Elena Sanovich, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 750, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, 301–594–8886, *sanoviche@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: November 8, 2012.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–27726 Filed 11–14–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel Genetics and Genomics.

Date: November 27, 2012.

Time: 10:15 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Cheryl M Corsaro, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2204, MSC 7890, Bethesda, MD 20892, (301) 435–1045, *corsaroc@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflict: AIDS and AIDS Related Research.

Date: December 3, 2012.

Time: 3:00 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Eduardo A Montalvo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7852, Bethesda, MD 20892, (301) 435–1168, *montalve@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflict: Child Psychopathology and Developmental Disabilities.

Date: December 10, 2012.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Melissa Gerald, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3172, MSC 7848, Bethesda, MD 20892, (301) 408–9107, *geraldmel@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel Small Business: Digestive Sciences.

Date: December 12–13, 2012.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Patricia Greenwel, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2178, MSC 7818, Bethesda, MD 20892, 301–435–1169, *greenwep@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel Small Business: Digestive Sciences.

Date: December 12–13, 2012.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Bonnie L Burgess-Beusse, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, 301–435–1783, *beusseb@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel RFA AI12–033: U.S. India Bilateral Collaborative Research Partnerships (CRP) on the Prevention of HIV/AIDS and CO-Morbidities.

Date: December 13, 2012.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Robert Freund, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5216, MSC 7852, Bethesda, MD 20892, 301–435–1050, *freundr@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 8, 2012.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–27690 Filed 11–14–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Nucleic Acid Metabolism.

Date: November 13, 2012.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Richard Panniers, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2212, MSC 7890, Bethesda, MD 20892, (301) 435–1741, *pannierr@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Translational Research in Diabetes, Obesity and Endocrine Disorders.

Date: November 14–15, 2012.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Nancy Sheard, SCD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6046–E, MSC 7892, Bethesda, MD 20892, 301–408–9901, *sheardn@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Immune Mechanisms of Autoimmunity.

Date: November 14, 2012.

Time: 4:00 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Jin Huang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4095G, MSC 7812, Bethesda, MD 20892, 301–435–1230, *jh377p@nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR12–155 Integrative Omics Data Analysis for Discovery in Lung Diseases.

Date: November 16, 2012.

Time: 1:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Richard Panniers, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2212, MSC 7890, Bethesda, MD 20892, (301) 435–1741, *pannierr@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 8, 2012.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–27694 Filed 11–14–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Advisory Committee to the Director, National Institutes of Health.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Advisory Committee to the Director, National Institutes of Health.

Date: December 6–7, 2012.

Time: 9:00 a.m. to 1:00 p.m.

Agenda: NIH Director's Report, ACD Working Group Implementation Team reports, NIH.

Place: Updates and other business of the Committee, National Institutes of Health, Building 31, C-Wing 6th Floor, Conference Room 6, 31 Center Drive, Bethesda, MD 20852.

Contact Person: Gretchen Wood, Staff Assistant, National Institutes of Health, Office of the Director, One Center Drive, Building 1, Room 103, Bethesda, MD 20892, 301–496–4272, *woodgs@od.nih.gov.*

Information is also available on the Institute's/Center's home page: *http://acd.od.nih.gov,* where an agenda and any additional information for the meeting will be posted when available.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: November 8, 2012.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–27687 Filed 11–14–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5607–N–35]

Notice of Proposed Information Collection: Comment Request; Eligibility of a Nonprofit Corporation/Housing Consultant Certification

AGENCY: Office of the Assistant Secretary for Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below

will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* January 14, 2013.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Reports Liaison Officer, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410 or the number for the Federal Information Relay Service (1–800–877–8339).

FOR FURTHER INFORMATION CONTACT: Dan Sullivan, Director, Office of Multifamily Housing Development, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410, telephone (202) 402–6130 (this is not a toll free number) for copies of the proposed forms and other available information.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection 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; (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 the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Eligibility of a Nonprofit Corporation/Housing Consultant Certification.

OMB Control Number, if applicable: 2502–0057.

Description of the need for the information and proposed use: The information collected on the ''Eligibility of a Nonprofit Corporation/Housing Consultant Certification'' form provides HUD with information to determine whether the sponsor has qualifications necessary for successful sponsorship of housing projects. HUD Program Offices use the data to evaluate a potential sponsor's/mortgagor's qualifications at the pre-application stage to determine that all the documentation required by Chapter 8 of the MAP and Chapter 14 of Handbook 4470.1

Agency form numbers, if applicable: HUD–3433, HUD–3434, HUD–3435, and HUD–92531.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: The number of burden hours is 43. The number of respondents is 100; the number of responses is 110. The frequency of response is on occasion; and the hourly burden is 1hour and 45 minutes.

Status of the proposed information collection: This is an extension of a currently approved collection.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C., chapter 35, as amended.

Dated: November 8, 2012.

Laura M. Marin,

Acting General Deputy Assistant Secretary for Housing—Deputy Federal Housing Commissioner.

[FR Doc. 2012–27799 Filed 11–14–12; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5607–N–34]

Notice of Proposed Information Collection: Comment Request; Multifamily Housing Service Coordinator Grant

AGENCY: Office of the Assistant Secretary for Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATE: *Comments Due Date:* January 14, 2013.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Departmental Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email *Colette.Pollard@HUD.gov.*

FOR FURTHER INFORMATION AND COPIES OF THE PROPOSED FORMS CONTACT: Carissa L. Janis, Housing Program Manager, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410, email *Carissa.L.Janis@hud.gov* and telephone (202) 708–3000. (This is not a toll free number.)

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to:

1. Evaluate whether the proposed collection 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;

3. Enhance the quality, utility, and clarity of the information to be collected; and minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Multifamily Housing Service Coordinator Program.

OMB Control Number: 2502–0447.

Description of the need for the information and proposed use:

1. HUD uses the grant applications (SF–424, HUD–91186, and other related documents) to assess the need and proposed use of grant funds and owners' ability to administer those funds.

2. HUD staff will use requests for extensions (HUD–91186–A) to evaluate anticipated program costs and the continued need for the program.

3. The LOCCS Payment Voucher (HUD–50080–SCMF) is used to monitor release of grant funds to reimburse eligible program costs over the term of the grant. Grant recipients will similarly use this voucher to track and record their requests for payment reimbursement for grant-funded expenses.

4. The Department is revising the Semi-Annual Performance Report, HUD–92456. Changes include the following:

A. Additional sources of funding;

B. Modification of resident statistics and the numbers of project tenants and neighborhood residents served by the Service Coordinator during the reporting period;

C. Adding hire date for the Service Coordinator and date of program inception;

D. Adding number of contacts to number of residents that the Service Coordinator links to various supportive services;

E. Providing a glossary of definitions of supportive service types;

F. Modifying the section for reporting time allocation of monthly work responsibilities;

G. Adding a new item to highlight community engagement; including meetings with community agencies and residents and Attendance at or planning of community events, and

H. Adding a new section to track aging in place statistics.

The semi-annual Performance Reports will be used to gauge program performance and effective use of Federal funds to meet stated program goals. The Department proposes the new changes to obtain more specific, accurate, and relevant data. To complete the form, Housing owners and Service Coordinators will develop and maintain meaningful data that reflect the efficacy of the Service Coordinator program. The Burden Hours per Response remains the same at six hours. (Previous requests had overstated the amount of time required to complete the report.)

5. The Department is proposing a new form to be used by field office staff to perform Service Coordinator program reviews. This proposed form is provided in this Notice to solicit comments from the public, even though the form is designed for use by HUD field office staff. The Department requires a consistent protocol to review and evaluate Service Coordinator programs. The use of this form will allow for consistent and thorough program assessment. It will also inform housing owners, management agents, and Service Coordinators about program requirements and expected performance.

6. SF–425

7. HUD–96010

Agency Form Numbers, If Applicable: HUD–2880, HUD–50080–SCMF, HUD–91186, HUD–91186–A, HUD–92455, HUD–92456, HUD–96010, SF–424, SF–424–Supp, SF–425, and SF–LLL.

Estimation of the Total Numbers of Hours Needed to Prepare The Information Collection Including Number of Respondents, Frequency of Response, and Hours of Response: The number of respondents is 10,290; the frequency of responses is quarterly, semi-annually, and annually, with a total of 22,070 total annual responses. The estimated time to prepare collection varies from 15 minutes to 40 hours, with a total of 74,800 annual burden hours.

Status of the Proposed Information Collection: This is a revision of a previously approved collection.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C., Chapter 35, as amended.

Dated: November 8, 2012.

Laura M. Marin,

Acting General Deputy Assistant Secretary for Housing—Acting General Deputy Housing Commissioner.

[FR Doc. 2012–27802 Filed 11–14–12; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5613–N–06–B]

Privacy Act of 1974; New System of Records, Office of General Counsel E-Discovery Management System: Republication of System Description and Solicitation of Comment

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: This notice solicits additional comment on a new system of records for the Office of General Counsel (OGC) E-Discovery Management System (EDMS). EDMS was first announced and described in a July 17, 2012, **Federal Register** notice, in which HUD solicited comment. Based on comment received, this notice makes certain revisions to the description of EDMS in the July 17, 2012, notice and solicits additional comment. Additional clarification is provided regarding the system of records: Category of Individuals Covered by the System; the Purpose Category; Retention Use and Disposal of Records Category, and System Location Category.

DATES: *Comments Due Date:* December 17, 2012.

ADDRESSES: Interested persons are invited to submit comments regarding this notice to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500. Communications must refer to the above docket number and title. There are two methods for submitting public comments. All submissions must refer to the above docket number and title.

1. *Submission of Comments by Mail.* Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500.

2. *Electronic Submission of Comments.* Interested persons may submit comments electronically through the Federal eRulemaking Portal at *http://www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *http://www.regulations.gov* Web site can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that Web site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of the rule.

No Facsimile Comments. Facsimile (FAX) comments are not acceptable.

Public Inspection of Public Comments. All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an advance appointment to review the public comments must be scheduled by calling the Regulations Division at (202) 708–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number through TTY by calling the Federal Relay Service at (800) 877– 8339. Copies of all comments submitted are available for inspection and downloading at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For inquiries pertaining to Privacy Act records, contact Donna Robinson-Staton, Chief Privacy Officer, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410 (Attention: Capitol View Building, 4th Floor) telephone number (202) 402–8073 (this telephone number is not toll free). A telecommunications device for hearing- and speech-impaired persons (TTY) is available by calling the Federal Relay Service's toll-free telephone number (800) 877–8339.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to the Privacy Act of 1974 (5 U.S.C. 552a) (Privacy Act), HUD published in the **Federal Register** on July 17, 2012, at 77 FR 41997, a notice that announced a new system of records for OGC's E-Discovery Management System (OGC–EDMS), a system expected to significantly improve the efficiency of OGC's processing of records during the preservation, discovery, and processing of litigation requests when litigation is ''reasonably anticipated'' [1] and reduce the time HUD staff spend on the document review and production process. OGC–EDMS is in response to and consistent with e-discovery preservation and production requirements in the Federal Rules of Civil Procedure.

The July 17, 2012, notice solicited public comment on OGC–EDMS for a period of 30 days. The notice advised that EDMS would carry a final effective date of August 16, 2012, unless HUD received comments which would result in a contrary determination. HUD received public comment in response to the July 17, 2012, notice. On August 15, 2012, at 77 FR 49011, HUD published a notice advising of a change the final effective date of OGC–EDMS, the commitment to re-publish the description of OGC–EDMS with certain clarifications, respond to public comments received in response to the July 17, 2012, notice, and seek additional public comment.

The system report was submitted to the Office of Management and Budget (OMB), the Senate Committee on Homeland Security and Governmental Affairs, and the House Committee on Government Reform pursuant to Paragraph 4c of Appendix l to OMB Circular No. A–130, ''Federal Agencies Responsibilities for Maintaining Records About Individuals,'' July 25, 1994 (59 FR 37914).

Discussion of Public Comments

In response to the July 17, 2012, notice, HUD received comments from a national professional association representing trial lawyers, and a coalition consisting of advocacy groups representing consumers, as well as advocacy groups fighting racial injustice and housing discrimination.

Comment: HUD should comply with the Federal Rules of Civil Procedure and should not destroy original documents. The commenters stated that OGC–EDMS should be regulated by the Federal Rules of Civil Procedure. The commenters further stated that they had significant concerns about the proposed retention and disposal policy which allowed HUD's OGC to destroy litigation data when closing a case. The commenters requested that original documents not be destroyed as part of an electronic data purge, and that copies of the case data be made available in the event of a Freedom of Information Act (FOIA) request or the need to revisit a particular case or series of cases.

HUD Response: In response to the commenters' concerns about the consistency of HUD's policies with the Federal Rules of Civil Procedure, HUD is providing additional operational information about EDMS and the other HUD electronic information systems. HUD is also clarifying that when litigation is ''reasonably anticipated,'' related electronic data is forensically copied and maintained in a secure server environment separate from HUD's network servers as part of the OGC–EDMS. In this secure server environment, electronic data is preserved in a way that prevents metadata spoliation by the system or the owner of the data. As part of the Electronic Discovery Reference Model, HUD users are able to review and analyze the relevant electronic data that has been forensically copied and maintained as part of the EDMS. Reviewing the forensically copied electronic data within the EDMS prevents users from altering or improperly handling original documents, which is in all parties' interests.

After authorization from an OGC manager, such as an Associate General Counsel or Regional Counsel, is received, OGC requests a case to be closed within the EDMS. The case and related electronic litigation data that has been copied and secured in a production environment for the purposes of litigation, is purged electronically from the EDMS. This purging does not include purging of electronic data from its original source such as network servers. Electronic data is properly retained on network servers and other sources as mandated by the HUD's Office of General Counsel Records Disposition Schedule 2—Legal Records, 2225.6 REV–1, CHG–APPENDIX 2 [2] and HUD's Office of the Chief Information Officer Electronic Mail Policy, 2400.1 REV01, CHG.[3] These handbooks are available on HUD's web pages through hudclips.

In response to commenters' concerns, HUD is revising its System of Records notice for the EDMS to clarify that original documents are not destroyed as part of HUD's E-Discovery efforts. Revisions to the text of the Retention and Disposal Section that follows should clarify the process. For the convenience of the public, HUD is providing a complete summary within this notice of the location, purposes, and operational description of EDMS to facilitate comment.

Authority: 5 U.S.C. 552a; 88 Stat. 1896; 42 U.S.C. 3535(d).

Dated: November 7, 2012.

Jerry E. Williams,

Chief Information Officer.

SUMMARY DESCRIPTION OF EDMS

OGC.CAGC.01

SYSTEM NAME:

Office General Counsel Electronic Discovery Management System. (OGC–EDMS)

SYSTEM LOCATIONS:

The EDMS application will be stored on servers located at 4701 Forbes Boulevard, Lanham, MD 20706. Custodian data to be retrieved is stored on servers and HUD workstations located throughout the country.[4]

PURPOSES:

OGC–EDMS provides OGC with a method to initiate, track, and manage the collection, organization, and production of paper and electronic documents for discovery requests, such as litigation hold memoranda, E-Discovery certifications, electronically stored information (ESI) search requests, closure letters, and any other documents and data relevant to the discovery process requiring analysis, review, redaction, and production to respond to litigation discovery requirements. The purpose of this system is to assist HUD to collect electronically stored information and data of any individual who is, or will be, in litigation with HUD, as well as the attorneys representing the plaintiff(s) and defendant(s) in response to claims by

[1] ''Reasonably anticipated'' is the legal test articulating the standard for when the duty to preserve electronically stored information begins. A key case is *Pension Comm. of the Univ. of Montreal Pension Plan* v. *Banc of Am. Secs., LLC,* 05 Civ. 9016 (SAS), 2010 U.S. Dist. LEXIS 4546, at * 14–15 (S.D.N.Y. Jan. 15, 2010).

[2] *http://portal.hud.gov/hudportal/HUD?src=/program_offices/administration/hudclips/handbooks/admh/2225.6.*

[3] *http://www.hud.gov/offices/adm/hudclips/handbooks/cioh/.*

[4] *http://portal.hud.gov/hudportal/documents/huddoc?id=append2.pdf.*

employees, former employees, and other individuals; to assist in the settlement of claims against the government; to represent HUD during litigation, and to maintain internal statistics. A new software component is being added to HUD's EDMS process that will streamline the collection, storage, and analysis of case data to be responsive to requests to HUD.

On December 1, 2006, the Federal Rules of Civil Procedure were amended to create and clarify responsibility for preserving and accessing ESI. The obligation to preserve ESI, as well as paper records, begins when an individual ''reasonably anticipates'' litigation and concludes that the evidence may be relevant to such future litigation. Once an individual ''reasonably anticipates'' litigation, he/she must suspend any document alteration or destruction to ensure the preservation of relevant documents and electronically stored information, including emails.

EDMS and its various capabilities will allow OGC to streamline and automate the document and data reviews it conducts, allow the attorneys to analyze the information in different formats, conduct the analysis in bulk more efficiently, and protect unwarranted disclosure of information by flagging files that contain information therein that is protected from disclosure.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The federal regulation(s)/statute(s) that gives OGC the authority to collect and store this information is Federal Rules of Civil Procedure (FRCP) 16(b) which allows the court to establish rules around disclosure, privilege, methods and work product prior to electronic discovery commencing. In this context, disclosure is the collection of data. Other relevant regulations surrounding the collection and management of electronic discovery are FRCP 26(b)(2), 26(b)(5)(B), 26(f), 33(d), 34(a), 34(b), 37(f), and 45.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Categories of individuals covered by this system include: (1) All persons subject to a litigation hold due to a ''reasonable anticipation of litigation'' as determined by HUD's OGC; (2) all persons deemed a participant of past or present litigation, investigations, or arbitration where HUD is involved; and (3) specified individuals impacted by FOIA requests, litigation, and other cases in HUD.

A wide variety of individuals are covered by the system including: individuals who either file administrative complaints with HUD or are the subject of administrative complaints initiated by HUD; individuals who are named parties in cases in which HUD believes it will or may become involved; individuals involved in matters within the jurisdiction of HUD either as plaintiffs or as defendants in both civil and criminal matters; witnesses, and to the extent not covered by any other system, tort and property claimants who have filed claims against the Government; individuals who are the subject of an action requiring approval or action by a HUD official, such as appeals, actions, training, awards, promotions, selections, grievances and delegations, including the OGC attorneys to whom cases are assigned, and attorneys and authorized representatives for whom HUD has received complaints regarding their practices before HUD.

CATEGORIES OF RECORDS IN THE SYSTEM:

Categories of records in this system include: (1) Custodian name; (2) Custodian work address; (3) Custodian email address; (4) Case Name; (5) Case number; (6) Custodian email data, including messages among other HUD employees and/or personnel of other federal agencies or outside entities, and attachments; (7) Custodian local/shared drive data of information collected or compiled from law enforcement or other agency databases; (8) Spreadsheets including data collections, often including personally identifiable information and sensitive law enforcement data used to track the process or investigations or focus investigative priorities; records relating to litigation by or against the U.S. Government (or litigation in which the U.S. Government is not a party, but has an interest) resulting from questions concerning HUD cases and legal actions that HUD either is involved in or in which it believes it will or may become involved; claims by or against the U.S. Government, other than litigation cases, arising from a transaction with HUD, and documents related thereto, including demographic information, vouchers, witness statements, legal decisions, and related material pertaining to such claims; investigation reports; legal authority; legal opinions and memoranda; criminal actions; criminal conviction records; claims and records regarding discrimination, including employment and sex discrimination; claims and records regarding the Rehabilitation Act of 1973 (26 U.S.C. 701); personnel matters; contracts; foreclosures; actions against HUD officials; records relating to requests for HUD records other than requests under the Freedom of Information Act and the Privacy Act of 1974; testimonies of HUD employees in federal, state, local, or administrative criminal or civil litigation; documentary evidence; supporting documents including the legal and programmatic issues of the case, correspondence, legal opinions and memoranda and related records; security clearance information; any type of legal document, including but not limited to complaints, summaries, affidavits, litigation reports, motions, subpoenas, and any other court filing or administrative filing or evidence; employee and former employee ethics question forms and responses; and court transcripts.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

1. To a Congressional office from the record of an individual in response to an inquiry from that Congressional office made at the request of the individual to whom the records pertain;

2. To the National Archives and Records Administration for use in its records management inspections and its role as an Archivist;

3. To the Department of Justice (DOJ) when seeking legal advice for a HUD initiative or in response to DOJ's request for the information, after either HUD or DOJ determine that such information is relevant to DOJ's representatives of the United States or any other component in legal proceedings before a court or adjudicative body, provided that, in each case, the agency also determines prior to disclosure that disclosure of the records to the DOJ is a use of the information contained in the records that is compatible with the purpose for which HUD collected the records. HUD on its own may disclose records in this system of records in legal proceedings before a court or administrative body after determining that the disclosure of the records to the court or administrative body is a use of the information contained in the records that is compatible with the purpose for which HUD collected the records; or to another agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law, and if the head of the agency or instrumentality has made a written request to the agency which maintains the record specifying the particular portion desired and the law enforcement activity for which the record is sought;

4. To third parties during the course of a law enforcement investigation to

the extent necessary to obtain information pertinent to the investigation;

5. To contractors, grantees, experts, consultants, and the agents thereof, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for HUD, when necessary to accomplish an agency function related to its system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to HUD officers and employees;

6. To third parties during the course of a law enforcement investigation to the extent necessary to obtain information pertinent to the investigation, provided disclosure is appropriate to the proper performance of the official duties of the officer making the disclosure;

7. To a court, magistrate, or administrative tribunal in the course of presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, or settlement negotiations or in connection with criminal law proceedings or in response to a subpoena;

8. To a grand jury agent pursuant either to a federal or state grand jury subpoena, or to a prosecution request that such record be released for the purpose of its introduction to a grand jury, where the subpoena or request has been specifically approved by a court; and

9. To appropriate agencies, entities, and persons when: (a) HUD suspects or has confirmed that the security or confidentiality of information in a system of records has been compromised; (b) HUD has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of systems or programs (whether maintained by HUD or another agency or entity) that rely upon the compromised information; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with HUD's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm for purposes of facilitating responses and remediation efforts in the event of a data breach.

POLICIES FOR STORING, RETRIEVING, AND DISPOSING OF SYSTEM RECORDS:

STORAGE:

Data collected by OGC–EDMS is stored electronically in a Storage Area Network/Network Attached. There are no manual records stored or maintained outside the system. Storage is at a secure Lockheed Martin facility, and backed up via an Avamar Backup Storage system.

RETRIEVABILITY:

Records will be retrieved by the (1) Custodian name; (2) Work address; (3) Custodian email address; (4) Case name; (5) Case number; (6) Custodian email data; (7) Custodian local drive data; (8) Custodian home/shared drive data; (9) Litigation hold closures; (10) Litigation hold memoranda; (11) Litigation preservation notices; (12) Litigation hold reminder notices; and (13) ESI identification email notifications. E-Discovery notifications data is only accessed by individually assigned legal counsel on a case by case basis.

SAFEGUARDS:

Strict controls have been imposed to minimize the risk of compromising the information that is being stored. Access to the computer system containing the records in this system is limited to those individuals who are authorized to access by appropriate security clearances and user ID/password permissions. Only assigned users with a need-to-know are allowed access, on a case-by-case basis after going through HUD's background investigation process.

RETENTION AND DISPOSAL:

In response to the FRCP 16(b), when litigation is ''reasonably anticipated,'' related electronic data is copied and maintained in a secure server environment separate from HUD's network servers as part of the EDMS.[5] Upon authorization from a HUD Associate General Counsel, Regional Counsel, or other designated official, OGC closes a case. The closed case and related electronic litigation data that has been copied and secured in a production environment for the purposes of litigation is purged electronically from the EDMS. The purging process does not extend to purging electronic data from its original source, such as network servers. Electronic data is properly retained on network servers and other sources as required by HUD's Office of General Counsel Records Disposition Schedule 2—Legal Records, 2225.6 REV–1, CHG–APPENDIX 2 [6] and the Electronic Mail Policy, 2400.1 REV01, CHG.[7]

SYSTEM MANAGERS AND ADDRESSES:

Office of General Counsel (OGC) Tenille Washburn, Assistant General Counsel, Field Management and IT Division, Department of Housing and Urban Development, 1250 Maryland Avenue SW., Suite 200, Washington, DC 20024. The phone contact information is (202) 402–6536. This is not a toll free number.

NOTIFICATION AND RECORD ACCESS PROCEDURES:

Individuals seeking to determine whether this system of records contains information about them, or those seeking access to such records, should address inquiries to Donna Staton-Robinson, Chief Privacy Officer, Department of Housing and Urban Development, 451 7th Street SW., Room 4156, Washington, DC 20410. (Attention: Capitol View Building, 4th Floor.) The phone contact information is (202) 708–5495. This is not a toll free number. Provide verification of your identity by providing two proofs of official identification. Your verification of identity must include your original signature and must be notarized.

CONTESTING RECORD PROCEDURES:

HUD's rules for contesting the contents of records and appealing initial denials by the individual concerned appear in 24 CFR part 16. If additional information or assistance is needed, it may be obtained by contacting HUD officials as follows:

(i) Contesting contents of records: The Department of Housing and Urban Development, Chief Privacy Officer, 451 Seventh Street SW., Washington, DC 20410;

(ii) Appeals of initial HUD determinations: In relation to contesting contents of records, the HUD Departmental Privacy Appeals Officers, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410.

RECORD SOURCE CATEGORIES:

Documents and records in this system originate from HUD and its components, courts, subpoenas, law enforcement agencies, other federal, state, and local agencies, inquiries and/or complaints from witnesses or members of the general public.

[5] Other relevant regulations surrounding the collection and management of electronic discovery are FRCP 26(b)(2), 26(b)(5)(B), 26(f), 33(d), 34(a), 34(b), 37(f), and 45.

[6] *http://portal.hud.gov/hudportal/HUD?src=/program_offices/administration/hudclips/handbooks/admh/2225.6.*

[7] *http://www.hud.gov/offices/adm/hudclips/handbooks/cioh/.*

EXEMPTIONS:

The records in EDMS are maintained for use in civil rather than criminal actions. For that reason, the relevant provision of the Privacy Act is 5 U.S.C. 552a(d)(5) which states ''nothing in this [Act] shall allow an individual access to any information compiled in reasonable anticipation of a civil action or proceeding.'' (See U.S. Department of Justice, Office of Privacy and Civil Liberties, Overview of the Privacy Act of 1974 (2010) 212.[8])

[FR Doc. 2012–27806 Filed 11–14–12; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Safety and Environmental Enforcement (BSEE)

[Docket ID BSEE–2012–0018; OMB Control Number 1014–0002]

Information Collection Activities: Oil and Gas Production Measurement, Surface Commingling, and Security; Proposed Collection; Comment Request

ACTION: 60-day Notice.

SUMMARY: To comply with the Paperwork Reduction Act of 1995 (PRA), BSEE is inviting comments on a collection of information that we will submit to the Office of Management and Budget (OMB) for review and approval. The information collection request (ICR) concerns a renewal to the paperwork requirements in the regulations under Subpart L, *Oil and Gas Production Measurement, Surface Commingling, and Security.*

DATES: You must submit comments by January 14, 2013.

ADDRESSES: You may submit comments by either of the following methods listed below.

- Electronically: go to *http://www.regulations.gov.* In the entry titled *Enter Keyword or ID,* enter BSEE–2012–0018 then click search. Follow the instructions to submit public comments and view all related materials. We will post all comments.
- Email *nicole.mason@bsee.gov.* Mail or hand-carry comments to the Department of the Interior; BSEE; Regulations and Standards Branch; ATTN: Nicole Mason; 381 Elden Street, HE 3313; Herndon, Virginia 20170–4817. Please reference ICR 1014–0002 in your comment and include your name and return address.

FOR FURTHER INFORMATION CONTACT: Nicole Mason, Regulations and Standards Branch at (703) 787–1605 to request additional information about this ICR.

SUPPLEMENTARY INFORMATION:

Title: 30 CFR Part 250, subpart L, Oil and Gas Production Measurement, Surface Commingling, and Security.

OMB Control Number: 1014–0002.

Abstract: The Outer Continental Shelf (OCS) Lands Act, as amended (43 U.S.C. 1331 *et seq.* and 43 U.S.C. 1801 *et seq.*), authorizes the Secretary of the Interior (Secretary) to prescribe rules and regulations necessary for the administration of the leasing provisions of the Act related to the mineral resources on the OCS. Such rules and regulations will apply to all operations conducted under a lease. Operations on the OCS must preserve, protect, and develop oil and natural gas resources in a manner that is consistent with the need to make such resources available to meet the Nation's energy needs as rapidly as possible; to balance orderly energy resource development with protection of human, marine, and coastal environments; to ensure the public a fair and equitable return on the resources of the OCS; and to preserve and maintain free enterprise competition.

The Federal Oil and Gas Royalty Management Act of 1982 (30 U.S.C. 1701, *et seq.*) at section 1712(b)(2) prescribes that an operator will ''develop and comply with such minimum site security measures as the Secretary deems appropriate, to protect oil or gas produced or stored on a lease site or on the Outer Continental Shelf from theft.''

The Independent Offices Appropriations Act (31 U.S.C. 9701), the Omnibus Appropriations Bill (Pub. L. 104–133, 110 Stat. 1321, April 26, 1996), and OMB Circular A–25, authorize Federal agencies to recover the full cost of services that confer special benefits. Under the Department of the Interior's (DOI) implementing policy, BSEE is required to charge fees for services that provide special benefits or privileges to an identifiable non-Federal recipient above and beyond those which accrue to the public at large. Applications for surface commingling and measurement applications are subject to cost recovery and BSEE regulations specify service fees for these requests.

Regulations at 30 CFR Part 250, subpart L, implement these statutory requirements. We use the information to ensure that the volumes of hydrocarbons produced are measured accurately, and royalties are paid on the proper volumes. Specifically, we need the information to:

- Determine if measurement equipment is properly installed, provides accurate measurement of production on which royalty is due, and is operating properly;
- Obtain rates of production data in allocating the volumes of production measured at royalty sales meters, which can be examined during field inspections;
- Ascertain if all removals of oil and condensate from the lease are reported;
- Determine the amount of oil that was shipped when measurements are taken by gauging the tanks rather than being measured by a meter;
- Ensure that the sales location is secure and production cannot be removed without the volumes being recorded; and
- Review proving reports to verify that data on run tickets are calculated and reported accurately.

We will protect information from respondents considered proprietary under the Freedom of Information Act (5 U.S.C. 552) and its implementing regulations (43 CFR part 2), and under regulations at 30 CFR 250.197, *Data and information to be made available to the public or for limited inspection.* No items of a sensitive nature are collected. Responses are mandatory.

Frequency: Varies by section, but primarily monthly, or on occasion.

Description of Respondents: Potential respondents comprise Federal oil, gas and sulphur lessees and/or operators.

Estimated Reporting and Recordkeeping Hour Burden: The currently approved annual reporting burden for this collection is a total of 32,957 hours. The following chart details the individual components and estimated hour burdens. In calculating the burdens, we assumed that respondents perform certain requirements in the normal course of their activities. We consider these to be usual and customary and took that into account in estimating the burden.

[8] *http://www.justice.gov/opcl/1974tenexemp.htm#one.*

Citation 30 CFR part 250 subpart L	Reporting or recordkeeping requirement	Hour burden
		Non-hour cost burdens
Liquid Hydrocarbon Measurement		
1202(a)(1), (b)(1); 1203(b)(1); 1204(a)(1).	Submit application for liquid hydrocarbon or gas measurement procedures or changes; or for commingling of production or changes.	24.5
Simple		$1,271 simple fee
Complex		$3,760 complex
No fee	Submit meter status and replacement notifications	5
1202(a)(4)	Copy & send pipeline (retrograde) condensate volumes upon request.	1.2
1202(c)(1), (2); 1202(e)(4); 1202(h)(1), (2), (3), (4); 1202(i)(1)(iv), (2)(iii); 1202(j).	Record observed data, correction factors & net standard volume on royalty meter and tank run tickets.	Respondents record these items as part of normal business records & practices to verify accuracy of production measured for sale purposes.
	Record master meter calibration runs	
	Record mechanical-displacement prover, master meter, or tank prover proof runs.	
	Record liquid hydrocarbon royalty meter malfunction and repair or adjustment on proving report; record unregistered production on run ticket.	
	List Cpl and Ctl factors on run tickets	
1202(c)(4)*	Copy & send all liquid hydrocarbon run tickets monthly	10 minutes
1202(d)(4); 1204(b)(1)	Request approval for proving on a schedule other than monthly; request approval for well testing on a schedule other than every 60 days.	2
1202(d)(5)*	Copy & submit liquid hydrocarbon royalty meter proving reports monthly & request waiver as needed.	15 minutes
1202(f)(2)*	Copy & submit mechanical-displacement prover & tank prover calibration reports.	16.5 minutes
1202(l)(2)*	Copy & submit royalty tank calibration charts before using for royalty measurement.	45 minutes
1202(l)(3)*	Copy & submit inventory tank calibration charts upon request; retain charts for as long as tanks are in use.	45 minutes; 10 minutes
Gas Measurement		
1203(b)(6), (8), (9)*	Copy & submit gas quality and volume statements monthly or as requested (most will be routine; few will take longer).	15 minutes; 36 minutes
1203(c)(1)	Request approval for proving on a schedule other than monthly	1.2
1203(c)(4)*	Copy & submit gas meter calibration reports upon request; retain for 2 years.	13 minutes; 7.5 minutes
1203(e)(1)*	Copy & submit gas processing plant records upon request	1.2
1203(f)(5)	Copy & submit measuring records of gas lost or used on lease upon request.	42 minutes
Surface Commingling		
1204(a)(2)	Provide state production volumetric and/or fractional analysis data upon request.	6
1205(a)(2)	Post signs at royalty or inventory tank used in royalty determination process.	2
1205(a)(4)	Report security problems (telephone)	18 minutes
Miscellaneous and Recordkeeping		
1200 thru 1205	General departure and alternative compliance requests not specifically covered elsewhere in subpart L.	1.3
1202(e)(6)	Retain master meter calibration reports for 2 years	23 minutes
1202(k)(5)	Retain liquid hydrocarbon allocation meter proving reports for 2 years.	10 minutes
1203(f)(4)	Document & retain measurement records on gas lost or used on lease for 2 years at field location and minimum 7 years at location of respondent's choice.	15 minutes
1204(b)(3)	Retain well test data for 2 years	6.7 minutes
1205(b)(3), (4)	Retain seal number lists for 2 years	5 minutes

*Respondents gather this information as part of their normal business practices. The BSEE only requires copies of readily available documents. There is no burden for testing, meter reading, etc.

Estimated Reporting and Recordkeeping Non-Hour Cost Burden: We have identified two non-hour cost burdens, both of which are cost recovery fees. Note that the actual fee amounts are specified in 30 CFR 250.125, which provide a consolidated table of all the fees required under the 30 CFR 250 regulations. The currently approved non-hour cost burden total in this collection of information is an estimated $600,065. The cost burdens are for: (1)

Filing fees associated with submitting requests for approval of simple applications (applications to temporarily reroute production (for a duration not to exceed 6 months); production tests prior to pipeline construction; departures related to meter proving, well testing, or sampling frequency ($1,271 per application)) or, (2) submitting a request for approval of a complex application (creation of new facility measurement points (FMPs); association of leases or units with existing FMPs; inclusion of production from additional structures; meter updates which add buyback gas meters or pigging meters; other applications which request deviations from the approved allocation procedures ($3,760 per application)).

Public Disclosure Statement: The PRA (44 U.S.C. 3501, *et seq.*) provides that an agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. Until OMB approves a collection of information, you are not obligated to respond.

Comments: Before submitting an ICR to OMB, PRA section 3506(c)(2)(A) requires each agency ''* * * to provide notice * * * and otherwise consult with members of the public and affected agencies concerning each proposed collection of information * * *''. Agencies must specifically solicit comments to: (a) Evaluate whether the collection is necessary or useful; (b) evaluate the accuracy of the burden of the proposed collection of information; (c) enhance the quality, usefulness, and clarity of the information to be collected; and (d) minimize the burden on the respondents, including the use of technology.

Agencies must also estimate the non-hour paperwork cost burdens to respondents or recordkeepers resulting from the collection of information. Therefore, if you have other than hour burden costs to generate, maintain, and disclose this information, you should comment and provide your total capital and startup cost components or annual operation, maintenance, and purchase of service components. For further information on this burden, refer to 5 CFR 1320.3(b)(1) and (2), or contact the Bureau representative listed previously in this notice.

We will summarize written responses to this notice and address them in our submission for OMB approval. As a result of your comments, we will make any necessary adjustments to the burden in our submission to OMB.

Public Comment Procedures: Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment–including your personal identifying information–may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Acting BSEE Information Collection Clearance Officer: Cheryl Blundon (703) 787–1607.

Dated: November 6, 2012.

Robert W. Middleton,

Deputy Chief, Office of Offshore Regulatory Programs.

[FR Doc. 2012–27773 Filed 11–14–12; 8:45 am]

BILLING CODE 4310–VH–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLIDB00100 L17110000.PH0000 4500043075]

Notice of Intent To Prepare an Environmental Assessment To Amend Bureau of Land Management, Boise District, Land Use Plans To Clarify Lands Eligible for Disposal; Correction

AGENCY: Bureau of Land Management, Interior.

ACTION: Correction.

SUMMARY: This action corrects the ZIP code referenced in the **ADDRESSES** section and the spelling of the name in the signature block in a notice published in the **Federal Register** on Thursday, October 18, 2012 (77 FR 64124).

On page 64124, column 2, line 14 of the notice, which reads ''District Office at 3894 Development'' is hereby corrected to read, ''District Office at 3948 Development.''

On page 64124, column 2, line 15 of the notice, which reads ''Ave., Boise, ID 38705'' is hereby corrected to read, ''Ave., Boise, ID 83705.''

On page 64124, column 2, line 20 of the notice, which reads ''3339; address: 3894 Development Ave.,'' is hereby corrected to read ''3339; address: 3948 Development Ave.''

On page 64124, column 2, line 21 of the notice, which reads ''Boise, ID 38705; email:'' is hereby corrected to read Boise, ID 83705; email:.''

On page 64125, column 2, line 9 of the notice, which reads ''Allen Sieglitz'' is hereby corrected to read, ''Aden Seidlitz''.

James M. Fincher,

Boise District Manager.

[FR Doc. 2012–27772 Filed 11–14–12; 8:45 am]

BILLING CODE 4310–GG–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–SERO–SAJU–11286; 5331–0901–630]

Notice of Intent To Prepare an Environmental Impact Statement for the Paseo del Morro National Recreational Trail Extension, San Juan National Historic Site, San Juan, Puerto Rico

AGENCY: National Park Service, Interior.

ACTION: Notice of Intent.

SUMMARY: Pursuant to the National Environmental Policy Act of 1969 (42 U.S.C. 4332) (2) (C), the National Park Service (NPS) will prepare an Environmental Impact Statement for the Paseo del Morro National Recreational Trail Extension (EIS). The EIS will include the involvement of multiple entities, including the Municipality of San Juan and the Commonwealth of Puerto Rico and neighborhoods along the trail corridor. Segments of the extension within and outside of the NPS boundary might include several amenities such as: Pedestrian trails, bicycle trail, Plaza, access to the Santa Maria Magdalena Cemetery, viewpoints, pocket seating areas, and drinking fountains. The project would be constructed in four phases according to the segments within the project extension. The first segment would run parallel to the Santa Maria Magdalena Cemetery, the second segment parallel to the community of La Perla, the third segment along the coastal area of Castillo San Cristobal, and the fourth segment through the ''Lomita de Los Vientos''. The characteristics of the trail, such as width of the primary and secondary trails, amenities, complementary programs, activities and methods of construction, would vary in the different segments of the projects.

The objectives of the project are: To create public access to the North Coast of the Old San Juan Islet and create recreational public space along coastal area in front of Old San Juan, protect the historic walls of El Morro, encourage educational tourism within the area. The DEIS will assess potential environmental impacts associated with a range of reasonable alternatives for extension of the Paseo del Morro on

park resources such as existing flora and fauna, soils, cultural resources, and public safety. Socioeconomic impacts and effects on visitor experience will also be analyzed.

DATES: Interested individuals, organizations, and agencies are encouraged to provide written comments or suggestions to assist the NPS in determining the scope of issues to be addressed in the EIS, identifying significant issues, and identifying reasonable alternatives. The NPS will accept comments from the public for January 14, 2013. The NPS will conduct a public scoping meeting in San Juan, Puerto Rico. When the public scoping meeting has been scheduled, its location, date, and time will be published in local media and on the NPS's Planning, Environment and Public Comment Web site: *http://parkplanning.nps.gov/saju.* Written comments must be received prior to the close of the scoping period or 15 days after the last public meeting, whichever is later. The NPS will provide additional opportunities for public participation upon publication of the draft EIS.

ADDRESSES: If you wish to provide scoping comments or suggestions, you may submit your comments by any one of several methods. The preferred method for submitting comments is via the internet at *http://parkplanning.nps.gov/saju.* Select ''Paseo del Morro National Recreational Trail Extension'' to reach the comment site. Written comments may also be sent to: Walter Chavez, Superintendent, San Juan National Historic Site, 501 Calle Norzagaray, San Juan, Puerto Rico 00901.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. We will always make submissions from organizations or businesses, and from individuals identifying themselves as representatives of or officials of organizations or businesses, available for public inspection in their entirety.

FOR FURTHER INFORMATION CONTACT: Information about the proposed action, the EIS, and the scoping process may be obtained from Mr. Walter Chavez at San Juan National Historic Site by phone at (787) 729–6777; or email *walter_chavez@nps.gov.* Additional information can be found on the NPS Planning, Environment, and Public Comment (PEPC) Web site, *http://parkplanning.nps.gov/saju.* Select ''Paseo del Morro National Recreational Trail Extension.''

SUPPLEMENTARY INFORMATION:

The park has involved the community in information gathering for developing a shared vision for the Paseo del Morro National Recreational Trail Extension as part of an effort led by the NPS Rivers, Trails, and Conservation Assistance (RTCA) Program. Meetings were held with the community in January 2010, August 2010, March 2011, and October 2011, to begin discussions on trail extension and connectivity. The development of the Draft EIS will use the information gathered in those meetings, along with future meetings in collaboration with the RTCA Program, to assist with alternative development.

The NPS will provide additional opportunities for the public to provide written comments upon publication of the Draft EIS. The NPS welcomes public participation by Federal, State, and local agencies as well as other concerned organizations and private citizens throughout the preparation process of the EIS.

The responsible official for this EIS is David Vela, Regional Director, Southeast Region, National Park Service, 100 Alabama Street SW., 1924 Building, Atlanta, Georgia 30303.

Dated: November 7, 2012.

Gordon Wissinger,

Acting Regional Director, Southeast Region.

[FR Doc. 2012–27758 Filed 11–14–12; 8:45 am]

BILLING CODE 4310–JD–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

Gulf of Mexico, Outer Continental Shelf (OCS), Western Planning Area (WPA), Oil and Gas Lease Sale 229

AGENCY: Bureau of Ocean Energy Management (BOEM), Interior.

ACTION: Notice of Availability (NOA) of a Record of Decision (ROD) for WPA Lease Sale 229 in the Gulf of Mexico OCS Oil and Gas Lease Sales: 2012–2017 Western Planning Area Lease Sales 229, 233, 238, 246, and 248, and Central Planning Area Lease Sales 227, 231, 235, 241, and 247 Final Environmental Impact Statement (Multisale FEIS).

Authority: This NOA is published pursuant to the regulations (40 CFR 1506) implementing the provisions of the National Environmental Policy Act (NEPA) of 1969, as amended (42 U.S.C. 4321 *et seq.* (1988)).

SUMMARY: BOEM has prepared a ROD for oil and gas WPA Lease Sale 229 scheduled for November 28, 2012. WPA Lease Sale 229 is the first WPA lease sale in the 2012–2017 OCS Oil and Gas Leasing Program. The proposed lease sale is in the Gulf of Mexico's WPA off the States of Texas and Louisiana. In making its decision, BOEM considered alternatives to the proposed action and the potential impacts as presented in the Multisale FEIS and all comments received throughout the NEPA process. The Multisale FEIS evaluated the environmental and socioeconomic impacts for WPA Lease Sale 229.

SUPPLEMENTARY INFORMATION: In the Multisale FEIS, BOEM evaluated three alternatives, which are summarized below:

Alternative A—The Proposed Action: This is BOEM's preferred alternative identified in the Multisale FEIS. This alternative would offer for lease all unleased blocks within the WPA for oil and gas operations, with the following exceptions:

(1) Whole and partial blocks within the boundary of the Flower Garden Banks National Marine Sanctuary (i.e., the boundary as of the publication date of the Multisale FEIS); and

(2) whole and partial blocks that lie within the 1.4 nautical mile buffer zone north of the maritime boundary between the United States and Mexico.

The proposed WPA lease sale area encompasses virtually all of the WPA's 28.58 million acres. As of August 2012, approximately 20.8 million acres of the WPA lease sale area are currently unleased. The estimated amount of resources projected to be developed as a result of proposed WPA Lease Sale 229 is 0.116–0.200 BBO and 0.538–0.938 Tcf of gas.

Alternative B—The Proposed Action Excluding the Unleased Blocks Near Biologically Sensitive Topographic Features: This alternative would offer for lease all unleased blocks in the WPA, as described for the proposed action (Alternative A), with the exception of any unleased blocks subject to the Topographic Features Stipulation.

Alternative C—No Action: This alternative would cancel the proposed WPA Lease Sale 229 and is identified as the environmentally preferred alternative.

After careful consideration, BOEM has selected the proposed action, identified as BOEM's preferred alternative (Alternative A) in the Multisale FEIS. BOEM's selection of the preferred alternative reflects an orderly resource development with protection

of the human, marine, and coastal environments, while also ensuring that the public receives an equitable return for these resources and that free-market competition is maintained.

Record of Decision Availability: To obtain a single printed or CD–ROM copy of the ROD for proposed WPA Lease Sale 229, you may contact the BOEM, Gulf of Mexico OCS Region, Public Information Office (GM 250I), 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123–2394 (1–800–200–GULF). An electronic copy of the ROD is available on BOEM's Internet Web site at *http://boem.gov/Environmental-Stewardship/Environmental-Assessment/NEPA/nepaprocess.aspx.*

FOR FURTHER INFORMATION CONTACT: For more information on the ROD, you may contact Mr. Gary D. Goeke, Bureau of Ocean Energy Management, Gulf of Mexico OCS Region, 1201 Elmwood Park Boulevard (GM 623E), New Orleans, Louisiana 70123–2394. You may also contact Mr. Goeke by telephone at (504) 736–3233.

Dated: November 8, 2012.

Tommy P. Beaudreau,

Director, Bureau of Ocean Energy Management.

[FR Doc. 2012–27755 Filed 11–14–12; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

Notice of Proposed Information Collection: Permanent Regulatory Program Requirements—Standards for Certification of Blasters

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSM) is announcing its intention to request approval to continue the collection of information for its regulations regarding the standards for certification of blasters. This information collection activity was previously approved by the Office of Management and Budget (OMB), and assigned control number 1029–0080.

DATES: Comments on the proposed information collection activity must be received by January 14, 2013, to be assured of consideration.

ADDRESSES: Comments may be mailed to John Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave. NW., Room 203—SIB, Washington, DC 20240. Comments may also be submitted electronically to *jtrelease@osmre.gov.*

FOR FURTHER INFORMATION CONTACT: To receive a copy of the information collection request, contact John Trelease at (202) 208–2783 or by email.

SUPPLEMENTARY INFORMATION: OMB regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub .L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [see 5 CFR 1320.8 (d)]. This notice identifies an information collection that OSM will be submitting to OMB for renewed approval. This collection is contained in 30 CFR Part 850—Permanent Regulatory Program Requirements—Standards for Certification of Blasters. The information submitted by respondents is required to obtain a benefit. OSM will request a 3-year term of approval for this information collection activity.

Comments are invited on: (1) The need for the collection of information for the performance of the functions of the agency; (2) the accuracy of the agency's burden estimates; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information. A summary of the public comments will accompany OSM's submission of the information collection request to OMB.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Title: 30 CFR Part 850—Permanent Regulatory Program Requirements—Standards for Certification of Blasters.

OMB Control Number: 1029–0080.

Summary: The information is used to identify and evaluate new blaster certification programs. Part 850 implements Section 719 of the Surface Mining Control and Reclamation Act (SMCRA). Section 719 requires the Secretary of the Interior to issue regulations which provide for each State regulatory authority to train, examine and certify persons for engaging in blasting or use of explosives in surface coal mining operations. Each State that wishes to certify blasters must submit a blasters certification program to OSM for approval.

Bureau Form Numbers: None.

Frequency of Collection: Once.

Description of Respondents: State regulatory authorities and Indian tribes.

Total Annual Responses: 1.

Total Annual Burden Hours: 267 hours.

Dated: November 7, 2012.

Andrew F. DeVito,

Chief, Division of Regulatory Support.

[FR Doc. 2012–27560 Filed 11–14–12; 8:45 am]

BILLING CODE 4310–05–M

INTERNATIONAL TRADE COMMISSION

[USITC SE–12–032]

Government In the Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: November 19, 2012 at 1:00 p.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agendas for future meetings: none.
2. Minutes.
3. Ratification List.
4. Vote in Inv. No. 731–TA–893 (Second Review) (Honey from China). The Commission is currently scheduled to transmit its determination and Commissioners' opinions to the Secretary of Commerce on or before November 29, 2012.
5. Outstanding action jackets: none.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting. Earlier notification of this meeting was not possible.

By order of the Commission:
Issued: November 13, 2012.

William R. Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2012–27981 Filed 11–13–12; 4:15 pm]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1103–NEW]

Agency Information Collection Activities; Proposed New Collection; Comments Requested: COPS Comparative Assessment of Cost Reduction by Agencies Survey

ACTION: 60-Day Notice of Information Collection Under Review.

The Department of Justice (DOJ) Office of Community Oriented Policing Services (COPS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. The purpose of this notice is to allow for 60 days for public comment until January 14, 2013. This process is conducted in accordance with 5 CFR 1320.10.

If you have comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Danielle Ouellette, Department of Justice, Office of Community Oriented Policing Services, 145 N Street NE., Washington, DC 20530.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Proposed new collection; comments requested.

(2) *Title of the Form/Collection:* COPS Comparative Assessment of Cost Reduction by Agencies Survey.

(3) *Agency form number, if any, and the applicable component of the Department sponsoring the collection:* None. U.S. Department of Justice Office of Community Oriented Policing Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Law enforcement agencies and other public and private entities that apply for COPS Office grants or cooperative agreements will be asked complete the COPS Comparative Assessment of Cost Reduction Survey. The survey will be used to review the approaches currently adopted by police agencies that reduce organizational and operational costs and will provide information about how these strategies have been implemented and evaluated. The survey allows for the identification of agencies that have undertaken extensive changes in programs to maintain their service delivery levels or to increase service efficiency and effectiveness while facing budget restraints.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that 268 respondents annually will complete the form within .42 hours (25 minutes).

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 113 total annual burden hours associated with this collection.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, 145 N Street NE., Room 3W–1407B, Washington, DC 20530.

Dated: November 8, 2012.

Jerri Murray,

Department Clearance Officer for PRA, Department of Justice.

[FR Doc. 2012–27691 Filed 11–14–12; 8:45 am]

BILLING CODE 4410–AT–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 12–51]

Karen Paul Holley, M.D.; Decision and Order

On July 27, 2012, Chief Administrative Law Judge John J. Mulrooney, Jr., issued the attached Recommended Decision. Neither party filed exceptions to the Recommended Decision.

Having reviewed the entire record, I have decided to adopt the ALJ's findings of fact, conclusions of law, and recommended order. According, I will order that Respondent's DEA Certificate of Registration be revoked and that any pending application to renew or modify her registration be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration Number BH8988339, issued to Karen P. Holley, M.D., be, and it hereby is, revoked. I further order that any pending application of Karen P. Holley, M.D., to renew or modify her registration, be, and it hereby is, denied. This Order is effective December 17, 2012.

Dated: October 26, 2012.

Michele M. Leonhart,

Administrator.

Theresa Krause, Esq., for the Government

John H. Musser, IV, Esq., for the Respondent

Order Granting the Government's Motion for Summary Disposition and Recommended Decision

Chief Administrative Law Judge John J. Mulrooney, Jr. The Deputy Assistant Administrator, Drug Enforcement Administration (Government), issued an Order to Show Cause (OSC), dated May 21, 2012, proposing to revoke the DEA Certificate of Registration (COR), Number BH8988339, of Karen Paul Holley, M.D. (Respondent), pursuant to 21 U.S.C. 824(a)(3) and (4) (2006), and to deny any pending applications for renewal or modification of such registration, pursuant to 21 U.S.C. 823(f). In the OSC, the Government alleges that revocation is necessary because the Respondent is ''without authority to handle controlled substances in the State of Louisiana,'' the state of the Respondent's registration. OSC, at 1–2.

On July 3, 2012, the DEA Office of Administrative Law Judges (OALJ)

received from the Respondent, through counsel, a timely filed request for hearing (Hearing Request) which, concedes that the Respondent lacks authority to handle controlled substances in the State of Louisiana. The same day, this tribunal issued an order: (1) Directing the Government to ''provide evidence to support the allegation that the Respondent lacks state authority to handle controlled substances'' on or before July 13, 2012; (2) setting a deadline of July 13, 2012, for the Government to file a motion for summary disposition; and (3) setting a deadline of July 25, 2012, for the Respondent to respond to any motion for summary disposition. Briefing Schedule, at 1–2.

On July 6, 2012, the Government filed a Motion for Summary Disposition (''MSD''), seeking: (1) Summary disposition; and (2) a recommendation that ''the Respondent's DEA COR as a practitioner be revoked, based on the Respondent's lack of a state license.'' MSD, at 5. A copy of an April 21, 2012, Order for Summary Suspension of Medical License issued by the Louisiana State Board of Medical Examiners (Louisiana Board Order) was attached to the motion. The Respondent did not file a response to the Government's motion within the time allowed. Accordingly, the motion will be deemed unopposed.

The Controlled Substances Act (CSA) requires that, in order to maintain a DEA registration, a practitioner must be authorized to handle controlled substances in ''the jurisdiction in which he practices.'' *See* 21 U.S.C. 802(21) (''[t]he term 'practitioner' means a physician * * * licensed, registered, or otherwise permitted, by * * * the jurisdiction in which he practices * * * to distribute, dispense, [or] administer * * * a controlled substance in the course of professional practice''); *see also id.* § 823(f) (''The Attorney General shall register practitioners * * * if the applicant is authorized to dispense * * * controlled substances under the laws of the State in which he practices.''). DEA has long held that possession of authority under state law to dispense controlled substances is an essential condition for obtaining and maintaining a DEA registration. *Serenity Café,* 77 FR 35027, 35028 (2012); *David W. Wang,* 72 FR 54297, 54298 (2007); *Sheran Arden Yeates,* 71 FR 39130, 39131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51104 (1993); *Bobby Watts, M.D.,* 53 FR 11919 (1988). Because ''possessing authority under state law to handle controlled substances is an essential condition for holding a DEA registration,'' this Agency has consistently held that ''the CSA requires the revocation of a registration issued to a practitioner who lacks [such authority].'' *Roy Chi Lung,* 74 FR 20346, 20347 (2009); *see also Scott Sandarg, D.M.D.,* 74 FR 17528, 174529 (2009); *John B. Freitas, D.O.,* 74 FR 17524, 17525 (2009); *Roger A. Rodriguez, M.D.,* 70 FR 33206, 33207 (2005); *Stephen J. Graham, M.D.,* 69 FR 11661 (2004); *Abraham A. Chaplan, M.D.,* 57 FR 55280 (1992); *see also Harrell E. Robinson,* 74 FR 61370, 61375 (2009). ''[R]evocation is warranted even where a practitioner's state authority has been summarily suspended and the State has yet to provide the practitioner with a hearing to challenge the State's action at which he may ultimately prevail.'' *Kamal Tiwari, M.D.,* 76 FR 71604, 71606, (2011); *see also Bourne Pharmacy, Inc.,* 72 FR 18273, 18274 (2007); *Anne Lazar Thorn,* 62 FR 12847 (1997).

Congress does not intend for administrative agencies to perform meaningless tasks. *See Philip E. Kirk, M.D.,* 48 FR 32887 (1983), *aff'd sub nom. Kirk* v. *Mullen,* 749 F.2d 297 (6th Cir. 1984); *see also Puerto Rico Aqueduct & Sewer Auth.* v. *EPA,* 35 F.3d 600, 605 (1st Cir. 1994); *NLRB* v. *Int'l Assoc. of Bridge, Structural & Ornamental Ironworkers, AFL–CIO,* 549 F.2d 634 (9th Cir. 1977); *United States* v. *Consol. Mines & Smelting Co.,* 455 F.2d 432, 453 (9th Cir. 1971). Thus, it is well-settled that, where no genuine question of fact is involved, or when the material facts are agreed upon, a plenary, adversarial administrative proceeding is not required. *See Jesus R. Juarez, M.D.,* 62 FR 14945 (1997); *Dominick A. Ricci, M.D.,* 58 FR 51104 (1993), Here, both parties agree, and the supplied Louisiana Board Order establishes, that the Respondent is without authorization to practice medicine or handle controlled substances in Louisiana, the jurisdiction where the Respondent holds the DEA COR that is the subject of this litigation.

Summary disposition of an administrative case is warranted where, as here, ''there is no factual dispute of substance.'' *See Veg-Mix, Inc.,* 832 F.2d 601, 607 (D.C. Cir. 1987) (''an agency may ordinarily dispense with a hearing when no genuine dispute exists'').[1] At this juncture, no genuine dispute exists over the fact that the Respondent lacks state authority to handle controlled substances in the State of Louisiana. Because the Respondent lacks such state authority, both the plain language of applicable federal statutory provisions and Agency interpretive precedent dictate that the Respondent is not entitled to maintain his DEA registration. Simply put, there is no contested factual matter adducible at a hearing that would provide DEA with the authority to allow the Respondent to continue to hold his COR. I therefore conclude that further delay in ruling on the Government's motion for summary disposition is not warranted. *See Gregory F. Saric, M.D.,* 76 FR 16821 (2011) (stay denied in the face of Respondent's petition based on pending state administrative action wherein he was seeking reinstatement of state privileges).

Accordingly, I hereby

Grant the Government's Motion for Summary Disposition; and *recommend* that the Respondent's DEA registration be *revoked* forthwith and any pending applications for renewal be *denied.*

Dated: July 27, 2012.

John J. Mulrooney, II,

Chief Administrative Law Judge

[FR Doc. 2012–27692 Filed 11–14–12; 8:45 am]

BILLING CODE 4410–09–P

[1] Even assuming *arguendo* the possibility that the Respondent's state controlled substances privileges could be reinstated, summary disposition would still be warranted because ''revocation is also appropriate when a state license has been suspended, but with the possibility of future reinstatement,'' *Rodriguez,* 70 FR at 33207 (citations omitted), and even where there is a judicial challenge to the state medical board action actively pending in the state courts. *Michael G. Dolin, M.D.,* 65 FR 5661, 5662 (2000).

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OJP (OVC) Docket No. 1609]

Meeting of the SANE/SART AI/AN Initiative Committee

AGENCY: Office for Victims of Crime, Justice.

ACTION: Notice of meeting.

SUMMARY: The National Coordination Committee on the Sexual Assault Nurse Examiner (SANE) Sexual Assault Response Team (SART) American Indian/Alaskan Native (AI/AN) Initiative (''SANE/SART AI/AN Initiative Committee'' or ''Committee'') will meet to carry out its mission to provide valuable advice to assist the Office for Victims of Crime (OVC) to promote culturally relevant, victim-centered responses to sexual violence within AI/AN communities.

Dates and Locations: The meeting will be held on the reservation of the Agua Caliente Band of Cahuilla Indians at the Agua Caliente Spa Hotel, located at E. Tahquitz Canyon Way and N. Calle Encilia, Palm Springs, California 92262, on Tuesday, December 4, 2012, and

Wednesday, December 5, 2012, from 9:00 a.m. to 5:00 p.m. PST.

FOR FURTHER INFORMATION CONTACT: Kathleen Gless, Designated Federal Officer (DFO) for the SANE/SART AI/AN Initiative Committee, Office for Victims of Crime, Office of Justice Programs, 810 7th Street NW., Washington, DC 20531; Phone: (202) 307–6049 [note: this is not a toll-free number]; Email: *kathleen.gless@usdoj.gov.*

SUPPLEMENTARY INFORMATION: The National Coordination Committee on the Sexual Assault Nurse Examiner (SANE) Sexual Assault Response Team (SART) American Indian/Alaskan Native (AI/AN) Initiative (''SANE/SART AI/AN Initiative Committee'' or ''Committee'') was established by the Attorney General to provide valuable advice to OVC to encourage the coordination federal, tribal, state, and local efforts to assist victims of sexual violence within AI/AN communities, and to promote culturally relevant, victim-centered responses to sexual violence within those communities.

Meeting Agenda: The agenda will include: (a) Traditional opening ceremonies, welcome, and introductions; (b) remarks from the Acting Director of OVC; (c) presentations by and about the AI/AN SANE–SART Initiative demonstration sites and federal Working Groups; (d) small and large group discussions; (e) the development of recommendations regarding the coordination of federal partners to address sexual violence; and (f) a closing ceremony and adjournment.

The meeting is open to the public. Photo identification will be required. Space is limited.

Kathleen Gless,

Victim Justice Program Specialist, Designated Federal Official—SANE–SART AI/AN Initiative Committee, Office for Victims of Crime.

[FR Doc. 2012–27789 Filed 11–14–12; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request: Main Fan Operation and Inspection (I–A, II–A, III, and V–A Mines)

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Mine Safety and Health Administration (MSHA) sponsored information collection request (ICR) titled, ''Main Fan Operation and Inspection (I–A, II–A, III, and V–A Mines),'' to the Office of Management and Budget (OMB) for review and approval for continued use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 *et seq.*).

DATES: Submit comments on or before December 17, 2012.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the RegInfo.gov Web site, *http://www.reginfo.gov/public/do/PRAMain,* on the day following publication of this notice or by contacting Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–MSHA, Office of Management and Budget, Room 10235, 725 17th Street, NW., Washington, DC 20503, Fax: 202–395–6881 (this is not a toll-free number), email: *OIRA_submission@omb.eop.gov.*

FOR FURTHER INFORMATION: Contact Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: Potentially gassy (explosive) conditions underground are largely controlled by main fans. When accumulations of explosive gases, such as methane, are not swept from the mine by the main fans, they may reasonably be expected to contact an ignition source. The results of such contacts are usually disastrous, and multiple fatalities may be reasonably expected to occur. The Main Fan Operation and Inspection standard contains significantly more stringent requirements for main fans in gassy mines than for main fans in other mines. Regulations 30 CFR 57.22204, which only applies to gassy metal and nonmetal underground mines, requires main fans to have pressure-recording systems. The standard also requires main fans to be inspected daily while operating if persons are underground and certification made of such inspections by signature and date. Certifications and pressure recordings must be retained for one year and made available to authorized representatives of the Secretary.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information if the collection of information does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1219–0030. The current approval is scheduled to expire on January 31, 2013; however, it should be noted that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional information, see the related notice published in the **Federal Register** on July 17, 2012 (77 FR 42004).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within 30 days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1219–0030. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: DOL–MSHA.

Title of Collection: Main Fan Operation and Inspection (I–A, II–A, III, and V–A Mines).

OMB Control Number: 1219–0030.

Affected Public: Private Sector—businesses or other for profits.

Total Estimated Number of Respondents: 7.

Total Estimated Number of Responses: 6,930.

Total Estimated Annual Burden Hours: 2,386.

Total Estimated Annual Other Costs Burden: $2,800.

Dated: November 8, 2012.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2012–27759 Filed 11–14–12; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

Preparations for the 24th Session of the UN Sub-committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) and Stakeholder Meeting

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice of Public Meeting.

SUMMARY: OSHA invites interested parties to participate in an open, informal public meeting to discuss proposals in preparation for the 24th session of the United Nations Sub-committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (UNSCEGHS). The UNSCEGHS meeting will be held December 12–14, 2012, in Geneva, Switzerland. OSHA, along with the U.S. Interagency GHS Coordinating Group, plans to consider the comments and information gathered at this public meeting when developing the U.S. Government positions for the UNSCEGHS meeting.

DATES: The date for the public meeting is as follows: November 28, 2012, beginning at 2 p.m., in Washington, DC.

ADDRESSES: The location for the public meeting is as follows: The U.S. Department of Labor, Francis Perkins Building, 200 Constitution Avenue NW., Washington, DC 20210, Room C5320, and Conference Room #6.

Conference Call Information: Conference call-in capability will be provided for this meeting. To participate by telephone, dial 1–800–369–1938, and enter participant passcode 12725. During the call, please press *6 to mute/unmute your individual lines.

FOR FURTHER INFORMATION CONTACT: Maureen Ruskin, Director, Office of Chemical Hazards-Metals, OSHA Directorate of Standards and Guidance, Room N–3718, U.S. Department of Labor, 200 Constitution Avenue NW., Washington DC 20210; telephone: (202) 693–1950; *email: ruskin.maureen@dol.gov.*

Copies of this **Federal Register** notice can be obtained as follows: Electronic copies are available at *http://www.regulations.gov.* This **Federal Register** notice, as well as other relevant information, is available also on the OSHA Web page at *http://www.osha.gov.*

SUPPLEMENTARY INFORMATION:

I. Meeting

OSHA is hosting an open informal public meeting of the U.S. Interagency GHS Coordinating Group to provide interested groups and individuals with an update on GHS-related issues and an opportunity to express their views orally and in writing for consideration in developing U.S. Government positions for the upcoming UNSCEGHS meeting. The public is invited to attend without prior notification.

The Meeting Agenda, in general, is as follows:

- Discussion of working papers for the 24th Session of the UNSCEGHS
- Update on UNSCEGHS correspondence group activity
- Discussion of the program of work for the 2013–2014 biennium

II. Background

The GHS was formally adopted by the United Nations Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals in December 2002. The GHS is a single, harmonized system for classification of chemicals according to their health, physical, and environmental effects. It also provides harmonized communication elements, including labels and safety data sheets. The GHS is considered to be a living document and is regularly revised and updated as necessary to reflect new technology and scientific developments or to provide additional explanatory text. OSHA incorporated the GHS 3rd revision into its Hazard Communication Standard on March 26th of this year, 77 FR 17574, and intends to update the standard from time to time through rulemaking in order to remain consistent with any revisions to the GHS as appropriate under the OSH Act.

The UNSCEGHS is responsible for maintaining and updating the GHS. The U.S. has been an active member of the UNSCEGHS for many years, and OSHA currently serves as the head of the U.S. delegation for this Sub-committee.

In preparation for the bi-annual meetings of the UNSCEGHS, the U.S. Interagency GHS Coordinating Group meets to discuss issues related to the GHS and to develop a coordinated U.S. position on issues and proposals regarding the GHS. The U.S. Interagency Coordinating Group consists of U.S. agencies that regulate in the area of chemical hazard communication and includes the Department of Transportation (DOT), the Environmental Protection Agency (EPA), the Consumer Product Safety Commission (CPSC), and OSHA.

Information on the work of the UNSCEGHS, including meeting agendas, reports, and documents from previous sessions, can be found on the United Nations Economic Commission for Europe (UNECE) Transport Division Web site located at the following web address: *http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html.* The UNSCEGHS bases its decisions on Working Papers. The Working Papers for the 24th session of the UNSCEGHS are located at *http://www.unece.org/trans/main/dgdb/dgsubc4/c42012.html.*

Informal Papers submitted to the UNSCEGHS provide information for the subcommittee and are used either as a mechanism to provide information to the subcommittee or as the basis for future Working Papers. Informal Papers for the 24th session of the UNSCEGHS are located at: *http://www.unece.org/trans/main/dgdb/dgsubc4/c4inf24.html.*

Authority and Signature

This document was prepared under the direction of David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, pursuant to sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657), and Secretary's Order 1–2012 (77 FR 3912), (Jan. 25, 2012).

Signed at Washington, DC, on November 9, 2012.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2012–27751 Filed 11–14–12; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (12–086)]

NASA Advisory Council; Science Committee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory committee Act, Public

Law 92–462, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Science Committee of the NASA Advisory Council (NAC). This Committee reports to the NAC. The meeting will be held for the purpose of soliciting, from the scientific community and other persons, scientific and technical information relevant to program planning.

DATES: Wednesday, November 14, 2012, 8:30 a.m. to 4:30 p.m., and Thursday, November 15, 2012, 8:30 a.m. to 3:00 p.m., Local Time.

ADDRESSES: NASA Headquarters, 300 E Street SW., Rooms 3H46 and 9H40, respectively, Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Ms. Marian Norris, Science Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–4452, fax (202) 358–4118, or *mnorris@nasa.gov.*

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the capacity of the room. This meeting is also available telephonically and by WebEx. Any interested person may call the USA toll free conference call number (888) 606–5936; pass code ''Science Committee'', to participate in this meeting by telephone. The WebEx link is *https://nasa.webex.com/,* the meeting number on November 14 is 993 494 156, and the password is SC@Nov14; the meeting number on November 15 is 991 469 535, and the password is SC@Nov15. The agenda for the meeting includes the following topics:

—Science Mission Directorate Overview and Program Status—Subcommittee Reports

—Joint Session with the NASA Advisory Council's Human Exploration and Operations Committee on the Mars Program Planning Group final report and Joint Robotics Precursor Activities

It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants. Attendees will be requested to sign a register and to comply with NASA security requirements, including the presentation of a valid picture ID to Security before access to NASA Headquarters. Foreign Nationals attending this meeting will be required to provide a copy of their passport and visa in addition to providing the following information no less than 10 working days prior to the meeting: Full name; gender; date/place of birth; citizenship; visa information (number, type, expiration date); passport information (number, country, expiration date); employer/affiliation information (name of institution, address, country, telephone); title/position of attendee; and home address to Marian Norris via email at *mnorris@nasa.gov* or by fax at (202) 358–4118. U.S. Citizens and Permanent Residents (green card holders) are requested to submit their name and affiliation 3 working days prior to the meeting to Marian Norris.

Patricia D. Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2012–27830 Filed 11–9–12; 4:15 pm]

BILLING CODE 7510–13–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Advisory Committee on Presidential Library-Foundation Partnerships

AGENCY: National Archives and Records Administration.

ACTION: Notice of Meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), the National Archives and Records Administration (NARA) announces a meeting of the Advisory Committee on Presidential Library-Foundation Partnerships. The meeting will be held to discuss the Presidential Library program and topics related to the public-private partnership between the Presidential Libraries and their Presidential Foundations.

DATES: The meeting will be held on November 29, 2012 from 9:00 a.m. to 12:00 noon.

ADDRESSES: The National Archives building at 700 Pennsylvania Avenue NW., Washington, DC, room 105.

FOR FURTHER INFORMATION CONTACT: Susan Donius, Director, Office of Presidential Libraries, at the National Archives and Records Administration, 8601 Adelphi Road, College Park, Maryland 20740, telephone number (301) 837–3250. Contact the Presidential Libraries staff at *denise.lebeck@nara.gov.*

SUPPLEMENTARY INFORMATION: The meeting will be open to the public. Meeting attendees may enter from the Pennsylvania Avenue entrance. Photo identification will be required. No visitor parking is available at the Archives building; however there are commercial parking lots and metered curb parking nearby.

Dated: November 8, 2012.

Patrice Little Murray,

Acting Committee Management Officer.

[FR Doc. 2012–27761 Filed 11–14–12; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Meetings of Humanities Panel

AGENCY: National Endowment for the Humanities.

ACTION: Notice of Meetings.

SUMMARY: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App.), notice is hereby given that 10 meetings of the Humanities Panel will be held during December, 2012 as follows. The purpose of the meetings is for panel review, discussion, evaluation, and recommendation of applications for financial assistance under the National Foundation on the Arts and Humanities Act of 1965 (20 U.S.C. 951–960, as amended).

DATES: See **SUPPLEMENTARY INFORMATION** section for meeting dates.

ADDRESSES: The meetings will be held at the Old Post Office Building, 1100 Pennsylvania Ave. NW., Washington, DC 20506. See Supplementary Information section for meeting room numbers.

FOR FURTHER INFORMATION CONTACT: Lisette Voyatzis, Committee Management Officer, 1100 Pennsylvania Ave. NW., Room, 529, Washington, DC 20506, or call (202) 606–8322. Hearing-impaired individuals are advised that information on this matter may be obtained by contacting the National Endowment for the Humanities' TDD terminal at (202) 606–8282.

SUPPLEMENTARY INFORMATION:

Meetings:

1. DATE: December 03, 2012.
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: 402.
This meeting will discuss applications for the Digital Humanities Start-Up Grants grant program on the subject of Education, submitted to the Office of Digital Humanities.

2. DATE: December 04, 2012.
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: 402.
This meeting will discuss applications for the Digital Humanities Start-Up Grants grant program on the subject of Geospatial and Visualization Research, submitted to the Office of Digital Humanities.

3. DATE: December 05, 2012.
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: 402.

This meeting will discuss applications for the Digital Humanities Start-Up Grants grant program on the subject of Archives and Digital Collections, submitted to the Office of Digital Humanities.

4. DATE: December 06, 2012.
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: 402.
This meeting will discuss applications for the Digital Humanities Start-Up Grants grant program on the subject of Computationally-Intensive Research, submitted to the Office of Digital Humanities.

4. DATE: December 10, 2012.
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: 402.
This meeting will discuss applications for the Digital Humanities Start-Up Grants grant program on the subject of Archives and Digital Collections, submitted to the Office of Digital Humanities.

6. DATE: December 11, 2012.
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: 415.
This meeting will discuss applications for the Humanities Collections and Reference Resources grant program on the subject of Music and Performing Arts, submitted to the Division of Preservation and Access.

7. DATE: December 12, 2012.
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: 402.
This meeting will discuss applications for the Digital Humanities Start-Up Grants grant program on the subject of Public Programs, submitted to the Office of Digital Humanities.

8. DATE: December 12, 2012.
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: 315.
This meeting will discuss applications for the Fellowship Programs at Independent Research Institutions grant program, submitted to the Division of Research Programs.

9. DATE: December 13, 2012.
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: 402.
This meeting will discuss applications for the Digital Humanities Start-Up Grants grant program on the subject of Scholarly Communications, submitted to the Office of Digital Humanities.

10. DATE: December 13, 2012.
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: 415.
This meeting will discuss applications for the Humanities Collections and Reference Resources grant program on the subject of U.S. History and Culture, submitted to the Division of Preservation and Access.

Because these meetings will include review of personal and/or proprietary financial and commercial information given in confidence to the agency by grant applicants, the meetings will be closed to the public pursuant to sections 552b(c)(4) and 552b(c)(6) of Title 5 U.S.C., as amended. I have made this determination pursuant to the authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee Meetings dated July 19, 1993.

Dated: November 8, 2012.

Lisette Voyatzis,

Committee Management Officer.

[FR Doc. 2012–27746 Filed 11–14–12; 8:45 am]

BILLING CODE 7536–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Issued Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permit issued under the Antarctic Conservation of 1978, Public Law 95–541.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permits issued under the Antarctic Conservation Act of 1978. This is the required notice.

FOR FURTHER INFORMATION CONTACT: Nadene G. Kennedy, Permit Office, Office of Polar Programs, Rm. 755, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

SUPPLEMENTARY INFORMATION: On August 8, 2012, the National Science Foundation published a notice in the **Federal Register** of a permit application received. A Waste Management Permit was issued on November 8, 2012 to: Harry R. Anderson, Permit No. 2013 WM–003.

Nadene G. Kennedy,

Permit Officer.

[FR Doc. 2012–27681 Filed 11–14–12; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL WOMEN'S BUSINESS COUNCIL

Data Collection Available for Public Comments and Recommendations

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the National Women's Business Council's intentions to request approval on a new information collection activity that is part of an ongoing research program.

DATES: Submit comments on or before January 1, 2013.

ADDRESSES: Send all comments regarding whether these information collections are necessary for the proper performance of the function of the agency, whether the burden estimates are accurate, and if there are ways to minimize the estimated burden and enhance the quality of the collections to Emily Bruno, Director of Research and Policy, National Women's Business Council, 409 3rd St. SW., Suite 210, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Emily Bruno, Director of Research and Policy, National Women's Business Council, 202–205–6826 (*Emily.Bruno@nwbc.gov*) or Curtis B. Rich, Management Analyst, 202–205–7030, *Curtis.Rich@sba.gov.*

SUPPLEMENTARY INFORMATION: The National Women's Business Council (NWBC) is a non-partisan federal advisory council that serves as an independent source of advice and counsel to the President, Congress, and the Small Business Administration on economic issues of importance to women business owners. Members of the Council are prominent women business owners and leaders of women's business organizations.

One of NWBC's current research priorities is to segment the market of women entrepreneurs to understand differences in opportunities, challenges, motivations, and expectations they face in starting and growing their businesses. To NWBC's knowledge, no government agency has yet delineated a segmentation of women entrepreneurs. At the same time, NWBC would like to understand if and how the motivations and expectations of women entrepreneurs may result in self-limiting perceptions about the potential of their businesses and would like to assess which messaging is most effective in overcoming potential self-limiting perceptions.

NWBC has acquired the services of a research firm to propose a segmentation of women entrepreneurs based on existing and available data and to conduct in-depth analysis of different segments of women entrepreneurs through qualitative research. The analysis will focus on how the expectations and motivations of each segment differs in order to provide insight into what messaging can best be used to help these different segments overcome potential self-limiting perceptions and grow their businesses. The research proposed would build knowledge about how women business owners view the potential for their

endeavors and provide guidance on how messages about entrepreneurship resonate with segments of women within this population. The resulting data can then inform the NWBC and other policymakers about how to reach out to women entrepreneurs to encourage maximum growth for their businesses.

The qualitative research would consist of a set of twelve focus groups with up to 12 individuals in each focus group with different segments of women entrepreneurs. Questions asked during the focus groups would elicit information on motivations and expectations of women entrepreneurs, as well as any self-limiting perceptions that the respondents may hold about their businesses and the potential for growth. The questions will also elicit reactions to messaging that is commonly provided to women through public and private small business service providers to determine which segments of the population are more receptive to the different messages and to identify any new messages that should be deployed.

Title: Focus Group Research: Women Entrepreneurs, Self-Limiting Perceptions, and Segmentation.

Description of Respondents: Women entrepreneurs in a range of industries and sectors across the United States.

Form Number: n/a.

Annual Responses: 144.

Annual Burden: 144.

Anmari J. Borja,

Executive Director.

[FR Doc. 2012–27784 Filed 11–14–12; 8:45 am]

BILLING CODE P

NEIGHBORHOOD REINVESTMENT CORPORATION

Finance, Budget & Program Committee Meeting of the Board of Directors; Sunshine Act Meeting Notice

TIME AND DATE: 9:00 a.m., Tuesday, November 20, 2012.

PLACE: 1325 G Street NW., Suite 800, Boardroom, Washington, DC 20005.

STATUS: Open.

CONTACT PERSON FOR MORE INFORMATION: Erica Hall, Assistant Corporate Secretary, (202) 220–2376; *ehall@nw.org.*

AGENDA:

I. Call To Order
II. Executive Session
III. Budget Update
IV. Committee Charter Review
V. Financial Report
VI. Corporate Investment Policy Review
VII. DC Lease and Move Budget Update
VIII. FY 12 & FY 13 Corporate Milestone Report and Dashboard
IX. NFMC and EHLP
X. NeighborhoodLIFT & CityLIFT
XI. FY12 Grants Report
XII. Adjournment

Erica Hall,

Assistant Corporate Secretary.

[FR Doc. 2012–27859 Filed 11–13–12; 11:15 am]

BILLING CODE 7570–02–P

NEIGHBORHOOD REINVESTMENT CORPORATION

Audit Committee Meeting of the Board of Directors

Sunshine Act Meeting Notice

TIME AND DATE: 3:30 p.m., Thursday, November 15, 2012.

PLACE: 1325 G Street NW., Suite 800, Boardroom, Washington, DC 20005.

STATUS: Open.

CONTACT PERSON FOR MORE INFORMATION: Erica Hall, Assistant Corporate Secretary, (202) 220–2376; *ehall@nw.org.*

AGENDA:

I. CALL TO ORDER
II. Executive Session with Internal Audit Director
III. Executive Session with Officers
IV. Internal Audit Report with Management's Response
V. Internal Audit Performance Scorecard
VI. Internal Audit Status Reports
VII. Internal Audit Response with Management's Response
VIII. FY 2013 Risk Assessment & Internal Audit Plan
IX. Internal Audit Performance Scorecard
X. Internal Audit Status Reports
XI. Memo—EHLP/NFMC-Quality Control Compliance/3rd Party CPA
XII. National Foreclosure Mitigation Counseling (NFMC) Compliance Update
XIII. OHTS Watch List and Overview of Organizational Assessment Review Process
XIV. Adjournment

Erica Hall,

Assistant Corporate Secretary.

[FR Doc. 2012–27862 Filed 11–13–12; 11:15 am]

BILLING CODE 7570–02–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–170; NRC–2012–0272]

The Armed Forces Radiobiology Research Institute TRIGA Reactor: Facility Operating License No. R–84

AGENCY: Nuclear Regulatory Commission.

ACTION: License renewal application; docketing; opportunity to comment; opportunity to request a hearing and petition for leave to intervene; order.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is considering an application for the renewal of Facility Operating License No. R–84 (Application), which currently authorizes the Armed Forces Radiobiology Research Institute (the licensee) to operate the Armed Forces Radiobiology Research Institute (AFFRI) TRIGA Reactor at a maximum steady-state thermal power of 1.1 megawatts (MW). The renewed license would authorize the licensee to operate the AFFRI TRIGA Reactor up to a steady-state thermal power of 1.1 MW for an additional 20 years from the date of issuance.

DATES: Submit comments by December 17, 2012. Requests for a hearing or leave to intervene must be filed by January 14, 2013. Any potential party as defined in Section 2.4 of Title 10 of the *Code of Federal Regulations* (10 CFR), who believes access to Sensitive Unclassified Non-Safeguards Information (SUNSI) is necessary to respond to this notice must request document access by November 26, 2012.

ADDRESSES: You may access information and comment submissions related to this document, which the NRC possesses and are publically available, by searching on *http://www.regulations.gov* under Docket ID NRC–2012–0272. You may submit comments by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0272. Address questions about NRC dockets to Carol Gallagher; telephone: 301–492–3668; email: *Carol.Gallagher@nrc.gov.*
- *Mail comments to:* Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Office of Administration, Mail Stop: TWB–05–B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.
- *Fax comments to:* RADB at 301–492–3446.

For additional direction on accessing information and submitting comments,

see ''Accessing Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Cindy Montgomery, Project Manager, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–3398; email: *Cindy.Montgomery@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Accessing Information and Submitting Comments

A. Accessing Information

Please refer to Docket ID NRC–2012–0272 when contacting the NRC about the availability of information regarding this document. You may access information related to this document, which the NRC possesses and are publicly available, by any of the following methods:

- *Federal Rulemaking Web Site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0272.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced. In addition, for the convenience of the reader, the ADAMS accession numbers for documents that pertain to the AFRRI license renewal are provided in Section II, Availability of Documents, of this document.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2012–0272 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information that that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Availability of Documents

The following documents pertain to the AFRRI License Renewal: June 24, 2004, (ML041800067, ML041800068, ML101650415); March 4, 2010, (ML101650422); August 13, 2010, (ML102310075); August 25, 2010, (ML102440034); September 27, 2010, (ML110260024); October 19, 2010, (ML103070125); October 21, 2010, (ML103070121); February 7, 2011, (ML110460687); June 3, 2011, (ML11165A016); June 20, 2011, (ML112232300); September 6, 2011, (ML11269A030); October 20, 2011, (ML113410120); November 28, 2011, (ML11341A133, ML113460085); January 17, 2012, (ML12032A054); April 20, 2012, (ML12122A146); September 21, 2012, (ML12272A303).

III. Introduction

The NRC is considering an application for the renewal of Facility Operating License No. R–84, which currently authorizes the licensee to operate the AFFRI TRIGA Reactor at a maximum steady-state thermal power of 1.1 MW. The renewed license would authorize the licensee to operate the AFFRI TRIGA Reactor up to a steady-state thermal power of 1.1 MW for an additional 20 years from the date of issuance.

On June 24, 2004, as supplemented by letters dated March 4, August 13, August 25, September 27, October 19, and October 21, 2010; February 7, June 3, June 20, September 6, October 20, and November 28, 2011; January 17, April 20, and September 21, 2012, the NRC received an application from the licensee filed pursuant to 10 CFR 50.51(a) to renew Facility Operating License No. R–84 for the AFFRI TRIGA Reactor.

The application contains SUNSI.

Based on its initial review of the application, the NRC staff determined that the licensee submitted sufficient information in accordance with 10 CFR 50.33 and 10 CFR 50.34 so that the application is acceptable for docketing. The current Docket No. 50–170 for Facility Operating License No. R–84 will be retained. The docketing of the renewal application does not preclude requests for additional information as the review proceeds, nor does it predict whether the Commission will grant or deny the application. Prior to a decision to renew the license, the Commission will make findings required by the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations.

Detailed guidance which the NRC uses to review applications for the renewal of non-power reactor licenses can be found in NUREG–1537, ''Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors.'' The detailed review guidance (NUREG–1537) may be accessed online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html* under ADAMS Accession No. ML042430055 for part one of NUREG–1537 and ADAMS Accession No. ML042430048 for part two of NUREG–1537.

IV. Opportunity To Request a Hearing and Petitions for Leave To Intervene

Requirements for hearing requests and petitions for leave to intervene are found in 10 CFR 2.309, ''Hearing requests, petitions to intervene, requirements for standing, and contentions.'' Interested persons should consult 10 CFR 2.309, which is available at the NRC's Public Document Room (PDR), located at O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852 (or call the PDR at 1–800–397–4209 or 301–415–4737). The NRC's regulations are also accessible electronically from the NRC Library on the NRC's public Web site at *http://www.nrc.gov/reading-rm/doc-collections/cfr/.*

Any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written petition for leave to intervene. As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding and how that interest may be affected by the results of the proceeding. The petition must provide the name, address, and telephone number of the petitioner and specifically explain the reasons why intervention should be permitted with

particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order that may be entered in the proceeding on the petitioner's interest.

A petition for leave to intervene must also include a specification of the contentions that the petitioner seeks to have litigated in the hearing. For each contention, the petitioner must provide a specific statement of the issue of law or fact to be raised or controverted, as well as a brief explanation of the basis for the contention. Additionally, the petitioner must demonstrate that the issue raised by each contention is within the scope of the proceeding and is material to the findings the NRC must make to support the granting of a license renewal in response to the application. The petition must also include a concise statement of the alleged facts or expert opinions which support the position of the petitioner and on which the petitioner intends to rely at hearing, together with references to the specific sources and documents on which the petitioner intends to rely. Finally, the petition must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact, including references to specific portions of the application for license renewal that the petitioner disputes and the supporting reasons for each dispute, or, if the petitioner believes that the application for license renewal fails to contain information on a relevant matter as required by law, the identification of each failure and the supporting reasons for the petitioner's belief. Each contention must be one that, if proven, would entitle the petitioner to relief.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that person's admitted contentions, including the opportunity to present evidence and to submit a cross-examination plan for cross-examination of witnesses, consistent with the NRC's regulations, policies, and procedures. The Atomic Safety and Licensing Board will set the time and place for any prehearing conferences and evidentiary hearings, and the appropriate notices will be provided.

Requests for hearing, petitions for leave to intervene, and motions for leave to file new or amended contentions that are filed after the 60-day deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the following three factors in 10 CFR 2.309(c)(1): (i) The information upon which the filing is based was not previously available; (ii) the information upon which the filing is based is materially different from information previously available; and (iii) the filing has been submitted in a timely fashion based on the availability of the subsequent information.

A State, county, municipality, Federally-recognized Indian tribe, or agencies thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(d)(2). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission by January 14, 2013. The petition must be filed in accordance with the filing instructions in Section V of this document, and should meet the requirements for petitions for leave to intervene set forth in this section, except that State, local governmental bodies, and Federally-recognized Indian tribes do not need to address the standing requirements in 10 CFR 2.309(d)(1) if the facility is located within its boundaries. The entities listed above could also seek to participate in a hearing as a nonparty pursuant to 10 CFR 2.315(c).

If a hearing is granted, any person who does not wish to become a party to the proceeding may, in the discretion of the presiding officer, be permitted to make a limited appearance under 10 CFR 2.315(a), by making an oral or written statement of his or her position on the issues at any session of the hearing or at any pre-hearing conference, within the limits and conditions fixed by the presiding officer. However, that person may not otherwise participate in the proceeding. A person making a limited appearance may make an oral or written statement of position on the issues, but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to such limits and conditions as may be imposed by the Atomic Safety and Licensing Board. Persons desiring to make a limited appearance are requested to inform the Secretary of the Commission by January 14, 2013.

V. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to request (1) a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/apply-certificates.html.* System requirements for accessing the E-Submittal server are detailed in NRC's ''Guidance for Electronic Submission,'' which is available on the agency's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC's Web site. Further information on the Web-

based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.*

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the agency's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the ''Contact Us'' link located on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) first class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket which is available to the public at *http://ehd1.nrc.gov/ehd/,* unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information for Contention Preparation

A. This Order contains instructions regarding how potential parties to this proceeding may request access to documents containing SUNSI.

B. Within 10 days after publication of this notice of hearing and opportunity to petition for leave to intervene, any potential party who believes access to SUNSI is necessary to respond to this notice may request such access. A ''potential party'' is any person who intends to participate as a party by demonstrating standing and filing an admissible contention under 10 CFR 2.309. Requests for access to SUNSI submitted later than 10 days after publication will not be considered absent a showing of good cause for the late filing, addressing why the request could not have been filed earlier.

C. The requester shall submit a letter requesting permission to access SUNSI to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, and provide a copy to the Associate General Counsel for Hearings, Enforcement and Administration, Office of the General Counsel, Washington, DC 20555–0001. The expedited delivery or courier mail address for both offices is: U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland 20852. The email address for the Office of the Secretary and the Office of the General Counsel are *Hearing.Docket@nrc.gov* and *OGCmailcenter@nrc.gov,* respectively.[1] The request must include the following information:

1. A description of the licensing action with a citation to this **Federal Register** notice;

2. The name and address of the potential party and a description of the potential party's particularized interest that could be harmed by the action identified in C.(1); and

3. The identity of the individual or entity requesting access to SUNSI and the requester's basis for the need for the information in order to meaningfully participate in this adjudicatory proceeding. In particular, the request must explain why publicly-available versions of the information requested would not be sufficient to provide the basis and specificity for a proffered contention.

D. Based on an evaluation of the information submitted under paragraph C.(3) the NRC staff will determine within 10 days of receipt of the request whether:

(1) There is a reasonable basis to believe the petitioner is likely to establish standing to participate in this NRC proceeding; and

(2) The requestor has established a legitimate need for access to SUNSI.

E. If the NRC staff determines that the requestor satisfies both D.(1) and D.(2) above, the NRC staff will notify the requestor in writing that access to SUNSI has been granted. The written notification will contain instructions on how the requestor may obtain copies of the requested documents, and any other conditions that may apply to access to those documents. These conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement

[1] While a request for hearing or petition to intervene in this proceeding must comply with the filing requirements of the NRC's ''E-Filing Rule,'' the initial request to access SUNSI under these procedures should be submitted as described in this paragraph.

or Affidavit, or Protective Order[2] setting forth terms and conditions to prevent the unauthorized or inadvertent disclosure of SUNSI by each individual who will be granted access to SUNSI.

F. Filing of Contentions. Any contentions in these proceedings that are based upon the information received as a result of the request made for SUNSI must be filed by the requestor no later than 25 days after the requestor is granted access to that information. However, if more than 25 days remain between the date the petitioner is granted access to the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline.

G. Review of Denials of Access.

(1) If the request for access to SUNSI is denied by the NRC staff after a determination on standing and need for access, the NRC staff shall immediately notify the requestor in writing, briefly stating the reason or reasons for the denial.

(2) The requester may challenge the NRC staff's adverse determination by filing a challenge within 5 days of receipt of that determination with: (a) The presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if he or she is unavailable, another administrative judge, or an administrative law judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) if another officer has been designated to rule on information access issues, with that officer.

H. Review of Grants of Access. A party other than the requester may challenge an NRC staff determination granting access to SUNSI whose release would harm that party's interest independent of the proceeding. Such a challenge must be filed with the Chief Administrative Judge within 5 days of the notification by the NRC staff of its grant of access.

If challenges to the NRC staff determinations are filed, these procedures give way to the normal process for litigating disputes concerning access to information. The availability of interlocutory review by the Commission of orders ruling on such NRC staff determinations (whether granting or denying access) is governed by 10 CFR 2.311.[3]

I. The Commission expects that the NRC staff and presiding officers (and any other reviewing officers) will consider and resolve requests for access to SUNSI, and motions for protective orders, in a timely fashion in order to minimize any unnecessary delays in identifying those petitioners who have standing and who have propounded contentions meeting the specificity and basis requirements in 10 CFR Part 2. Attachment 1 to this Order summarizes the general target schedule for processing and resolving requests under these procedures.

It is so ordered.

For the Nuclear Regulatory Commission.

Dated at Rockville, Maryland, this 8th day of November 2012.

Annette L. Vietti-Cook,

Secretary of the Commission.

Attachment 1—General Target Schedule for Processing and Resolving Requests for Access to Sensitive Unclassified Non-Safeguards Information in This Proceeding

Day	Event/activity
0	Publication of FEDERAL REGISTER notice of hearing and opportunity to petition for leave to intervene, including order with instructions for access requests.
10	Deadline for submitting requests for access to Sensitive Unclassified Non-Safeguards Information (SUNSI) with information: supporting the standing of a potential party identified by name and address; describing the need for the information in order for the potential party to participate meaningfully in an adjudicatory proceeding.
60	Deadline for submitting petition for intervention containing: (i) Demonstration of standing; (ii) all contentions whose formulation does not require access to SUNSI (+25 Answers to petition for intervention; +7 petitioner/requestor reply).
20	Nuclear Regulatory Commission (NRC) staff informs the requester of the staff's determination whether the request for access provides a reasonable basis to believe standing can be established and shows need for SUNSI. (NRC staff also informs any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information.) If NRC staff makes the finding of need for SUNSI and likelihood of standing, NRC staff begins document processing (preparation of redactions or review of redacted documents).
25	If NRC staff finds no ''need'' or no likelihood of standing, the deadline for petitioner/requester to file a motion seeking a ruling to reverse the NRC staff's denial of access; NRC staff files copy of access determination with the presiding officer (or Chief Administrative Judge or other designated officer, as appropriate). If NRC staff finds ''need'' for SUNSI, the deadline for any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information to file a motion seeking a ruling to reverse the NRC staff's grant of access.
30	Deadline for NRC staff reply to motions to reverse NRC staff determination(s).
40	(Receipt +30) If NRC staff finds standing and need for SUNSI, deadline for NRC staff to complete information processing and file motion for Protective Order and draft Non-Disclosure Affidavit. Deadline for applicant/licensee to file Non-Disclosure Agreement for SUNSI.
A	If access granted: Issuance of presiding officer or other designated officer decision on motion for protective order for access to sensitive information (including schedule for providing access and submission of contentions) or decision reversing a final adverse determination by the NRC staff.
A + 3	Deadline for filing executed Non-Disclosure Affidavits. Access provided to SUNSI consistent with decision issuing the protective order.
A + 28	Deadline for submission of contentions whose development depends upon access to SUNSI. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline.
A + 53	(Contention receipt +25) Answers to contentions whose development depends upon access to SUNSI.
A + 60	(Answer receipt +7) Petitioner/Intervenor reply to answers.

[2] Any motion for Protective Order or draft Non-Disclosure Affidavit or Agreement for SUNSI must be filed with the presiding officer or the Chief Administrative Judge if the presiding officer has not yet been designated, within 30 days of the deadline for the receipt of the written access request.

[3] Requesters should note that the filing requirements of the NRC's E-Filing Rule (72 FR 49139; August 28, 2007) apply to appeals of NRC staff determinations (because they must be served on a presiding officer or the Commission, as applicable), but not to the initial SUNSI request submitted to the NRC staff under these procedures.

Day	Event/activity
>A + 60	Decision on contention admission.

[FR Doc. 2012–27757 Filed 11–14–12; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on Planning and Procedures; Notice of Meeting

The ACRS Subcommittee on Planning and Procedures will hold a meeting on December 5, 2012, Room T–2B1, 11545 Rockville Pike, Rockville, Maryland.

The meeting will be open to public attendance with the exception of a portion that may be closed pursuant to 5 U.S.C. 552b(c)(2) and (6) to discuss organizational and personnel matters that relate solely to the internal personnel rules and practices of the ACRS, and information the release of which would constitute a clearly unwarranted invasion of personal privacy.

The agenda for the subject meeting shall be as follows:

Wednesday, December 5, 2012—12:00 p.m. Until 1:00 p.m.

The Subcommittee will discuss proposed ACRS activities and related matters. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Antonio Dias (Telephone 301–415–6805 or Email: *Antonio.Dias@nrc.gov*) five days prior to the meeting, if possible, so that arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 18, 2012, (77 FR 64146–64147).

Information regarding changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the DFO if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, MD. After registering with security, please contact Mr. Theron Brown (240–888–9835) to be escorted to the meeting room.

Dated: November 6, 2012.

Girija Shukla,

Acting Chief, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2012–27741 Filed 11–14–12; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on Regulatory Policies and Practices; Notice of Meeting

The ACRS Subcommittee on Regulatory Policies and Practices will hold a meeting on December 5, 2012, Room T–2B3, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Wednesday, December 5, 2012—8:30 a.m. Until 12:00 p.m.

The Subcommittee will review the staff's efforts to develop a revision to the Station Blackout Rule. The Subcommittee will hear presentations by and hold discussions with the NRC staff and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Christina Antonescu (Telephone 301–415–6792 or Email: *Christina.Antonescu@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 18, 2012, (77 FR 64146–64147).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs*. Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the Web site cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, MD. After registering with security, please contact Mr. Theron Brown (Telephone 240–888–9835) to be escorted to the meeting room.

Dated: November 6, 2012.

Antonio Dias,

Technical Advisor, Advisory Committee on Reactor Safeguards.

[FR Doc. 2012–27750 Filed 11–14–12; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on Fukushima; Notice of Meeting

The ACRS Subcommittee on Fukushima will hold a meeting on December 4, 2012, Room T–2B1, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Tuesday, December 4, 2012—8:30 a.m. Until 12:00 p.m.

The Subcommittee will review and discuss the development of a notation vote paper with possible options for addressing the Near-Term Task Force (NTTF) Recommendation 1: Enhanced Regulatory Framework. The Subcommittee will hear presentations by and hold discussions with the NRC staff and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Antonio Dias (Telephone 301–415–6805 or Email: *Antonio.Dias@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 18, 2012 (77 FR 64146–64147).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs.* Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the Web site cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, MD. After registering with security, please contact Mr. Theron Brown (Telephone 240–888–9835) to be escorted to the meeting room.

Dated: November 6, 2012.

Girija Shukla,

Acting Chief, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2012–27754 Filed 11–14–12; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on Fukushima; Notice of Meeting

The ACRS Subcommittee on Fukushima will hold a meeting on December 5, 2012, Room T–2B3, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Wednesday, December 5, 2012—1:00 p.m. Until 5:00 p.m.

The Subcommittee will review guidance documents for conducting seismic and flooding reevaluations requested in the March 2012 10 CFR 50.54(f) letters to address Fukushima Near-Term Task Force Report, Task 2.1. The Subcommittee will hear presentations by and hold discussions with the NRC staff and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Derek Widmayer (Telephone 301–415–7366 or Email: *Derek.Widmayer@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 18, 2012, (77 FR 64146–64147).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs.* Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the Web site cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, MD. After registering with security, please contact Mr. Theron Brown (Telephone 240–888–9835) to be escorted to the meeting room.

Dated: November 8, 2012.

Antonio Dias,

Technical Advisor, Advisory Committee on Reactor Safeguards.

[FR Doc. 2012–27769 Filed 11–14–12; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on Radiation Protection and Nuclear Materials; Notice of Meeting

The ACRS Subcommittee on Radiation Protection and Nuclear Materials will hold a meeting on December 4, 2012, Room T–2B3, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Tuesday, December 4, 2012—1:00 p.m. Until 4:00 p.m.

The Subcommittee will review Draft Final Regulatory Guide 4.22, ''Decommissioning Planning During Operations.'' The Subcommittee will hear presentations by and hold discussions with the NRC staff and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Derek Widmayer (Telephone 301–415–7366 or Email: *Derek.Widmayer@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 18, 2012, (77 FR 64146–64147).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs.* Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the Web site cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, MD. After registering with security, please contact Mr. Theron Brown (Telephone 240–888–9835) to be escorted to the meeting room.

Dated: November 8, 2012.

Antonio Dias,

Technical Advisor, Advisory Committee on Reactor Safeguards.

[FR Doc. 2012–27767 Filed 11–14–12; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on Regulatory Policies and Practices; Notice of Meeting

The ACRS Subcommittee on Regulatory Policies and Practices will hold a meeting on December 3, 2012, Room T–2B1, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Monday, December 3, 2012—1:00 p.m. Until 5:00 p.m.

The Subcommittee will review and discuss Regulatory Guide 1.79, ''Preoperational Testing of Emergency Core Cooling Systems for Pressurized Water Reactors,'' Revision 2, and Regulatory Guide 1.79.1, ''Initial Test Program of Emergency Core Cooling Systems for New Boiling Water Reactors,'' Revision 0 (DG–1277). The Subcommittee will hear presentations by and hold discussions with the NRC staff and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Zena Abdullahi (Telephone 301–415–8716 or Email: *Zena.Abdullahi@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 18, 2012 (77 FR 64146–64147).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs.* Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the Web site cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, MD. After registering with security, please contact Mr. Theron Brown (Telephone 240–888–9835) to be escorted to the meeting room.

Dated: November 6, 2012.

Antonio Dias,

Technical Advisor, Advisory Committee on Reactor Safeguards.

[FR Doc. 2012–27748 Filed 11–14–12; 8:45 am]

BILLING CODE 7590–01–P

OVERSEAS PRIVATE INVESTMENT CORPORATION

Sunshine Act Meeting Notice—November 28, 2012 Public Hearing

TIME AND DATE: 2:00 p.m., Wednesday, November 28, 2012.

PLACE: Offices of the Corporation, Twelfth Floor Board Room, 1100 New York Avenue NW., Washington, DC.

STATUS: Hearing OPEN to the Public at 2:00 p.m.

PURPOSE: Public Hearing in conjunction with each meeting of OPIC's Board of Directors, to afford an opportunity for any person to present views regarding the activities of the Corporation.

PROCEDURES: Individuals wishing to address the hearing orally must provide advance notice to OPIC's Corporate Secretary no later than 5 p.m. Wednesday, November 21, 2012. The notice must include the individual's name, title, organization, address, and telephone number, and a concise

summary of the subject matter to be presented.

Oral presentations may not exceed ten (10) minutes. The time for individual presentations may be reduced proportionately, if necessary, to afford all participants who have submitted a timely request an opportunity to be heard.

Participants wishing to submit a written statement for the record must submit a copy of such statement to OPIC's Corporate Secretary no later than 5 p.m. Wednesday, November 21, 2012. Such statement must be typewritten, double-spaced, and may not exceed twenty-five (25) pages.

Upon receipt of the required notice, OPIC will prepare an agenda, which will be available at the hearing, that identifies speakers, the subject on which each participant will speak, and the time allotted for each presentation.

A written summary of the hearing will be compiled, and such summary will be made available, upon written request to OPIC's Corporate Secretary, at the cost of reproduction.

Written summaries of the projects to be presented at the December 6, 2012 Board meeting will be posted on OPIC's Web site on or about Friday, November 16, 2012.

CONTACT PERSON FOR INFORMATION: Information on the hearing may be obtained from Connie M. Downs at (202) 336–8438, via facsimile at (202) 408–0297, or via email at *Connie.Downs@opic.gov*.

Dated: November 9, 2012.

Connie M. Downs,

OPIC Corporate Secretary.

[FR Doc. 2012–27853 Filed 11–13–12; 11:15 am]

BILLING CODE 3210–01–P

POSTAL SERVICE

Board of Governors; Sunshine Act Meeting

Board Votes To Close November 1, 2012, Meeting

By telephone vote on November 1, 2012, members of the Board of Governors of the United States Postal Service met and voted unanimously to close to public observation its meeting held in Washington, DC, via teleconference. The Board determined that no earlier public notice was possible.

MATTERS CONSIDERED:

1. Strategic Issues
2. Financial Matters.
3. Pricing.
4. Personnel Matters and Compensation Issues.

GENERAL COUNSEL CERTIFICATION: The General Counsel of the United States Postal Service has certified that the meeting was properly closed under the Government in the Sunshine Act.

CONTACT PERSON FOR MORE INFORMATION: Requests for information about the meeting should be addressed to the Secretary of the Board, Julie S. Moore, at (202) 268–4800.

Julie S. Moore,

Secretary.

[FR Doc. 2012–27840 Filed 11–13–12; 11:15 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: [77 FR 67408, November 9, 2012]

STATUS: Closed Meeting.

PLACE: 100 F Street NE., Washington, DC.

DATE AND TIME OF PREVIOUSLY ANNOUNCED MEETING: Friday, November 9, 2012.

CHANGE IN THE MEETING: Cancellation of Meeting.

The Closed Meeting scheduled for Friday, November 9, 2012 at 9:00 a.m. has been cancelled.

For further information please contact the Office of the Secretary at (202) 551–5400.

Dated: November 9, 2012.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2012–27867 Filed 11–13–12; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68179; File No. SR–NYSEARCA–2012–121]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the NYSE Arca Options Fee Schedule Relating to Pricing Applicable to Electronic Transactions in Non-Penny Pilot Issues

November 8, 2012.

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 October 25, 2012, NYSE Arca, Inc. (the ''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE Arca Options Fee Schedule (''Fee Schedule'') to restructure the pricing applicable to electronic transactions in non-Penny Pilot issues. The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to restructure the pricing applicable to electronic transactions in non-Penny Pilot issues.[4] The Exchange proposes to make the fee change operative on November 1, 2012.

Currently, all transactions in non-Penny Pilot issues are considered ''standard executions,'' as opposed to the ''Post-Take'' pricing structure that

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] As provided under NYSE Arca Options Rule 6.72, options on certain issues have been approved to trade with a minimum price variation of $0.01 as part of a pilot program that is currently scheduled to expire on December 31, 2012. The proposed change will not have an impact on pricing applicable to manual transactions in non-Penny Pilot issues, except that, as proposed, Marketing Charges would no longer apply. However, the Exchange does propose to amend the Fee Schedule to reflect that Firm, Broker Dealer and Customer electronic executions would become ''N/A'' with respect to standard executions.

currently applies only to electronic executions in Penny Pilot issues.[5] The Exchange now proposes to apply the Post-Take pricing structure to electronic executions in non-Penny Pilot issues. As a result, electronic transactions in non-Penny Pilot issues would be subject to Post-Take credits and fees, as is currently applicable for Penny Pilot issues. Under this structure, an electronic order or quote is charged a fee upon execution if it executes against a resting order or quote in the Consolidated Book (i.e., taking liquidity), or, alternatively, a resting electronic order or quote in the Consolidated Book (i.e., posted liquidity) generally receives a liquidity credit when an incoming order or quote executes against it.[6]

To remain competitive, the Exchange is adopting Post-Take pricing for electronic transactions in all non-Penny Pilot issues, but the rates would be different than those that currently apply to Penny Pilot issues. To encourage greater Customer participation, the proposed new rates would provide a higher rebate to Customers that post liquidity, as compared to other market participants, and a rate for Customer orders that take liquidity that is comparable to other market participants. The proposed rates for Lead Market Makers (''LMMs'') and Market Makers for taking liquidity would be similar to each other, although not identical because of differing levels of obligations. The proposed rates also provide for higher rebates for posting liquidity for Market Makers, in order to offset the higher fees for taking liquidity. Firm and Broker Dealer electronic orders that are posted in the Consolidated Book will continue to be charged an execution fee, which would be the same as the current fee, despite such transactions posting liquidity.

The proposed new fees would be as follows:

	Electronic executions in non-Penny Pilot issues	
	Post liquidity	Take liquidity
Customer Electronic	−$0.75	$0.79
LMM	−0.40	0.78
NYSE Arca Market Maker	−0.30	0.80
Firm and Broker Dealer Electronic	0.50	0.85

[5] Manual transactions in Penny Pilot issues are considered standard executions and billed as such.

[6] As described below, a Firm or Broker Dealer electronic transaction in a non-Penny Pilot issue would be charged a fee, even if it is posting liquidity.

As with the Penny Pilot issues, there would be no charges for executions in non-Penny Pilot issues on the opening auction. Also, orders originating from the Trading Floor that execute against the Consolidated Book so as to complete a manual transaction would continue to be charged manual order fees, as is currently the case for Penny Pilot issues, for which standard execution fees apply.[7]

In addition, the Exchange proposes to eliminate Marketing Charges on the Exchange.[8] Marketing Charges do not currently apply to transactions in Penny Pilot issues and, related to the proposal to apply Post-Take pricing to non-Penny Pilot issues, the Exchange has decided to eliminate Marketing Charges entirely.

The Exchange also proposes conforming changes to the endnotes in the Fee Schedule to account for the application of Post-Take pricing for non-Penny Pilot issues. Specifically, the Exchange proposes to amend endnote 5 to specify that only manual executions would be considered ''standard executions'' (i.e., they would not be subject to Post-Take pricing). The Exchange also proposes to amend endnote 6 to specify that, as is currently the case for Penny Pilot issues, transaction fees do not apply to executions occurring during the Opening Auction, as described above. The Exchange also proposes to amend endnote 6 to address the proposal that Firms and Broker Dealers be charged a fee for posting liquidity in non-Penny Pilot issues.

The Exchange notes that the proposed fees are similar to those recently adopted by the NASDAQ Stock Market LLC (''NASDAQ'') for transactions on the NASDAQ Options Market (''NOM'') in non-Penny Pilot Options.[9] Additionally, the proposed fees and credits for non-Penny Pilot issues are similar to fees and rebates currently in place at BATS Exchange, Inc. (''BATS'') Options (''BATS Options'').[10]

[7] *See* endnote 5 in the Fee Schedule.

[8] A Marketing Charge of $0.65 currently applies to LMM and Market Maker transactions against Customers.

[9] *See* Exchange Act Release No. 68029 (October 10, 2012), 77 FR 63384 (October 16, 2012) (SR–NASDAQ–2012–114).

[10] BATS assesses a Non-Penny Pilot Option Fee of $0.80 [sic] per contract for accessing liquidity for a Professional, Firm or Market Maker order that removes liquidity from the BATS Options order book and a $0.75 per contract rebate for a Customer order that removes liquidity from the BATS Options order book. Additionally, BATS pays a $0.70 per contract rebate for a Professional, Firm or Market Maker order that adds liquidity to the BATS Options order book and a $0.75 rebate per contract for a Customer order that adds liquidity to the BATS Options order book.

The Exchange notes that the proposed changes are not otherwise intended to address any other issues surrounding fees for non-Penny Pilot issues and the Exchange is not aware of any problems that OTP Holders and OTP Firms would have in complying with the proposed change.

The Exchange proposes to make the fee change operative on November 1, 2012.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[11] in general, and furthers the objectives of Section 6(b)(4) of the Act,[12] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange operates in a highly competitive market, comprised of 10 U.S. options exchanges, in which sophisticated and knowledgeable market participants can and do send order flow to competing exchanges if they deem fee levels at a particular exchange to be excessive or the rebate offered to be inadequate. The Exchange believes that the proposed fee and rebate structure is competitive and similar to other fees and rebates in place on other exchanges.[13] The Exchange believes that this competitive marketplace materially impacts the fees and rebates present on the Exchange today and substantially influences the proposal set forth herein. The Exchange believes that it is equitable and not unfairly discriminatory to apply the proposed non-Penny Pilot issue pricing to the various market participants, as noted in this proposal. In this regard, all market participants transacting in non-Penny Pilot issues would be subject to the fees and rebates proposed herein.

The Exchange believes that the proposed Customer credit to post liquidity in non-Penny Pilot issues is reasonable because it would continue to incent OTP Holders and OTP Firms to transact Customer order flow on the Exchange. In this regard, Customer order flow benefits all market participants through the increased liquidity that it brings to the market. Customers would be subject to a $0.79 per contract fee to remove liquidity in non-Penny Pilot issues, as compared to

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(4).

[13] *See supra* notes 9 and 10.

no fee today, which the Exchange believes is reasonable due to the opportunity to receive the proposed credit. The Exchange believes that its proposal to offer a Customer credit to post liquidity in non-Penny Pilot issues (from no credit today, to $0.75 per contract as proposed) is reasonable because other market participants will benefit from the increased order flow to the Exchange.

The Exchange believes that charging a fee for Firm and Broker Dealer executions that post liquidity and increasing the fee for their executions that take liquidity in non-Penny Pilot issues is reasonable because the fees would enable the Exchange to incentivize Customers to post greater amounts of liquidity in non-Penny Pilot issues. The Exchange believes that its success at attracting Customer order flow benefits all market participants by improving the quality of order interaction and executions at the Exchange, including for Firms and Broker Dealers.

The Exchange believes that it is equitable and not unfairly discriminatory to assess Firms and Broker Dealers a fee for posting liquidity in non-Penny Pilot issues, but to provide a credit to other market participants for posting liquidity in non-Penny Pilot issues. The Exchange notes that Firms and Broker Dealers would be assessed the same $0.50 per contract fee that they are currently assessed for posting liquidity in non-Penny Pilot issues. More specifically, the Exchange believes that not assessing a Customer, LMM or NYSE Arca Market Maker a fee for posting liquidity in non-Penny Pilot issues, as compared to Firms and Broker Dealers, is equitable and not unfairly discriminatory because Customers, LMMs, and NYSE Arca Market Makers differ from Firms and Broker Dealers. In this regard, the Exchange believes that Customer order flow benefits all market participants by improving liquidity and the quality of order interaction. Additionally, LMMs and Market Makers have obligations to the market and regulatory requirements,[14] which normally do not apply to other market participants. For example, an LMM has the obligation to make continuous markets 90% of the time that the Exchange is open for trading, while other Market Makers have the obligation to make continuous markets 60% of the time that the Exchange is open for trading. Both LMMs and other Market Makers must also engage in a course of dealing that is consistent with the maintenance of a fair and orderly market. Accordingly, the Exchange believes that it is equitable and not unfairly discriminatory to charge Firms and Broker Dealers for posting liquidity but to not charge other market participants for doing so.

The proposed differentiation between pricing for Customers, LMMs, NYSE Arca Market Makers and other market participants is also equitable and not unfairly discriminatory because it reflects the differing contributions made to the liquidity and trading environment on the Exchange by Customers, LMMs, and NYSE Arca Market Makers, as well as the differing mix of orders entered. The Exchange believes that increasing the Firm and Broker Dealer fees for taking liquidity in non-Penny Pilot issues to $0.85 per contract is equitable and not unfairly discriminatory because Firms and Broker Dealers will be assessed the same fee. Further, the amount of the fee is reasonable because it is the same as the rate charged to Firms and Broker Dealers on other exchanges. For example, NOM charges Professionals, Non-NOM Market Makers and Firms $0.85 per contract to take liquidity in non-Penny Pilot issues. Customers, LMMs and Market Makers would be assessed a lower fee for taking liquidity in non-Penny Pilot issues, as compared to Firms and Broker Dealers, because, as mentioned above, the fees reflect the differing contributions made to the liquidity and trading environment on the Exchange by Customers, LMMs, and Market Makers, as well as the differing mix of orders.

The Exchange believes that the rates proposed for LMMs and Market Makers are equitable and not unfairly discriminatory. In this regard, non-Penny Pilot issues are typically less liquid than Penny Pilot issues and thus the heightened quoting obligation of the LMM in these issues requires a differentiated posting incentive as compared to Penny Pilot issues. Accordingly, since there is much greater risk for a liquidity provider when posting versus taking in less liquid names and the LMM's quoting obligation is 50% higher than a regular Market Maker, they require a meaningfully higher posting rebate. Taking liquidity is not as much of the core function of the liquidity provider, thus the difference in take rates do not have to be as substantial, which the Exchange believes is reasonable.

The Exchange also believes that, overall, the proposed fees for taking liquidity are reasonable because in the current U.S. options market, many of the contracts are quoted in pennies. Under this pricing structure, the minimum penny tick increment equates to a $1.00 economic value difference per contract, given that a single standardized U.S. option contract covers 100 shares of the underlying stock.

For contracts that are quoted in $0.05 increments (non-pennies), the value per tick is $5.00 in proceeds to the investor transacting in these contracts. Liquidity rebate and access fee structures on the make-take exchanges, including the Exchange's Post-Take pricing structure, for securities quoted in penny increments are commonly in the $0.30 to $0.45 per contract range. A $0.30 per contract rebate in a penny quoted security is a rebate equivalent to 30% of the value of the minimum tick. A $0.45 per contract fee in a penny quoted security is a charge equivalent to 45% of the value of that minimum tick. In other words, in penny quoted securities, where the price is improved by one tick with an access fee of $0.45 per contract, an investor paying to access that quote is still $0.55 better off than trading at the wider spread, even without the access fee ($1.00 of price improvement less a $0.45 access fee equals $0.55 better economics). This computation is equally true for securities quoted in wider increments. Rebates and access fees near the $0.85 per contract level equate to only 17% of the value of the minimum tick in non-Penny Pilot issues, less than the experience today in Penny Pilot issues. For example, a retail investor transacting a single contract in a non-penny quoted security quoted a single tick tighter than the rest of the market, and paying an access fee of $0.79 per contract, is receiving an economic benefit of $4.21 ($0.05 improved tick equals $5.00 in proceeds less $0.79 access fee, which equals $4.21). The Exchange believes that encouraging LMMs and Market Makers to quote more aggressively by giving credits to post liquidity and incenting Customer orders to post on NYSE Arca will narrow the spread in non-Penny Pilot issues to the benefit of investors and all market participants by improving the overall economics of the resulting transactions that occur on the Exchange, even if the access fee paid in connection with such transactions is higher. Accordingly, the Exchange believes that the proposed fees and rebates for the non-Penny Pilot issues are reasonable, equitable and not unfairly discriminatory.

As with Penny Pilot issues, there will be no fees for transactions on the Opening Auction. The Exchange believes that this is equitable and not unfairly discriminatory because it

[14] *See* NYSE Arca Rules 6.32 (Market Maker Defined), 6.37 (Obligations of Market Makers), 6.37A (Obligations of Market Makers—OX) and 6.37B (Market Maker Quotations—OX).

would apply to trading interest from all market participants, and is reasonable because a determination of posting liquidity or taking liquidity is difficult prior to the establishment of the opening market.

The Exchange believes the application of manual fees to orders represented by a Floor Broker and partially executed against the Consolidated Book are reasonable, equitable and not unfairly discriminatory, because the fees are those expected by the market participant that submits the order, and does not alter the fees or credits expected by the market participant whose order or quote is resting in the Consolidated Book.

The Exchange believes that eliminating Marketing Charges on the Exchange is reasonable because it would eliminate a fee for Market Makers and LMMs that the Exchange has decided to no longer apply in light of the proposed application of Post-Take pricing to non-Penny Pilot issues—currently, Marketing Charges do not apply to Penny Pilot issues. This is equitable and not unfairly discriminatory because the charges are currently collected only from LMMs and Market Makers who interact with Customer orders, and, as a result of the proposed change, would no longer be collected from any participant on the Exchange. As a result, Customers would receive direct credit for posted liquidity, rather than a payment for order flow in an indirect manner.

Finally, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and credits to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

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 received one unsolicited, written comment on the proposed rule change from an LMM on the Exchange. The LMM commented that the proposed pricing structure would negatively impact its business because it trades less liquid issues with wider markets, and that the restructuring of the fees will not provide a sufficient incentive to him to provide tighter markets to receive credits for posting liquidity. The LMM also stated that the proposed pricing structure will encourage order flow providers to send mid-market trades (orders between the bid and offer) to the Exchange to collect payment (posted liquidity credits) and gain priority, and then direct market-taking orders to other exchanges where the order flow provider would not be charged a market taker fee.

Additionally, the LMM believed that the proposed pricing structure would encourage competition from Customers who would have an incentive to improve on the LMM's markets to collect posted liquidity credits and also gain priority, diminishing the value of being an OTP-holding market maker on the Exchange. Lastly, the LMM commented that there might or might not be an increase in order flow between the bid and offer, but that other, more sophisticated firms would be more competitive, and, therefore, the LMM would not see the benefits of the proposed pricing structure.

In response to the LMM's statements, the Exchange believes, as described above, that the proposed fee and rebate structure is competitive and similar to other fees and rebates in place on other exchanges. The LMM's complaints are that he will not be able to compete against Customers or more sophisticated firms. The Exchange believes that attracting Customer order flow benefits all market participants by improving the quality of order interaction and executions at the Exchange, including for Firms and Broker Dealers. Encouraging LMMs and Market Makers to quote more aggressively by giving credits to post liquidity and incenting Customer orders to post on NYSE Arca will narrow the spread in non-Penny Pilot issues to the benefit of investors and all market participants by improving the overall economics of the resulting transactions that occur on the Exchange, and by increasing competition between the LMM and Customers and competing Market Makers, spreads will narrow and more attractive order flow will be available on the Exchange, enhancing the markets for all participants.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [15] of the Act and subparagraph (f)(2) of Rule 19b–4 [16] thereunder, because it establishes a due, fee, or other charge imposed by the NYSE Arca.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEARCA–2012–121 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEARCA–2012–121. 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 20549–1090, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such

[15] 15 U.S.C. 78s(b)(3)(A).

[16] 17 CFR 240.19b–4(f)(2).

filing also will be available for inspection and copying at the NYSE's principal office and on its Internet Web site at *www.nyse.com.* All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEARCA–2012–121, and should be submitted on or before December 6, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27712 Filed 11–14–12; 8:45 am]

BILLING CODE 8011–01–P

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68182; File No. SR–CHX–2012–16]

Self-Regulatory Organizations; Chicago Stock Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Single-Sided Orders Fees and Rebates

November 8, 2012

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 2, 2012, the Chicago Stock Exchange, Inc. (''CHX'' or ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. CHX has filed the proposal pursuant to Section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] 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 the Substance of the Proposed Rule Change

The CHX proposes to amend its Schedule of Fees and Assessments (the ''Fee Schedule''), effective November 2, 2012, to create a separate fee and rebate structure for each derivative and non-derivative Tape A, B and C security, with respect to single-sided order executions of 100 or more shares. The text of this proposed rule change is available on the Exchange's Web site at *http://www.chx.com/rules/proposed_rules.htm* and in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549.

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 Statutory Basis for, the Proposed Rule Change

1. Purpose

Through this filing, the Exchange proposes to amend its Schedule of Fees and Assessments (the ''Fee Schedule''), effective November 2, 2012, to amend Section E.1 of the Fee Schedule, which concerns single-sided order executions of 100 or more shares, to establish fees and rebates specific to each derivative and non-derivative Tape A, B and C security type.

Current Section E.1

On January 9, 2012, the Exchange adopted the current Fee Schedule that incorporated, *inter alia,* a separate fee and rebate structure for Derivative Securities Products (''DSPs'')[5] and removed references to Tape A, B and C securities throughout its Fee Schedule.[6] Specifically, with respect to Section E.1, the Exchange eliminated the distinction in the fee and rebate structure for Tape A, B and C securities[7] and replaced it with a structure based on DSPs and non-DSPs.

With respect to the current fees and rebates of Section E.1, for transactions in DSPs priced greater than or equal to $1.00/share that are executed in the Regular Trading Session, the current Fee Schedule charges a fee of $0.003/share for removing liquidity and gives a rebate of $0.0022/share for providing liquidity. For transactions in non-DSPs priced equal to or greater than $1.00/share that are executed in the Regular Trading Session, the current Fee Schedule charges a fee of $0.003/share for removing liquidity, but gives no rebate for providing liquidity. For transactions in all securities priced equal to or less than $1.00/share that are executed in the Early and Late Trading Sessions, the current Fee Schedule charges a fee of $0.003/share for removing liquidity and gives a rebate of $0.0022/share for providing liquidity. For transactions in all securities priced less than $1.00/share, the current Fee Schedule charges a fee of 0.30% of trade value for removing liquidity and gives a rebate of $0.00009/share for providing liquidity.

Proposed Section E.1

The Exchange now proposes to amend Section E.1 to reincorporate references to Tape A, B and C securities, while maintaining the distinction between DSPs and non-DSPs, so as to establish fees and rebates specific to each derivative and non-derivative Tape A, B and C security type and to maintain the current rebate and fee values, but for two exceptions. Specifically, the Exchange proposes to distinguish between ''Regular'' and ''Early and Late'' trading sessions. Each trading session will be further divided into six categories, one for each derivative and non-derivative Tape A, B and C security. Finally, each one of the six security-types will be then divided into securities priced greater than or equal to $1.00/share or priced less than $1.00/share. At this point, each security-type will be assigned a specific fee and rebate value, resulting in a total of twenty-four (24) distinct sets of fees and rebates.

With respect to the actual values of the fees and rebates of proposed Section E.1, the Exchange proposes to mostly adopt the fee and rebate values currently in Section E.1. Specifically, for transactions in Tape A and B Non-DSP securities priced greater than or equal to $1.00/share executed during the Regular Trading Session, the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(2).

[5] Per Section E.1 of the current Fee Schedule, ''Derivative Securities Product'' is defined as any type of option, warrant, hybrid securities product or any other security, other than a single equity option or a security futures product, whose value is based, in whole or in part, upon the performance of, or interest in, an underlying instrument. This definition is drawn from Rule 19b–4(e). *See* 17 CFR 240.19b–4(e).

[6] *See* Exchange Act. Release No. 66139 (January 11, 2012), 77 F.R. 2583 (January 18, 2012) (SR–CHX–2012–01).

[7] Tape A securities are those securities for which the New York Stock Exchange, Inc. is the primary listing market. Tape C securities are those securities for which the NASDAQ Stock Exchange, Inc. is the primary listing center. Tape B securities are those securities for which some other national securities exchange is the primary listing market.

Exchange proposes to maintain no liquidity providing rebate and a $0.0030/share liquidity removing fee. Also, for transactions in Tapes A and B DSP securities priced greater than or equal to $1.00/share executed during the Regular Trading Session and all Tapes DSP and Non-DSP securities priced greater than or equal to $1.00 executed during the Early or Late Trading Session, the Exchange proposes to maintain a liquidity providing rebate of $0.0020/share and a liquidity removing fee of $0.0030/share. Furthermore, for transactions in all Tapes Non-DSP securities priced less than $1.00/share executed in the Regular, Early or Late Trading Sessions, the Exchange proposes to maintain a liquidity providing rebate of $0.00009/share and a liquidity removing fee of 0.30% of trade value.

However, the Exchange proposes a new fee and rebate for Tape C DSP and Non-DSP securities priced greater than or equal to $1.00/share executed in the Regular Trading Session. Currently, for transactions in Tape C non-DSP securities priced greater than or equal to $1.00/share executed in the Regular Trading Session, there is no liquidity providing rebate and a $0.0030/share liquidity removing fee. Moreover, for transactions in Tape C DSP securities priced greater than or equal to $1.00/share executed in the Regular Trading Session, there is currently a liquidity providing rebate of $0.0020/share and a liquidity removing fee of $0.0030/share. In lieu of these current values, the Exchange now proposes a liquidity providing rebate of $0.00010/share and a liquidity removing fee of $0.0006/share, for both of these security types. The Exchange submits that the imposition of these new fee and rebate values is necessary to promote order flow in Tape C securities to the Exchange.

Generally speaking, the purpose of this new fee and rebate structure is to create greater granularity in the Exchange's billing structure, which will in turn provide it with greater flexibility in setting fees and rebates.[8] This granularity will allow the Exchange to make fine-tuned adjustments, through future proposed fee filings pursuant to Rule 19b–4, to incentivize order flow in a specific group of securities, such as in Tape C securities, without affecting other fees or rebates associated with orders in other groups of securities that the Exchange does not wish to impact. That is, such flexibility will allow the Exchange to adapt to fast-paced changes in today's orders marketplace and will, in turn, allow the Exchange to remain competitive for such orders.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act[9] in general, and furthers the objectives of Section 6(b)(4) of the Act[10] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and other persons using any facility or system which the Exchange operates or controls. Specifically, since the proposed fee and rebate structure will apply to all single-sided orders of 100 or more shares executed in the CHX Matching System, the Exchange believes that it will equitably allocate the fees and rebates among Participants in a non-discriminatory nature. In addition, because quoting and trading activity is different among certain categories of securities, such as DSPs, as well as those securities on different Tapes, the Exchange believes that it is fair and reasonable to impose specific fees and rebates for each of the six security-types in order to better incent activity by Participants on the Exchange's trading facilities in those particular categories. Furthermore, the proposed values for the liquidity removing fees for each of the security types are reasonable where such values will either remain the same as the current fees or will decrease (in the case of transactions in Tape C DSP and Non-DSP securities priced greater than or equal to $1.00/share executed in the Regular Trading Session) and where the proposed fee values are generally similar to the fees of other exchanges, such as NASDAQ.[11]

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.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The proposed rule change is to take effect pursuant to Section 19(b)(3)(A)(ii) of the Act[12] and subparagraph (f)(2) of Rule 19b–4 thereunder[13] because it establishes or changes a due, fee or other charge applicable to the Exchange's members and non-members, which renders the proposed rule change effective upon filing.

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–CHX–2012–16 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CHX–2012–16. 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

[8] The Exchange endeavors to incorporate this new security-type specific fee structure throughout its Fee Schedule, to the extent applicable, through proposed rule filings, such as this one and SR–CHX–2012–15. SR–CHX–2012–15 proposes the adoption of a similar security-type specific fee structure in the context of order cancellation fees.

[9] 15 U.S.C. 78f.

[10] 15 U.S.C. 78f(b)(4).

[11] NASDAQ pricing provides for a flat fee of $0.0030/share to remove liquidity for transactions in all Tape securities priced greater than or equal to $1.00/share and a fee of 0.30% of total dollar volume for transactions in securities priced less than $1.00/share.

[12] 15 U.S.C. 78s(b)(3)(A)(ii).

[13] 17 CFR 240.19b–4(f)(2).

change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the CHX. 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–CHX–2012–16, and should be submitted on or before December 6, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27715 Filed 11–14–12; 8:45 am]

BILLING CODE 8011–01–P

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68196; File No. SR–Phlx–2012–128]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify Fees Assessed Under Section VII. C. of the Pricing Schedule

November 8, 2012.

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 October 26, 2012, NASDAQ OMX PHLX LLC (''PHLX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit 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 the Substance of the Proposed Rule Change

The Exchange proposes to modify fees assessed under Section VII. C. of the PHLX Pricing Schedule relating to the Central Registration Depository (''CRD system''), which are collected by FINRA. PHLX is proposing that the implementation date of the proposed rule change will be January 2, 2013. The text of the proposed rule change is available at *http://nasdaqomxphlx.cchwallstreet.com,* at PHLX's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item III [sic] 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

PHLX is amending its fees assessed under Section VII. C. of the PHLX Pricing Schedule to reflect a recent fee change made by FINRA,[3] relating to the CRD system.[4] The fees assessed under Section VII. C. are collected and retained by FINRA via the CRD system for the registration of associated persons of Exchange members that are not also FINRA members. The Exchange originally adopted the fees under Section VII. C. to mirror the fees assessed by FINRA on its members for use of the CRD system in connection with the Exchange's participation in Web CRD.[5] FINRA recently amended the fees assessed for use of the CRD system, which will become effective January 2, 2013.[6] The CRD system fees are use-based and there is no distinction in the cost incurred by FINRA if the user is a FINRA member or a member of an exchange that is not a FINRA member. Accordingly, the Exchange is proposing to amend the fees under Section VII. C. to mirror those assessed by FINRA, which will be implemented concurrently with the amended FINRA fees on January 2, 2013.[7]

In addition to increasing the existing CRD system fees, FINRA adopted a new fee for the additional processing of each initial or amended Form BD that includes the initial reporting, amendment, or certification of one or more disclosure events or proceedings.[8] Member firms use the Form BD to, among other things, report disclosure matters in which they or a control affiliate have been involved. Prior to the adoption of the new fee, FINRA did not have a fee designed to cover the costs associated with the review of Form BD notwithstanding the review is similar to that performed of member firms' Forms U4 and U5. Such reviews include confirming that the matter is properly reported; reviewing any documentation submitted and determining whether additional documentation is required; conducting any necessary independent research; and, depending on the matter reported, analyzing whether the event or proceeding subjects the individual or member to a statutory disqualification pursuant to Section 3(a)(39) of the Act.[9] FINRA adopted a $110 fee for the review of a Form BD, which mirrors the increased fee adopted for the review of Forms U4 and U5. As such, the Exchange is adopting the identical fee for FINRA's review of a Form BD submitted by Exchange members that are not members of FINRA.

The Exchange is proposing that the implementation date of the proposed

[3] *See* Securities Exchange Act Release No. 67247 (June 25, 2012), 77 FR 38866 (June 29, 2012) (SR–FINRA–2012–030).

[4] The CRD system is the central licensing and registration system for the U.S. securities industry. The CRD system enables individuals and firms seeking registration with multiple states and self-regulatory organizations to do so by submitting a single form, fingerprint card and a combined payment of fees to FINRA. Through the CRD system, FINRA maintains the qualification, employment and disciplinary histories of registered associated persons of broker-dealers.

[5] *See* Securities Exchange Act Release No. 53688 (April 20, 2006), 71 FR 24885 (April 27, 2006) (SR–Phlx–2006–24). *See also,* Section 4(b)(3) of Schedule A to the FINRA By-Laws.

[6] *Supra* note 3.

[7] The Exchange notes that it is not adopting all of the changes made in the FINRA filing. Certain fees and requirements are specific to FINRA and the Exchange elected to not adopt them because either such fees did not apply to Exchange-only members or such fees did not directly cover the costs associated with the use of the CRD system. For example, under FINRA Section 4(h) of Schedule A FINRA assesses a fee of $10 per day, up to $300 for each day that a new disclosure event or a change in the status of a previously reported disclosure event is not timely filed on an initial or amended Form U5 or an amended Form U4. [sic] This fee provides a financial incentive to a FINRA member to file its Forms U4 and U5 timely. The Exchange elected to not adopt such a fee applicable to its members that are not also FINRA members.

[8] *Id.*

[9] 15 U.S.C. 78c(a)(39).

rule change will be January 2, 2013. Specifically, the proposed initial/transfer registration, disclosure filing, and fingerprint fees would become effective for filings or fingerprints submitted on or after January 2, 2013. Lastly, the proposed system processing fee would become effective for the 2013 Renewal Program.[10]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[11] in general, and with Section 6(b)(4) of the Act[12] and Section 6(b)(5) of the Act,[13] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which the Exchange operates or controls, and it does not unfairly discriminate between customers, issuers, brokers or dealers. All similarly situated members are subject to the same fee structure, and every member firm must use the CRD system for registration and disclosure.

The change is reasonable because the proposed fees are identical to those adopted by FINRA for use of the CRD system for disclosure and the registration of associated persons of FINRA members. As FINRA noted in amending its fees, it believed the fees are reasonable based on the increased costs associated with operating and maintaining the CRD system, and listed a number of enhancements made to the CRD system since the last fee increase, including: (1) Incorporation of various uniform registration form changes; (2) electronic fingerprint processing; (3) Web EFT™, which allows subscribing firms to submit batch filings to the CRD system; (4) increases in the number and types of reports available through the CRD system; and (5) significant changes to BrokerCheck, including making BrokerCheck easier to use and expanding the amount of information made available through the system. These increased costs are similarly borne by FINRA when a member of the Exchange that is not a member of FINRA uses the CRD system. Accordingly, the fees collected for such use should likewise increase in lockstep with the fees assessed FINRA members, as is proposed by the Exchange.

The proposed change, like FINRA's proposal, is consistent with an equitable allocation of fees because the fees will apply equally to all individuals and members required to report information to the CRD system. Thus, those members that register more individuals or submit more filings through the CRD system will generally pay more in fees than those members that use the CRD system to a lesser extent.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

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

Pursuant to Section 19(b)(3)(A)(ii) of the Act,[14] PHLX has designated this proposal as establishing or changing a due, fee, or other charge imposed by the self-regulatory organization on any person, whether or not the person is a member of the self-regulatory organization, which renders the proposed rule change effective upon filing.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

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–Phlx–2012–128 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-Phlx-2012-128. 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 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2012–128, and should be submitted on or before December 6, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27779 Filed 11–14–12; 8:45 am]

BILLING CODE 8011–01–P

[10] As part of FINRA's 2013 Renewal Program, Preliminary Renewal Statements reflecting the proposed $45 system processing fee will be made available to members in the fourth quarter of 2012.

[11] 15 U.S.C. 78f.

[12] 15 U.S.C. 78f(b)(4).

[13] 15 U.S.C. 78f(b)(5).

[14] 15 U.S.C. 78s(b)(3)(A)(ii).

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68195; File No. SR–BX–2012–070]

Self-Regulatory Organizations; NASDAQ OMX BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify Fees Assessed Under Rule 7003(a)

November 8, 2012.

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 October 26, 2012, NASDAQ OMX BX, Inc. (''BX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to modify fees assessed under Rule 7003(a) relating to the Central Registration Depository (''CRD system''), which are collected by FINRA. BX is proposing that the implementation date of the proposed rule change will be January 2, 2013. The text of the proposed rule change is available at *http://nasdaqomxbx.cchwallstreet.com,* at BX's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item III [sic] below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

BX is amending its fees assessed under Rule 7003(a) to reflect a recent fee change made by FINRA,[3] relating to the CRD system.[4] The fees assessed under Rule 7003(a) are collected and retained by FINRA via the CRD system for the registration of associated persons of Exchange members that are not also FINRA members. The Exchange originally adopted the fees under Rule 7003(a) to mirror the fees assessed by FINRA on its members for use of the CRD system in connection with the resumption of its cash equities trading business.[5] FINRA recently amended the fees assessed for use of the CRD system, which will become effective January 2, 2013.[6] The CRD system fees are use-based and there is no distinction in the cost incurred by FINRA if the user is a FINRA member or a member of an exchange that is not a FINRA member. Accordingly, the Exchange is proposing to amend the fees under Rule 7003(a) to mirror those assessed by FINRA, which will be implemented concurrently with the amended FINRA fees on January 2, 2013.[7]

In addition to increasing the existing CRD system fees, FINRA adopted a new fee for the additional processing of each initial or amended Form BD that includes the initial reporting, amendment, or certification of one or more disclosure events or proceedings.[8] Member firms use the Form BD to, among other things, report disclosure matters in which they or a control affiliate have been involved. Prior to the adoption of the new fee, FINRA did not have a fee designed to cover the costs associated with the review of Form BD notwithstanding the review is similar to that performed of member firms' Forms U4 and U5. Such reviews include confirming that the matter is properly reported; reviewing any documentation submitted and determining whether additional documentation is required; conducting any necessary independent research; and, depending on the matter reported, analyzing whether the event or proceeding subjects the individual or member to a statutory disqualification pursuant to Section 3(a)(39) of the Act.[9] FINRA adopted a $110 fee for the review of a Form BD, which mirrors the increased fee adopted for the review of Forms U4 and U5. As such, the Exchange is adopting the identical fee for FINRA's review of a Form BD submitted by Exchange members that are not members of FINRA.

The Exchange is proposing that the implementation date of the proposed rule change will be January 2, 2013. Specifically, the proposed initial/transfer registration, disclosure filing, and fingerprint fees would become effective for filings or fingerprints submitted on or after January 2, 2013. Lastly, the proposed system processing fee would become effective for the 2013 Renewal Program.[10]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[11] in general, and with Section 6(b)(4) of the Act [12] and Section 6(b)(5) of the Act,[13] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which the Exchange operates or controls, and it does not unfairly discriminate between customers, issuers, brokers or dealers. All similarly situated members are subject to the same fee structure, and

[3] *See* Securities Exchange Act Release No. 67247 (June 25, 2012), 77 FR 38866 (June 29, 2012) (SR–FINRA–2012–030).

[4] The CRD system is the central licensing and registration system for the U.S. securities industry. The CRD system enables individuals and firms seeking registration with multiple states and self-regulatory organizations to do so by submitting a single form, fingerprint card and a combined payment of fees to FINRA. Through the CRD system, FINRA maintains the qualification, employment and disciplinary histories of registered associated persons of broker-dealers.

[5] *See* Securities Exchange Act Release No. 54264 [sic] (February 2, 2009), 74 FR 6441 (February 9, 2009) (SR–BX–2009–004). *See also,* Section 4(b)(3) of Schedule A to the FINRA By-Laws.

[6] *Supra* note 3.

[7] The Exchange notes that it is not adopting all of the changes made in the FINRA filing. Certain fees and requirements are specific to FINRA and the Exchange elected to not adopt them because either such a fee did not apply to Exchange-only members or such fees did not directly cover the costs associated with the use of the CRD system. For example, under FINRA Section 4(h) of Schedule A FINRA assesses a fee of $10 per day, up to $300 for each day that a new disclosure event or a change in the status of a previously reported disclosure event is not timely filed on an initial or amended Form U5 or an amended Form U4. [sic] This fee provides a financial incentive to a FINRA member to file its Forms U4 and U5 timely. The Exchange elected to not adopt such a fee applicable to its members that are not also FINRA members.

[8] *Id.*

[9] 15 U.S.C. 78c(a)(39).

[10] As part of FINRA's 2013 Renewal Program, Preliminary Renewal Statements reflecting the proposed $45 system processing fee will be made available to members in the fourth quarter of 2012.

[11] 15 U.S.C. 78f.

[12] 15 U.S.C. 78f(b)(4).

[13] 15 U.S.C. 78f(b)(5).

every member firm must use the CRD system for registration and disclosure.

The change is reasonable because the proposed fees are identical to those adopted by FINRA for use of the CRD system for disclosure and the registration of associated persons of FINRA members. As FINRA noted in amending its fees, it believed the fees are reasonable based on the increased costs associated with operating and maintaining the CRD system, and listed a number of enhancements made to the CRD system since the last fee increase, including: (1) Incorporation of various uniform registration form changes; (2) electronic fingerprint processing; (3) Web EFT™, which allows subscribing firms to submit batch filings to the CRD system; (4) increases in the number and types of reports available through the CRD system; and (5) significant changes to BrokerCheck, including making BrokerCheck easier to use and expanding the amount of information made available through the system. These increased costs are similarly borne by FINRA when a member of the Exchange that is not a member of FINRA uses the CRD system. Accordingly, the fees collected for such use should likewise increase in lockstep with the fees assessed FINRA members, as is proposed by the Exchange.

The proposed change, like FINRA's proposal, is consistent with an equitable allocation of fees because the fees will apply equally to all individuals and members required to report information to the CRD system. Thus, those members that register more individuals or submit more filings through the CRD system will generally pay more in fees than those members that use the CRD system to a lesser extent.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

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

Pursuant to Section 19(b)(3)(A)(ii) of the Act,[14] BX has designated this proposal as establishing or changing a due, fee, or other charge imposed by the self-regulatory organization on any person, whether or not the person is a member of the self-regulatory organization, which renders the proposed rule change effective upon filing.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BX–2012–070 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BX–2012–070. 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 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BX–2012–070, and should be submitted on or before December 6, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27778 Filed 11–14–12; 8:45 am]

BILLING CODE 8011–01–P

[14] 15 U.S.C. 78s(b)(3)(A)(ii).

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68194; File No. SR–NYSEArca–2012–114]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Commentary .05 and .07 to NYSE Arca Rule 6.4 Regarding Strike Price Intervals for Classes in the Short Term Option Series Program

November 8, 2012.

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 October 26, 2012, 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 Commentary .07 to NYSE Arca Rule 6.4 to allow the Exchange to provide: (i) That the strike price interval for classes in the Short Term Option Series (''STOS'') Program that normally trade in $1 Strike Price Intervals shall be

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

$0.50 or greater; and for classes in the STOS Program that do not normally trade in $1 Strike Price Intervals, the strike price interval shall be $0.50 or greater strike price intervals [sic] where the strike price is less than $75 and $1.00 or greater strike price intervals [sic] where the strike price is between $75 and $150; and (ii) that the strike price intervals for the Related non-STOS options shall be the same as the strike price intervals for STOS from the Thursday prior to expiration week of an option class that is selected for the STOS Program. The Exchange also proposes to amend Commentary .05 and .07 to provide that strike price intervals for the Related non-STOS options shall be the same as the strike price intervals for STOS starting the Thursday prior to the expiration week of an option class that is selected for the STOS Program. The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Commentary .07 to NYSE Arca Rule 6.4 to provide that the Exchange may open for trading Short Term Option Series (''STOS'')[4] at $0.50 or greater strike price intervals if the class normally trades in $1 strike price intervals. If the class normally trades in a greater interval, the Exchange may open STOS at a strike price interval of $0.50 where the strike price is less than $75, $1.00 or greater strike price intervals where the strike price is between $75 and $150, and strike price intervals the same as strike prices for series in that same option class that expire in accordance with the normal monthly expiration cycle [sic]. The Exchange also proposes that the strike price intervals for the Related non-STOS options[5] shall be the same as the strike price intervals for STOS starting the Thursday prior to the expiration week of an option class that is selected for the STOS Program.

This is a competitive filing that is based on two recently approved filings submitted by the International Securities Exchange, LLC (''ISE'') and NASDAQ OMX PHLX, LLC (''Phlx'').[6] The ISE and Phlx filings both made changes to the strike price interval setting parameter rules for their respective STOS Programs. Weekly options are not listed to expire during the same week as non-Weekly options. As a result, both ISE and Phlx amended their rules to permit non-STOS options to have the same strike price interval setting parameters for Weekly options during the week that non-Weekly options expire.

ISE and Phlx also both amended the strike price interval setting parameters for their STOS Programs, but the revisions to their respective rules differ. Specifically, ISE permits $0.50 strike price intervals for Weekly options for option classes that trade in one dollar increments and are in the STOS Program.[7] Phlx permits $0.50 strike price intervals when the strike price is below $75, and $1 strike price intervals when the strike price is between $75 and $150. Phlx also provides that related non-Weekly option series may be opened during the week prior to expiration week pursuant to the same strike price interval parameters that exist for Weekly options. Thus a related non-Weekly option may be opened in Weekly option strike price intervals on a Thursday or a Friday that is a business day before the non-Weekly option expiration week.[8] If the Phlx is not open for business on the respective Thursday or Friday, however, the non-Weekly option may be opened in Weekly option intervals on the first business day immediately prior to that respective Thursday or Friday.[9] Chicago Board Options Exchange, Incorporated (''CBOE'') highlighted the differences between the two filings during the notice and comment period and submitted a comment letter on that subject.[10]

The Exchange is proposing to adopt strike price interval setting parameters that are currently in effect for both ISE and Phlx in order to remain competitive. The Exchange notes that while it believes that there is substantial overlap between the two strike price interval setting parameters, the Exchange believes there are gaps that would enable Phlx to initiate a series that ISE would not be able to initiate and vice versa.[11] Since uniformity is not required for the STOS Programs that

[4] Short Term Options Series (''STOS'') also known as ''Weekly options'' or ''weeklies'' trade under the STOS Program. For all practical purposes, the terms STOS, Weekly options, and weeklies are interchangeable.

[5] As proposed, a non-Short Term Option that is on a class that has been selected to participate in the Short Term Option Series Program is referred to as a ''Related non-Short Term Option.'' The Related non-STOS option will be the same option class as the STOS option but will have a longer expiration cycle (*e.g.,* a SPY monthly option as compared to a SPY weekly option).

[6] *See* Securities Exchange Act Release Nos. 67754 (August 29, 2012), 77 FR 54629 (September 5, 2012) (order approving SR–ISE–2012–33) (''ISE filing'') and 67753 (August 29, 2012), 77 FR 54635 (September 5, 2012) (order approving SR–Phlx–2012–78) (''Phlx filing'').

[7] The permissible $0.50 strike price intervals may only be opened on the Weekly option Opening Date that expire on the Weekly option Expiration date and no additional series, including additional series of the related non-Weekly option, may be opened during expiration week in classes that are listed pursuant to the newly amended ISE rules.

[8] This opening timing is consistent with the principle that the Exchange may add new series of options until five business days prior to expiration. *See* Rules 6.4 and 5.19(c)(2).

[9] On the Exchange, the STOS opening process is set forth in NYSE Arca Rules 6.4, Commentary .07: After an option class has been approved for listing and trading on the Exchange, the Exchange may open for trading on any Thursday or Friday that is a business day (''Short Term Option Opening Date'') series of options on that class that expire on the Friday of the following business week that is a business day (''Short Term Option Expiration Date''). If the Exchange is not open for business on the respective Thursday or Friday, the Short Term Option Opening Date will be the first business day immediately prior to that respective Thursday or Friday. Similarly, if the Exchange is not open for business on the Friday of the following business week, the Short Term Option Expiration Date will be the first business day immediately prior to that Friday.

[10] A copy of CBOE's comment letter may be accessed at: *http://sec.gov/comments/sr-phlx-2012-78/phlx201278-1.pdf.* For example, in the comment letter CBOE noted its belief that the Phlx strike price interval setting parameters were broader since they applied to all classes that participate in the STOS Program where the ISE proposal provided increased granularity only to those classes in which $1 strike price intervals are currently permitted.

[11] The Exchange is making a distinction between initiating series and cloning series. The Exchange and the majority, if not all, of the other options exchanges that have adopted a STOS Program have a similar rule that permits the listing of series that are opened by other exchanges. *See* Rule 6.4, Commentary 12. This filing is concerned with the ability to initiate series. For example, if a class is selected to participate in the STOS Program and non-STOS on that class do not trade in dollar increments, the Exchange believes that Phlx would be permitted to initiate $0.50 strikes on that class and ISE would not. Similarly, the strike price interval for exchange-traded fund (''ETF'') options is generally $1 or greater where the strike price is $200 or less. If, an ETF class is selected to participate in the STOS Program, the Exchange believes that ISE would be permitted to initiate $0.50 strike price intervals where the strike price is between $151 and $200, but Phlx would not be.

have been adopted by the various options exchanges, the Exchange proposes to revise its strike price intervals setting parameters so that it has the ability to initiate strike prices in the same manner (*i.e.,* intervals) as both ISE and Phlx. Accordingly, the Exchange proposes to adopt aspects of both the ISE rule text language and the Phlx rule text language that the SEC recently approved.

The STOS Program is codified in Commentary .07 to Exchange Rule 6.4.[12] The Rule states that after an option class has been approved for listing and trading on the Exchange, the Exchange may open for trading on any Thursday or Friday that is a business day series of options on no more than five option classes that expire on the Friday of the following business week that is a business day. In addition to the five-option class limitation, there is also a limitation that no more than twenty series for each expiration date in those classes may be initially opened for trading.[13] Furthermore, the strike price of each STOS has to be fixed with approximately the same number of strike prices being opened above and below the value of the underlying security at about the time that the short term options are initially opened for trading on the Exchange, and with strike prices being within thirty percent (30%) above or below the closing price of the underlying security from the preceding day. The Exchange does not propose any changes to the current program limitations. The Exchange proposes only to specify that STOS can have interval prices of $0.50 and $1, as proposed under Commentary .07 to Exchange Rule 6.4.[14]

The principal reason for the proposed interval pricing structure is market demand for weekly options. There is continuing strong customer demand for having the ability to execute hedging and trading strategies effectively via STOS, particularly in the current fast, multi-faceted trading and investing environment that extends across numerous markets and platforms.[15] The Exchange has observed increased demand for STOS classes and/or series, particularly when market moving events such as significant market volatility, corporate events, or large market, sector, or individual issue price swings have occurred. The STOS Program is one of the most popular and quickly expanding options expiration programs.

In the two years since the application of the STOS Program to multiply listed issues, it has steadily expanded to the point that as of August 31, 2012, STOS represent 4.69% of the total options volume on the Exchange and 12.6% of the total options volume in the United States.[16] The STOS volumes become even more significant when the volumes of an STOS class are compared to the volumes of the Related non-STOS options class. As an example, through the first eight months of 2012, on the Exchange there were 2,090,189 contracts of SPY STOS traded and 34,967,949 contracts of SPY monthly options traded; and 1,047,903 contracts of AAPL STOS traded and 8,818,945 contracts of AAPL monthly options traded. From the 4th quarter of 2010 to the 4th quarter of 2011, STOS volume expanded more than 90%,[17] and the Exchange believes that STOS volumes will continue to expand in 2012. The Exchange believes that, as such, while STOS are currently one of most popular (high volume) expiration lengths of options traded on NYSE Arca and other options exchanges, STOS will only become more popular as market participants continue to gain knowledge about more effective uses of these products for trading and hedging purposes.

Moreover, the Commission has approved the use of $0.50 and $1 strike price intervals on the Exchange as well as in the options industry, particularly at lower price levels (*e.g.,* below $150). Numerous options products are listed (trade) on the Exchange at $0.50 and $1 strike price intervals. For example, there are two individual ETF options listed on the Exchange with $0.50 strike price intervals. There are approximately 50 options listed on the Exchange at $0.50 strike price intervals pursuant to the $0.50 Strike Program. There are 820 options listed on the Exchange with $1 strike price intervals. Moreover, the Commission has recently approved certain products to trade at $0.50 and $1 strike price intervals on CBOE within exactly the same strike price points that are proposed by the Exchange in this filing, namely $75 and $150.[18]

The Exchange believes that the benefits of the ability to trade STOS at $0.50 and $1 intervals at lower price levels cannot be underestimated. The proposed intervals would clearly allow traders and investors, and in particular public (retail) investors to more effectively and with greater precision consummate trading and hedging strategies on the Exchange. The Exchange believes that this precision is increasingly necessary, and in fact crucial, as traders and investors engage in trading and hedging strategies across various investment platforms (*e.g.,* equity and ETF, index, derivatives, futures, foreign currency, and even commodities products); particularly when many of these platforms enjoy substantially smaller strike price differentiations (*e.g.,* as low as $.05).[19]

Weekly options have characteristics that are attractive for certain trading and hedging strategies. Thus, weeklies may be attractive for retail trading strategies that could benefit from the inherent accelerated time decay of weekly

[12] On July 12, 2005, the Commission approved the STOS Program on a pilot basis. *See* Securities Exchange Act Release No. 52013 (July 12, 2005), 70 FR 41471 (July 19, 2005) (SR–PCX–2005–32). The STOS Program was made permanent on June 23, 2010. *See* Securities Exchange Act Release No. 62369 (June 23, 2010), 75 FR 37868 (June 30, 2010) (SR–NYSEArca–2010–59).

[13] However, if the Exchange opens twenty (20) short term options for a Short Term Option Expiration Date, up to 10 additional series may be opened for trading on the Exchange when the Exchange deems it necessary to maintain an orderly market, to meet customer demand or when the market price of the underlying security moves substantially from the exercise price or prices of the series already opened. Any additional strike prices listed by the Exchange shall be within thirty percent (30%) above or below the current price of the underlying security. The Exchange may also open additional strike prices of STOS that are more than 30% above or below the current price of the underlying security provided that demonstrated customer interest exists for such series, as expressed by institutional, corporate or individual customers or their brokers (market-makers trading for their own account shall not be considered when determining customer interest under this provision).

[14] As of August 31, 2012, there are 159 option classes across all options exchanges that have STOS options expiring on September 7, 2012.

[15] These include, without limitation, options, equities, futures, derivatives, indexes, exchange traded funds, exchange traded notes, currencies, and over-the-counter instruments.

[16] The Exchange notes that, in fact, the volume increase in STOs since their inception just over two years ago greatly exceeds the volume increase of any other length option (*e.g.,* monthly, quarterly, or long term) over the same equivalent time period.

[17] During the same time period, monthly options volume decreased by 8%.

[18] *See* Securities Exchange Act Release No. 64189 (April 5, 2011), 76 FR 20066 (April 11, 2011) (SR–CBOE–2011–008) (order granting approval of $0.50 and $1 strike price intervals for certain volatility options where the strike prices are less than $75 and between $75 and $150, respectively). In approving the CBOE proposal, the Commission stated that the proposal appears to strike a reasonable balance between the Exchange's desire to offer a wider array of investment opportunities and the need to avoid unnecessary proliferation of options series and the corresponding increase in quotes and market fragmentation. The Exchange notes that other options exchanges including NYSE MKT, ISE, NOM, and Phlx, have made similar rule changes.

[19] As an example, per the CME Web site, strike prices for options on futures may be at an interval of $.05, $.10, and $.25 per specified parameters. *See http://www.cmegroup.com/trading/equityindex/files/EQUITY_FLEX_Options.pdf* (options on S&P 500 and NASDAQ–100 contracts) and *http://www.cmegroup.com/rulebook/files/S_5734_x11–0518x_Change_in_Listing_Rules_for_Goldx_Silverx_Copper_Options.pdf* (options on metals contracts).

options, such as selling (buying) vertical or calendar spreads. And weeklies may be particularly attractive instruments for short-term institutional hedging needs (*e.g.,* sudden price movements against large option positions during expiration week; maintenance or adjustment of complex option positions) as well as for retail hedging needs (*e.g.,* preceding large earnings plays). In every case, trading and hedging is more effective when it can be closely tailored. The current wider STOS price intervals have negatively impacted investors and traders, particularly retail public customers, who have on several occasions requested the Exchange for finer, narrower STOS intervals. The proposal would fix this.

The following is an example of how inadequately narrow STOS intervals negatively impact trading and hedging opportunities. If an investor needs to purchase an STOS call option in CSCO (03/26/12 closing price $20.84), the current $1 strike interval would offer less opportunity and choice for an investor seeking to keep cash expenditures low. For example, an investor wishing to buy an in-the-money call option for less than a $2.50 investment per call purchase has only two strike prices that meet his criteria from which to choose: the 19 strike and the 20 strike. Such call options with five days until expiration might offer ''ask prices'' (option premiums) of $1.75 and $.75. However, if CSCO had $0.50 strike prices as proposed, the same investor would have a selection of March 18.50, 19.00, 19.50, 20.00, and the 20.50 strike call options that may have options premiums from approximately $2.25 down to approximately $.25. This expanded range of strikes, and commensurate option premiums, offers far more choice and a considerably lower cost of entry to the investor, thereby garnering the investor more than a 66% options premium savings. Lower intervals increase effective liquidity by offering investors and traders more price points at which they may execute trading and hedging strategies.[20] This allows investors and traders the ability to more effectively execute their strategies at lower cost. Clearly, more efficient pricing is advantageous to all market participants, from retail to institutional investors. The changes proposed by the Exchange should allow execution of more trading and hedging strategies on the Exchange.

The Exchange notes that in conformance with Exchange Rules, the Exchange shall not list $0.50 or $1 strike price intervals on Related non-STOS options within five days of expiration. For example, if a Related non-STOS in an options class is set to expire on Friday, September 21, the Exchange could begin to trade $0.50 strike price intervals surrounding that Related non-STOS on Thursday, September 13, but no later than Friday September 14.

The Exchange proposes to list the expiring Related non-STOS on the Thursday or Friday prior to expiration week, so that investors can close a position in an expiring STOS and open a position at the same strike price in a Related non-STOS. The listing of the $0.50 or $1 strike price intervals for expiring Related non-STOS on the Thursday or Friday prior to expiration week is intended to be consistent with the ''overlap'' of STOS today, which facilitates investors desire to ''roll'' a position from one STOS expiration to another. If the $0.50 or $1 interval strikes are not available until the opening on Monday of expiration week, an investor who had a position in the prior week's $0.50 or $1 interval STOS could not close a position in the expiring STOS and open a position at the same strike in the Related non-STOS.

Furthermore, the inadequate price intervals for STOS, particularly at the lower price levels proposed by the Exchange, may discourage retail and other customers from executing STOS orders when they could be the most advantageous for effective execution of trading and hedging strategies on regulated and transparent exchanges. The Exchange feels that it is essential that such negative, potentially costly and time-consuming impacts on retail investors are eliminated by offering tighter intervals within the STOS Program. The changes proposed by the Exchange should allow execution of more trading and hedging strategies on the Exchange.[21]

With regard to the impact of this proposal on system capacity, the Exchange has analyzed its capacity and represents that it and the Options Price Reporting Authority (''OPRA'') have the necessary systems capacity to handle the potential additional traffic associated with trading in the Program at $.50 or $1 intervals, as applicable under the proposal. The Exchange notes that this proposal would not increase the number of listed STOS, but only the interval between them. The Exchange believes that its OTP Holders and OTP Firms will not have a capacity issue as a result of this proposal.

The Exchange also proposes that Related non-STOS shall be opened on the Thursday or Friday prior to the expiration week that such Related non-STOS expire in the same manner as permitted in Rule 6.4, subsection (a) of Commentary .07, and in the same strike price intervals for the STOS permitted in this [sic] Rule 6.4, subsection (e) of Commentary .07. The Exchange proposes to make this change to ensure conformity between STOS options and Related non-STOS options that are in the same options class (*e.g.,* weekly and monthly SPY options). The Exchange believes that not having such a conforming change would be counter-productive and not beneficial for trading and hedging purposes.[22]

The Exchange believes that the STOS Program has provided investors with greater trading opportunities and flexibility and the ability to more closely tailor their investment and risk management strategies and decisions. Furthermore, the Exchange has had to reject trading requests because of the limitations imposed by the Program. For these reasons, the Exchange requests a modification of the strike price intervals in the Program and the opportunity to provide investors with better weekly option choices for investment, trading, and risk management purposes.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[23] in general, and furthers the objectives of Section 6(b)(5),[24] 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

[20] Moreover, lower strike intervals provide additional price points for liquidity providers. This allows the liquidity providers to improve theoretical pricing as well as hedging capabilities, thereby enabling them to increase the size and quality of their markets.

[21] In addition, there is a competitive impact. First, the proposal would enable the Exchange to provide market participants with an opportunity to execute their strategies (*e.g.,* complex option spreads) wholly on their preferred market, namely the Exchange. Second, the proposal would diminish the potential for foregone market opportunities on the Exchange caused by the need to use a more advantageous (that is, interval-precise) platform than STOs currently allow.

[22] Moreover, the Exchange notes that STOS options are not listed and traded during the expiration week of the Related non-STOS options. During this week, the non-STOS options are materially and financially equivalent to the STOS options. The proposed change would allow traders and hedgers to have the noted benefits of the STOS Program during each week in a month.

[23] 15 U.S.C. 78f(b).

[24] 15 U.S.C. 78f(b)(5).

mechanism of a free and open market and a national market system.

The Exchange believes that providing strike prices of $.50 and $1 intervals in STOS eligible classes will result in a continuing benefit to investors by giving them more flexibility to closely tailor their investment decisions and hedging decisions in a greater number of securities. The Exchange also believes that providing the same strike price intervals for options classes that are in the STOS Program and for the Related non-STOS options just prior to and during expiration week will provide the investing public and other market participants with additional opportunities to hedge their investment, thus allowing these investors to better manage their risk exposure. In addition, the Exchange believes that the proposal will ensure conformity between STOS options and Related non-STOS options that are in the same options class. The Exchange believes that allowing the listing of expiring Related non-STOS on the on the Thursday or Friday prior to expiration week will help facilitate the ability of investors and other market participants to close a position in an expiring STOS and open a position at the same strike price in a Related non-STOS is a manner that is designed to promote just and equitable principles of trade. While the expansion of the STOS Program will generate additional quote traffic, the Exchange does not believe that this increased traffic will become unmanageable since the proposal remains limited to a fixed number of classes.

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. In this regard and as indicated above, the Exchange notes that the rule change is being proposed as a competitive response to existing ISE and PHLX rules. The Exchange believes this proposed rule change is necessary to permit fair competition among the options exchanges with respect to their short term options programs.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule 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 if consistent with the protection of investors and the public interest, provided that the self-regulatory organization has given 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 proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [25] and Rule 19b–4(f)(6) thereunder.[26]

The Exchange asked the Commission to waive the 30-day operative delay period for non-controversial proposed rule changes to allow the proposed rule change to be operative upon filing.[27] The Commission believes it is consistent with the public interest to waive the 30-day operative delay. The proposed rule change is substantially similar in all material respects to existing ISE and PHLX rules, which permit the listing of Short Term Options Series at finer strike price intervals; the proposal presents no novel issues.[28] Waiver of the operative delay will allow the Exchange to expand its STOS Program to the current parameters of those SROs and compete without undue delay. Therefore, the Commission grants such waiver and designates the proposal operative upon filing.[29]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

[25] 15 U.S.C. 78s(b)(3)(A).

[26] 17 CFR 240.19b–4(f)(6).

[27] As required under Rule 19b–4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change along with a brief description and the 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.

[28] *See* ISE Filing and Phlx Filing, *supra* note 6.

[29] 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).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2012–114 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2012–114. 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 Section, 100 F Street NE., Washington, DC 20549, on official business days between 10:00 a.m. and 3:00 p.m. Copies of the filing will also be available for inspection and copying at the NYSE's principal office and on its Internet Web site at *www.nyse.com.* All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2012–114 and should be submitted on or before December 6, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[30]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27777 Filed 11–14–12; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68193; File No. SR–NYSEMKT–2012–53]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Commentary to Exchange Rule 903 Regarding Strike Price Intervals for Classes in the Short Term Option Series Program

November 8, 2012.

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 October 26, 2012, NYSE MKT LLC (the ''Exchange'' or ''NYSE MKT'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been substantially 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 Commentary .10 to Exchange Rule 903 to allow the Exchange to provide: (i) That the strike price interval for classes in the Short Term Option Series (''STOS'') Program that normally trade in $1 Strike Price Intervals shall be $0.50 or greater; and for classes in the STOS Program that do not normally trade in $1 Strike Price Intervals, the strike price interval shall be $0.50 or greater strike price intervals [sic] where the strike price is less than $75 and $1.00 or greater strike price intervals [sic] where the strike price is between $75 and $150; and (ii) that the strike price intervals for the Related non-STOS options shall be the same as the strike price intervals for STOS from the Thursday prior to expiration week of an option class that is selected for the STOS Program. The Exchange also proposes to amend Commentary .05 and .10 to provide that strike price intervals for the Related non-STOS options shall be the same as the strike price intervals for STOS starting the Thursday prior to the expiration week of an option class that is selected for the STOS Program. In addition, the Exchange proposes to delete Commentary .08 to Exchange Rule 903. The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Commentary .10 to Exchange Rule 903 to provide that the Exchange may open for trading Short Term Option Series (''STOS'')[4] at $0.50 or greater strike price intervals if the class normally trades in $1 strike price intervals. If the class normally trades in a greater interval, the Exchange may open STOS at a strike price interval of $0.50 where the strike price is less than $75, $1.00 or greater strike price intervals [sic] where the strike price is between $75 and $150, and strike price intervals the same as strike prices for series in that same option class that expire in accordance with the normal monthly expiration cycle [sic]. The Exchange also proposes that the strike price intervals for the Related non-STOS options[5] shall be the same as the strike price intervals for STOS starting the Thursday prior to the expiration week of an option class that is selected for the STOS Program. In addition, the Exchange proposes to delete Commentary .08 to Exchange Rule 903 because it is duplicative of subsection (d) to Commentary .10.

This is a competitive filing that is based on two recently approved filings submitted by the International Securities Exchange, LLC (''ISE'') and NASDAQ OMX PHLX, LLC (''Phlx'').[6] The ISE and Phlx filings both made changes to the strike price interval setting parameter rules for their respective STOS Programs. Weekly options are not listed to expire during the same week as non-Weekly options. As a result, both ISE and Phlx amended their rules to permit non-Weekly options to have the same strike price interval setting parameters for Weekly options during the week that non-Weekly options expire.

ISE and Phlx also both amended the strike price interval setting parameters for their STOS Programs, but the revisions to their respective rules differ. Specifically, ISE permits $0.50 strike price intervals for Weekly options for option classes that trade in one dollar increments and are in the STOS Program.[7] Phlx permits $0.50 strike price intervals when the strike price is below $75, and $1 strike price intervals when the strike price is between $75 and $150. Phlx also provides that related non-Weekly option series may be opened during the week prior to expiration week pursuant to the same strike price interval parameters that exist for Weekly options. Thus a related non-Weekly option may be opened in Weekly option strike price intervals on a Thursday or a Friday that is a business day before the non-Weekly option expiration week.[8] If the Phlx is not open for business on the respective Thursday or Friday, however, the non-Weekly option may be opened in Weekly option

[30] 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] Short Term Options Series (''STOS'') also known as ''Weekly options'' or ''weeklies'' trade under the STOS Program. For all practical purposes, the terms STOS, Weekly options, and weeklies are interchangeable.

[5] As proposed, a non-Short Term Option that is on a class that has been selected to participate in the Short Term Option Series Program is referred to as a ''Related non-Short Term Option.'' The Related non-STOS option will be the same option class as the STOS option but will have a longer expiration cycle (*e.g.,* a SPY monthly option as compared to a SPY weekly option).

[6] *See* Securities Exchange Act Release Nos. 67754 (August 29, 2012), 77 FR 54629 (September 5, 2012) (order approving SR–ISE–2012–33) (''ISE filing'') and 67753 (August 29, 2012) 77 FR 54635 (September 5, 2012) (order approving SR–Phlx–2012–78) (''Phlx filing'').

[7] The permissible $0.50 strike price intervals may only be opened on the Weekly option Opening Date that expire on the Weekly option Expiration date and no additional series, including additional series of the related non-Weekly option, may be opened during expiration week in classes that are listed pursuant to the newly amended ISE rules.

[8] This opening timing is consistent with the principle that the Exchange may add new series of options until five business days prior to expiration. *See* Rule 903, Commentary .04.

intervals on the first business day immediately prior to that respective Thursday or Friday.[9] Chicago Board Options Exchange, Incorporated (''CBOE'') highlighted the differences between the two filings during the notice and comment period and submitted a comment letter on that subject.[10]

The Exchange is proposing to adopt strike price interval setting parameters that are currently in effect for both ISE and Phlx in order to remain competitive. The Exchange notes that while it believes that there is substantial overlap between the two strike price interval setting parameters, the Exchange believes there are gaps that would enable Phlx to initiate a series that ISE would not be able to initiate and vice versa.[11] Since uniformity is not required for the STOS Programs that have been adopted by the various options exchanges, the Exchange proposes to revise its strike price intervals setting parameters so that it has the ability to initiate strike prices in the same manner (*i.e.,* intervals) as both ISE and Phlx. Accordingly, the Exchange proposes to adopt aspects of both the ISE rule text language and the Phlx rule text language that the SEC recently approved.

The STOS Program is codified in Commentary .08 and .10 to Exchange Rule 903.[12] The Rules state that after an option class has been approved for listing and trading on the Exchange, the Exchange may open for trading on any Thursday or Friday that is a business day series of options on no more than five option classes that expire on the Friday of the following business week that is a business day. In addition to the five-option class limitation, there is also a limitation that no more than twenty series for each expiration date in those classes may be initially opened for trading.[13] Furthermore, the strike price of each STOS has to be fixed with approximately the same number of strike prices being opened above and below the value of the underlying security at about the time that the short term options are initially opened for trading on the Exchange, and with strike prices being within thirty percent (30%) above or below the closing price of the underlying security from the preceding day. The Exchange does not propose any changes to the current program limitations. The Exchange proposes only to specify that STOS can have interval prices of $0.50 and $1, as proposed under Commentary .10 to Exchange Rule 903.[14]

The principal reason for the proposed interval pricing structure is market demand for weekly options. There is continuing strong customer demand for having the ability to execute hedging and trading strategies effectively via STOS, particularly in the current fast, multi-faceted trading and investing environment that extends across numerous markets and platforms.[15] The Exchange has observed increased demand for STOS classes and/or series, particularly when market moving events such as significant market volatility, corporate events, or large market, sector, or individual issue price swings have occurred. The STOS Program is one of the most popular and quickly expanding options expiration programs.

In the two years since the application of the STOS Program to multiply listed issues, it has steadily expanded to the point that as of August 31, 2012, STOS represent 6.72% of the total options volume on the Exchange and 12.6% of the total options volume in the United States.[16] The STOS volumes become even more significant when the volumes of an STOS class are compared to the volumes of the Related non-STOS options class. As an example, through the first eight months of 2012, on the Exchange there were 3,878,385 contracts of SPY STOS traded and 46,640,772 contracts of SPY monthly options traded; and 1,456,154 contracts of AAPL STOS traded and 17,808,928 contracts of AAPL monthly options traded. From the 4th quarter of 2010 to the 4th quarter of 2011, STOS volume expanded more than 90%,[17] and the Exchange believes that STOS volumes will continue to expand in 2012. The Exchange believes that, as such, while STOS are currently one of most popular (high volume) expiration lengths of options traded on the Exchange and other options exchanges, STOS will only become more popular as market participants continue to gain knowledge about more effective uses of these products for trading and hedging purposes.

Moreover, the Commission has approved the use of $0.50 and $1 strike price intervals on the Exchange as well as in the options industry, particularly at lower price levels (*e.g.,* below $150). Numerous options products are listed (trade) on the Exchange at $0.50 and $1 strike price intervals. For example, there are two individual ETF options listed on the Exchange with $0.50 strike price intervals. There are approximately 50 options listed on the Exchange at $0.50 strike price intervals pursuant to the

[9] On the Exchange, the STOS opening process is set forth in NYSE MKT Rule 903(h): After an option class has been approved for listing and trading on the Exchange, the Exchange may open for trading on any Thursday or Friday that is a business day (''Short Term Option Opening Date'') series of options on that class that expire on the Friday of the following business week that is a business day (''Short Term Option Expiration Date''). If the Exchange is not open for business on the respective Thursday or Friday, the Short Term Option Opening Date will be the first business day immediately prior to that respective Thursday or Friday. Similarly, if the Exchange is not open for business on the Friday of the following business week, the Short Term Option Expiration Date will be the first business day immediately prior to that Friday.

[10] A copy of CBOE's comment letter may be accessed at: *http://sec.gov/comments/sr-phlx-2012–78/phlx201278–1.pdf.* For example, in the comment letter CBOE noted its belief that the Phlx strike price interval setting parameters were broader since they applied to all classes that participate in the Weekly Program where the ISE proposal provided increased granularity only to those classes in which $1 strike price intervals are currently permitted.

[11] The Exchange is making a distinction between initiating series and cloning series. The Exchange and the majority, if not all, of the other options exchanges that have adopted a STOS Program have a similar rule that permits the listing of series that are opened by other exchanges. *See* Rule 903A(b)(vi). This filing is concerned with the ability to initiate series. For example, if a class is selected to participate in the STOS Program and non-STOS options on that class do not trade in dollar increments, the Exchange believes that Phlx would be permitted to initiate $0.50 strikes on that class and ISE would not. Similarly, the strike price interval for exchange-traded fund (''ETF'') options is generally $1 or greater where the strike price is $200 or less. If, an ETF class is selected to participate in the STOS Program, the Exchange believes that ISE would be permitted to initiate $0.50 strike price intervals where the strike price is between $151 and $200, but Phlx would not be.

[12] On July 12, 2005, the Commission approved the STOS Program on a pilot basis. *See* Securities Exchange Act Release No. 52014 (July 12, 2005), 70 FR 41244 (July 18, 2005) (Amex–2005–035). The STOS Program was made permanent on June 23, 2010. *See* Securities Exchange Act Release No.62370 (June 23, 2010), 75 FR 37870 (June 30, 2010) (SR–NYSEAmex–2010–62).

[13] However, if the Exchange opens twenty (20) short term options for a Short Term Option Expiration Date, up to 10 additional series may be opened for trading on the Exchange when the Exchange deems it necessary to maintain an orderly market, to meet customer demand or when the market price of the underlying security moves substantially from the exercise price or prices of the series already opened. Any additional strike prices listed by the Exchange shall be within thirty percent (30%) above or below the current price of the underlying security. The Exchange may also open additional strike prices of STOS that are more than 30% above or below the current price of the underlying security provided that demonstrated customer interest exists for such series, as expressed by institutional, corporate or individual customers or their brokers (market-makers trading for their own account shall not be considered when determining customer interest under this provision).

[14] As of August 31, 2012, there are 159 option classes across all options exchanges that have STOS options expiring on September 7, 2012.

[15] These include, without limitation, options, equities, futures, derivatives, indexes, exchange traded funds, exchange traded notes, currencies, and over-the-counter instruments.

[16] The Exchange notes that, in fact, the volume increase in STOs since their inception just over two years ago greatly exceeds the volume increase of any other length option (*e.g.,* monthly, quarterly, or long term) over the same equivalent time period.

[17] During the same time period, monthly options volume decreased by 8%.

$0.50 Strike Program. There are 820 options listed on the Exchange with $1 strike price intervals. Moreover, the Commission has recently approved certain products to trade at $0.50 and $1 strike price intervals on CBOE within exactly the same strike price points that are proposed by the Exchange in this filing, namely $75 and $150.[18]

The Exchange believes that the benefits of the ability to trade STOS at $0.50 and $1 intervals at lower price levels cannot be underestimated. The proposed intervals would clearly allow traders and investors, and in particular public (retail) investors to more effectively and with greater precision consummate trading and hedging strategies on the Exchange. The Exchange believes that this precision is increasingly necessary, and in fact crucial, as traders and investors engage in trading and hedging strategies across various investment platforms (*e.g.,* equity and ETF, index, derivatives, futures, foreign currency, and even commodities products); particularly when many of these platforms enjoy substantially smaller strike price differentiations (*e.g.,* as low as $.05).[19]

Weekly options have characteristics that are attractive for certain trading and hedging strategies. Thus, weeklies may be attractive for retail trading strategies that could benefit from the inherent accelerated time decay of weekly options, such as selling (buying) vertical or calendar spreads. And weeklies may be particularly attractive instruments for short-term institutional hedging needs (*e.g.,* sudden price movements against large option positions during expiration week; maintenance or adjustment of complex option positions) as well as for retail hedging needs (*e.g.,* preceding large earnings plays). In every case, trading and hedging is more effective when it can be closely tailored. The current wider STOS price intervals have negatively impacted investors and traders, particularly retail public customers, who have on several occasions requested the Exchange for finer, narrower STOS intervals. The proposal would fix this.

The following is an example of how inadequately narrow STOS intervals negatively impact trading and hedging opportunities. If an investor needs to purchase an STOS call option in CSCO (03/26/12 closing price $20.84), the current $1 strike interval would offer less opportunity and choice for an investor seeking to keep cash expenditures low. For example, an investor wishing to buy an in-the-money call option for less than a $2.50 investment per call purchase has only two strike prices that meet his criteria from which to choose: the 19 strike and the 20 strike. Such call options with five days until expiration might offer ''ask prices'' (option premiums) of $1.75 and $.75. However, if CSCO had $0.50 strike prices as proposed, the same investor would have a selection of March 18.50, 19.00, 19.50, 20.00, and the 20.50 strike call options that may have options premiums from approximately $2.25 down to approximately $.25. This expanded range of strikes, and commensurate option premiums, offers far more choice and a considerably lower cost of entry to the investor, thereby garnering the investor more than a 66% options premium savings. Lower intervals increase effective liquidity by offering investors and traders more price points at which they may execute trading and hedging strategies.[20] This allows investors and traders the ability to more effectively execute their strategies at lower cost. Clearly, more efficient pricing is advantageous to all market participants, from retail to institutional investors. The changes proposed by the Exchange should allow execution of more trading and hedging strategies on the Exchange. The Exchange notes that in conformance with Exchange Rules, the Exchange shall not list $0.50 or $1 strike price intervals on Related non-STOS options within five (5) days of expiration. For example, if a Related non-STOS in an options class is set to expire on Friday, September 21, the Exchange could begin to trade $0.50 strike price intervals surrounding that Related non-STOS on Thursday, September 13, but no later than Friday September 14.

The Exchange proposes to list the expiring Related non-STOS on the Thursday or Friday prior to expiration week, so that investors can close a position in an expiring STOS and open a position at the same strike price in a Related non-STOS. The listing of the $0.50 or $1 strike price intervals for expiring Related non-STOS on the Thursday or Friday prior to expiration week is intended to be consistent with the ''overlap'' of STOS today, which facilitates investors' desire to ''roll'' a position from one STOS expiration to another. If the $0.50 or $1 interval strikes are not available until the opening on Monday of expiration week, an investor who had a position in the prior week's $0.50 or $1 interval STOS could not close a position in the expiring STOS and open a position at the same strike in the Related non-STOS.

Furthermore, the inadequate price intervals for STOS, particularly at the lower price levels proposed by the Exchange, may discourage retail and other customers from executing STOS orders when they could be the most advantageous for effective execution of trading and hedging strategies on regulated and transparent exchanges. The Exchange feels that it is essential that such negative, potentially costly and time-consuming impacts on retail investors are eliminated by offering tighter intervals within the STOS Program. The changes proposed by the Exchange should allow execution of more trading and hedging strategies on the Exchange.[21]

With regard to the impact of this proposal on system capacity, the Exchange has analyzed its capacity and represents that it and the Options Price Reporting Authority (''OPRA'') have the necessary systems capacity to handle the potential additional traffic associated with trading in the Program at $.50 or $1 intervals, as applicable under the proposal. The Exchange notes that this proposal would not increase the number of listed STOS, but only the interval between them. The Exchange believes that its OTP Holders and OTP Firms will not have a capacity issue as a result of this proposal.

[18] *See* Securities Exchange Act Release No. 64189 (April 5, 2011), 76 FR 20066 (April 11, 2011) (SR–CBOE–2011–008) (order granting approval of $0.50 and $1 strike price intervals for certain volatility options where the strike prices are less than $75 and between $75 and $150, respectively). In approving the CBOE proposal, the Commission stated that the proposal appears to strike a reasonable balance between the Exchange's desire to offer a wider array of investment opportunities and the need to avoid unnecessary proliferation of options series and the corresponding increase in quotes and market fragmentation. The Exchange notes that other options exchanges including NYSE Arca, ISE, NOM, and Phlx, have made similar rule changes.

[19] As an example, per the CME Web site, strike prices for options on futures may be at an interval of $.05, $.10, and $.25 per specified parameters. *See http://www.cmegroup.com/trading/equityindex/files/EQUITY_FLEX_Options.pdf* (options on S&P 500 and NASDAQ–100 contracts) and *http://www.cmegroup.com/rulebook/files/S_5734_x11-0518x_Change_in_Listing_Rules_for_Goldx_Silverx_Copper_Options.pdf* (options on metals contracts).

[20] Moreover, lower strike intervals provide additional price points for liquidity providers. This allows the liquidity providers to improve theoretical pricing as well as hedging capabilities, thereby enabling them to increase the size and quality of their markets.

[21] In addition, there is a competitive impact. First, the proposal would enable the Exchange to provide market participants with an opportunity to execute their strategies (*e.g.,* complex option spreads) wholly on their preferred market, namely the Exchange. Second, the proposal would diminish the potential for foregone market opportunities on the Exchange caused by the need to use a more advantageous (that is, interval-precise) platform than STOs currently allow.

The Exchange also proposes that Related non-STOS shall be opened on the Thursday or Friday prior to the expiration week that such Related non-STOS expire in the same manner as permitted in Rule 903(h) and in the same strike price intervals for the STOS permitted in this [sic] Rule 903, subsection (d) of Commentary .10. The Exchange proposes to make this change to ensure conformity between STOS options and Related non-STOS options that are in the same options class (*e.g.,* weekly and monthly SPY options). The Exchange believes that not having such a conforming change would be counter-productive and not beneficial for trading and hedging purposes.[22]

The Exchange believes that the STOS Program has provided investors with greater trading opportunities and flexibility and the ability to more closely tailor their investment and risk management strategies and decisions. Furthermore, the Exchange has had to reject trading requests because of the limitations imposed by the Program. For these reasons, the Exchange requests a modification of the strike price intervals in the Program and the opportunity to provide investors with better weekly option choices for investment, trading, and risk management purposes.

In addition, the Exchange proposes to delete Commentary .08 to Exchange Rule 903 because it is duplicative of subsection (d) to Commentary .10.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[23] in general, and furthers the objectives of Section 6(b)(5),[24] 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 Exchange believes that providing strike prices of $.50 and $1 intervals in STOS eligible classes will result in a continuing benefit to investors by giving them more flexibility to closely tailor their investment decisions and hedging decisions in a greater number of securities. The Exchange also believes that providing the same strike price intervals for options classes that are in the STOS Program and for the Related non-STOS options just prior to and during expiration week will provide the investing public and other market participants with additional opportunities to hedge their investment, thus allowing these investors to better manage their risk exposure. In addition, the Exchange believes that the proposal will ensure conformity between STOS options and Related non-STOS options that are in the same options class. The Exchange believes that allowing the listing of expiring Related non-STOS on the Thursday or Friday prior to expiration week will help facilitate the ability of investors and other market participants to close a position in an expiring STOS and open a position at the same strike price in a Related non-STOS is a manner that is designed to promote just and equitable principles of trade. While the expansion of the STOS Program will generate additional quote traffic, the Exchange does not believe that this increased traffic will become unmanageable since the proposal remains limited to a fixed number of classes.

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. In this regard and as indicated above, the Exchange notes that the rule change is being proposed as a competitive response to existing ISE and PHLX rules. The Exchange believes this proposed rule change is necessary to permit fair competition among the options exchanges with respect to their short term options programs.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule 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 if consistent with the protection of investors and the public interest, provided that the self-regulatory organization has given 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 proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[25] and Rule 19b–4(f)(6) thereunder.[26]

The Exchange asked the Commission to waive the 30-day operative delay period for non-controversial proposed rule changes to allow the proposed rule change to be operative upon filing.[27] The Commission believes it is consistent with the public interest to waive the 30-day operative delay. The proposed rule change is substantially similar in all material respects to existing ISE and PHLX rules, which permit the listing of Short Term Options Series at finer strike price intervals; the proposal presents no novel issues.[28] Waiver of the operative delay will allow the Exchange to expand its STOS Program to the current parameters of those SROs and compete without undue delay. Therefore, the Commission grants such waiver and designates the proposal operative upon filing.[29]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

[22] Moreover, the Exchange notes that STOS options are not listed and traded during the expiration week of the Related non-STOS options. During this week, the non-STOS options are materially and financially equivalent to the STOS options. The proposed change would allow traders and hedgers to have the noted benefits of the STOS Program during each week in a month.

[23] 15 U.S.C. 78f(b).

[24] 15 U.S.C. 78f(b)(5).

[25] 15 U.S.C. 78s(b)(3)(A).

[26] 17 CFR 240.19b–4(f)(6).

[27] As required under Rule 19b–4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change along with a brief description and the 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.

[28] *See* ISE Filing and Phlx Filing, *supra* note 6.

[29] 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).

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEMKT–2012–53 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEMKT–2012–53. 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 Section, 100 F Street NE., Washington, DC 20549, on official business days between 10:00 a.m. and 3:00 p.m. Copies of the filing will also be available for inspection and copying at the NYSE's principal office and on its Internet Web site at *www.nyse.com.* All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEMKT–2012–53 and should be submitted on or before December 6, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[30]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27775 Filed 11–14–12; 8:45 am]

BILLING CODE 8011–01–P

[30] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68192; File No. SR–FINRA–2012–048]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Repeal the Changes Described in SR–FINRA–2011–019

November 8, 2012.

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 2, 2012, Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''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 receipt of this filing by 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 repeal the changes described in SR–FINRA–2011–019, which proposed to rename FINRA's inter-dealer quotation system.

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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6).

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On April 25, 2011, FINRA filed a proposed rule change to replace references to ''OTC Bulletin Board'' and ''OTCBB'' with ''Non-NMS Quotation Service'' and ''NNQS,'' respectively, in the FINRA Rulebook.[4] As described in the Original Filing, the purpose of renaming FINRA's inter-dealer quotation system was to remove certain impediments to the completion of a transaction whereby FINRA would divest itself of the OTCBB trademark, related domain name, and all informational content from the *www.OTCBB.com* Web site that was not otherwise required to be retained by FINRA for regulatory purposes (''OTCBB assets''). FINRA no longer is proceeding with the sale of the OTCBB assets as described in SR–FINRA–2011–019, making the renaming changes unnecessary. Therefore, FINRA is filing this proposed rule change to delete the pending references to ''Non-NMS Quotation Service'' and ''NNQS'' and retain ''OTC Bulletin Board'' and ''OTCBB.'' [5] The FINRA Rule 6500 Series will continue to govern the operation of the OTCBB and the functionality of the OTCBB is not proposed to be changed in this filing.

FINRA has filed the proposed rule change for immediate effectiveness. FINRA is proposing that the implementation date of the proposed rule change will be December 3, 2012.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[6] 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

[4] *See* Securities Exchange Act Release No. 64397 (May 4, 2011); 76 FR 27123 (May 10, 2011) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2011–019) (''SR–FINRA–2011–019'' or ''Original Filing'').

[5] In the Original Filing, FINRA stated that the implementation date of the proposed rule change would be no later than 270 days following the date of filing, but in no event would be sooner than 120 days following the date of filing of the proposed rule change. On January 20, 2012, FINRA extended the implementation date to no sooner than 120 days following the date of filing, but no later than December 31, 2012. *See* Securities Exchange Act Release No. 66244 (January 26, 2012); 77 FR 5069 (February 1, 2012) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2012–003) (Proposed Rule Change to Delay the Implementation Date of SR–FINRA–2011–019).

[6] 15 U.S.C. 78*o*–3(b)(6).

general, to protect investors and the public interest. Section 15A(b)(11) of the Act[7] requires that FINRA rules include provisions governing the form and content of quotations relating to securities sold otherwise than on a national securities exchange which may be distributed or published by any member or person associated with a member, and the persons to whom such quotations may be supplied. In addition, Section 15A(b)(11) of the Act[8] requires that such rules be designed to produce fair and informative quotations, to prevent fictitious or misleading quotations, and to promote orderly procedures for collecting, distributing, and publishing quotations.

FINRA believes the proposed rule change is consistent with Section 15A(b)(6) and (11) of the Exchange Act in that it maintains FINRA's continued ability to operate an interdealer quotation system for use by market makers in OTC equity securities under its historical name.

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.

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[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]

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–2012–048 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–FINRA–2012–048. 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 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of 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–2012–048 and should be submitted on or before December 6, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27765 Filed 11–14–12; 8:45 am]

BILLING CODE 8011–01–P

[7] 15 U.S.C. 78*o*–3(b)(11).

[8] 15 U.S.C. 78*o*–3(b)(11).

[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 self-regulatory organization to give the Commission written notice of the self-regulatory organization'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.

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68189; File No. SR–EDGX–2012–33]

Self-Regulatory Organizations; EDGX Exchange, Inc.; Notice of Withdrawal of Proposed Rule Change To Amend EDGX Rule 11.5(c) To Add the Edge Market Close[SM] Order

November 8, 2012.

I. Introduction

On July 27, 2012, the EDGX Exchange, Inc. (''Exchange'' or ''EDGX'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change that would have introduced the Edge Market Close[SM] (''EMC'') Order as a new order type. The proposed rule change was published for comment in the **Federal Register** on August 10, 2012.[3] The Commission received two comments on the proposed rule change.[4] On September 19, 2012, the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 67598 (August 6, 2012), 77 FR 47899 (''Notice'').

[4] *See* letters to Elizabeth M. Murphy, Secretary, Commission, from: Alex Kogan, Vice President and Deputy General Counsel, The NASDAQ OMX Group, Inc., dated September 5, 2012 (''NASDAQ Letter''); and Janet McGinness, Executive Vice President and Corporate Secretary, General Counsel, NYSE Euronext, dated September 11, 2012 (''NYSE Letter''). The Exchange submitted a letter responding to these comments. *See* letter to Elizabeth M. Murphy, Secretary, Commission, from William O'Brien, Chief Executive Officer, DirectEdge, dated November 8, 2012.

Exchange extended the time period for the Commission to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be approved or disapproved, to November 8, 2012.

On November 6, 2012, the Exchange withdrew the proposed rule change (SR–EDGX–2012–33).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[5]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27763 Filed 11–14–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68180; File No. SR–CHX–2012–18]

Self-Regulatory Organizations; Chicago Stock Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Alter Its Fee Schedule To Amend Its Institutional Broker Credits

November 8, 2012.

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 October 31, 2012, the Chicago Stock Exchange, Inc. (''CHX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. CHX has filed the proposal pursuant to Section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] 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 the Substance of the Proposed Rule Change

The CHX proposes to amend its Schedule of Participant Fees and Assessments (the ''Fee Schedule''), effective November 1, 2012, to alter its schedule of fees for Participants relating to credits to Institutional Brokers. The text of this proposed rule change is available on the Exchange's Web site at *http://www.chx.com/rules/proposed_rules.htm* and in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549.

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 Statutory Basis for, the Proposed Rule Change

1. Purpose

Through this filing, the Exchange proposes to amend its Schedule of Participant Fees and Assessments (the ''Fee Schedule''), effective November 1, 2012, to amend its existing credits related to Institutional Brokers. Currently, Institutional Brokers are charged monthly fees for their transactions.[5] To reduce the burden of such fees on certain Institutional Brokers, the Exchange historically developed a credit system whereby certain Institutional Brokers receive credits on a percentage basis of their transaction and clearing submission fees. This credit system applies to only certain Institutional Brokers as, for example, the Exchange distributes a credit to an Institutional Broker's Clearing Broker to defray the Institutional Broker's transaction fee costs. Also, related to clearing submissions, only FINRA-registered Institutional Brokers may take advantage of the fee credit. This fee change is being proposed to remove credits for transactions types that are rarely used, to reduce current Institutional Broker Credits, to remove inapplicable definitions, and to make the fee credits for transaction fees and clearing submission fees consistent.

The Exchange proposes to amend its current credits to Institutional Brokers related to transaction fees. Currently, the Exchange credits Institutional Brokers at a rate of 12% of their transaction fees per month. Such fees relate to agency trades executed by the Institutional Broker. The credit is paid to the Clearing Broker for its handling of the transactions. To increase revenue to the Exchange as well as to defray the technical and regulatory costs associated with supporting the Institutional Broker program, the Exchange proposes to reduce its credit for transaction fees to Institutional Brokers to a rate of 10% per month. Because the volume of transaction fees is significant, the Exchange will gain notable revenue by lowering its transaction fee credits. The Exchange is proposing to reduce these credits specifically from its Institutional Brokers because of the increased regulatory costs related to Institutional Brokers. The Exchange also proposes to remove references related to the rarely used transaction fees by removing the 4% credit for payment to Originating Brokers. The Exchange has found that this type of transaction is rarely utilized and, therefore, such credits are not necessary. Therefore, the Exchange proposes to use one 10% credit in relation to transaction fees. The Exchange further proposes to remove the definition of ''Originating Broker'' from the rule. The Exchange believes the removal of the term is warranted in that the term Originating Broker is used only once in the rule and, through this proposed rule change, the Exchange is deleting that one use. Therefore, to avoid retaining inapplicable definitions in its rules, the Exchange proposes to delete the definition of Originating Broker.

The Exchange also proposes to amend its current credits related to clearing submissions. Currently, Institutional Brokers receive a credit on fees for their clearing submissions. That credit is at a rate of 8% per side and is paid to the Clearing Broker handling the transactions. Further, this credit is only available to those Institutional Brokers who are members of the Financial Industry Regulatory Authority (''FINRA''). The Exchange proposes to raise the credit related to clearing submissions to a rate of 10%. The Exchange believes that this amendment will bring result in an equitable allocation of reasonable fees to its Institutional Brokers in that both the Transaction Fee Credit and the Clearing Submission Fee Credit will be at a 10% rate. Notably, due to the volume of transactions on the Exchange, the Transaction Fee Credits have a higher impact on the Exchange's revenue while its Clearing Submission Fees do not. The Exchange, therefore, proposes to lower the percentage credits related to

[5] 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).

[4] 17 CFR 240.19b–4(f)(2).

[5] Fee Schedule Section A.

Transaction Fees to increase its revenue. Correspondingly, the Exchange proposes to raise credits related to clearing submissions as it experiences less volume related to clearing submissions. Such change will equitably allocate fee credits at a 10% rate while fairly allowing Institutional Brokers who send clearing submissions through the Exchange a moderate increase in credits.

2. Statutory Basis

The Exchange believes that the proposed rule changes are consistent with Section 6(b) of the Act [6] in general, and further the objectives of Section 6(b)(4) of the Act [7] in particular. The Exchange believes that the proposed amendments to the fee structure are necessary responses to the increasing regulatory costs. Section 6(b)(4) states that exchange rules must ''provide for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities.'' To increase revenue to the Exchange and thereby defray technical and regulatory costs associated with supporting its Institutional Broker program, the Exchange proposes to amend its fee schedule to allocate additional costs specifically to the Institutional Brokers as an equitable solution. The Exchange believes that such change will allow for fees and credits that are not designed to permit unfair discrimination between customers, issuers, brokers or dealers since the rules will apply only to certain groups of Institutional Brokers that incur additional costs to the Exchange. In reducing the credits related to transaction fees, the Exchange will gain revenue due to the significant amount of transactions that are charged fees on the Exchange. The Exchange is raising credits related to clearing submissions because it does not experience as many clearing submissions as it does transactions. To fairly compensate its Institutional Brokers for the reduction in transaction fee credits, it has proposed to minimally raise its clearing submission fee credits. The revenue the Exchange will gain from lowering its transaction fee credits will far outweigh the funds it will expend in raising the clearing submission fee credits. The Exchange believes that by lowering the transaction fee credits and raising the clearing submission fee credits is a reasonable solution to gain more revenue while still allocating enough credits to its Institutional Brokers. Finally, the Exchange believes that eliminating Section F(2) subsection (a), outlining credits for rarely used transactions, will benefit the Exchange to better reflect the business of its Institutional Brokers while bringing clarity to its rules. Because its Institutional Brokers only rarely utilize this type of transaction, the Exchange believes that it is not necessary to provide related credits.

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.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act [8] and subparagraph (f)(2) of Rule 19b–4 thereunder [9] because it establishes or changes a due, fee or other charge applicable to the Exchange's members and non-members, which renders the proposed rule change effective upon filing.

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–CHX–2012–18 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CHX–2012–18. This file number should be included on the subject line if email is used.

To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of CHX. 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–CHX–2012–18, and should be submitted on or before December 6, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27713 Filed 11–14–12; 8:45 am]

BILLING CODE 8011–01–P

[6] 15 U.S.C. 78f.

[7] 15 U.S.C. 78f(b)(4).

[8] 15 U.S.C. 78s(b)(3)(A)(ii).

[9] 17 CFR 240.19b–4(f)(2).

[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68181; File No. SR–CHX–2012–17]

Self-Regulatory Organizations; Chicago Stock Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Alter Its Fee Schedule To Increase Its DEA Fees

November 8, 2012.

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 1, 2012, the Chicago Stock Exchange, Inc. (''CHX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. CHX has filed the proposal pursuant to Section 19(b)(3)(A) of the Act [3] and Rule 19b–4(f)(2) thereunder,[4] 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 the Substance of the Proposed Rule Change

The CHX proposes to amend its Schedule of Participant Fees and Assessments (the ''Fee Schedule''), effective November 1, 2012, to alter its schedule of fees for Participants relating to its DEA fees and renumber items in the Fee Schedule. The text of this proposed rule change is available on the Exchange's Web site at *http://www.chx.com/rules/proposed_rules.htm* and in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549.

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 Statutory Basis for, the Proposed Rule Change

1. Purpose

Through this filing, the Exchange proposes to amend its Schedule of Participant Fees and Assessments (the ''Fee Schedule''), effective November 1, 2012, to amend its existing DEA fees and renumber items in the Fee Schedule. This fee change is being proposed in response to the increased importance and expense of the Exchange's regulatory efforts and competitive pricing pressures and to ensure that the Fee Schedule's numbering system is consistent.

The Exchange proposes to increase its DEA fees to reflect increased current and planned expenses related to the Exchange's regulatory responsibilities. Currently, the Exchange's DEA fee is $1,000 per month for each firm for which the Exchange is its DEA. Through this filing, the Exchange proposes increasing the DEA fee to $1,200 per month. As the Exchange participates in a highly competitive market in which regulatory costs are continually increasing, the Exchange believes that increasing its DEA fees will help enable the Exchange to continue to fulfill its regulatory responsibilities.

The Exchange also proposes to renumber certain items in its Fee Schedule to correct the inadvertent absence of ''K'' in its numbering system. Specifically, the Fee Schedule skipped letter ''K'' and numbered ''J.'' to ''L.'' directly. Consequently, the Exchange proposes to renumber items ''L.'' through ''P.'' to incorporate ''K.'' into its numbering scheme. No other changes to these rules are being proposed at this time.

2. Statutory Basis

The Exchange believes that the proposed rule changes are consistent with Section 6(b) of the Act [5] in general, and further the objectives of Section 6(b)(4) of the Act [6] in particular, in that an increase in, but still reasonable fees will be equitably allocated to Participants for which the Exchange is the DEA. Further, the Exchange believes the proposed changes are also consistent with Section 6(b)(1) of the Act [7] as the increased DEA fee will help ensure CHX has the adequate resources to regulate its Participants and ensure their accordance with provisions of the Exchange Act, rules thereunder, and CHX's rules. Also, the Exchange believes that the proposed change is reasonable because the increased fees reflect the higher regulatory costs in the industry. Finally, the Exchange believes the change to the Fee Schedule's numbering systems is reasonable in that it will further clarity in the Exchange's rules and foster ease of use.

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.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act [8] and subparagraph (f)(2) of Rule 19b–4 thereunder [9] because it establishes or changes a due, fee or other charge applicable to the Exchange's members and non-members, which renders the proposed rule change effective upon filing.

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–CHX–2012–17 on the subject line.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(2).

[5] 15 U.S.C. 78f.

[6] 15 U.S.C. 78f(b)(4).

[7] 15 U.S.C. 78f(b)(1).

[8] 15 U.S.C. 78s(b)(3)(A)(ii).

[9] 17 CFR 240.19b–4(f)(2).

Paper Comments

• Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CHX–2012–17. 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 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of CHX. 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–CHX–2012–17, and should be submitted on or before December 6, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27714 Filed 11–14–12; 8:45 am]

BILLING CODE 8011–01–P

[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68183; File No. SR–NYSEMKT–2012–54]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Increase the Options Regulatory Fee and To Revise the Circumstances Under Which NYSE Amex Options LLC Will Collect the Options Regulatory Fee

November 8, 2012.

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 7, 2012, NYSE MKT LLC (the ''Exchange'' or ''NYSE MKT'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, 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 the Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE Amex Options Fee Schedule to increase its Options Regulatory Fee (''ORF'') and to revise the circumstances under which the Exchange will collect the ORF. The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to increase its ORF and to revise the circumstances under which the Exchange will collect the ORF.

Background

The ORF, which is currently $0.004 per contract, is assessed by the Exchange on each ATP Holder for all options transactions executed or cleared by the ATP Holder that are cleared by The Options Clearing Corporation (''OCC'') in the customer range, i.e., transactions that clear in the customer account of the ATP Holder's clearing firm at OCC, regardless of the marketplace of execution.[4] In other words, the Exchange imposes the ORF on all customer-range transactions executed by an ATP Holder even if the transactions do not take place on the Exchange. In the case where an ATP Holder executes a transaction and a different ATP Holder clears the transaction, the ORF is assessed to the ATP Holder who executes the transaction. In the case where a non-ATP Holder executes a transaction and an ATP Holder clears the transaction, the ORF is assessed to the ATP Holder who clears the transaction.

The dues and fees paid by ATP Holders go into the general funds of the Exchange, a portion of which is used to help pay the costs of regulation. In particular, the ORF is designed to recover a material portion of the costs to the Exchange of the supervision and regulation of ATP Holders, including performing routine surveillance and investigations, as well as policy, rulemaking, interpretive and enforcement activities. The Exchange monitors the amount of revenue collected from the ORF so that, in combination with other regulatory fees and fines, it does not exceed regulatory costs. The ORF is collected indirectly from ATP Holders through their clearing firms by OCC on behalf of the Exchange.

Proposed Change

The Exchange proposes to (1) increase the ORF from $0.004 per contract to $0.005 per contract in order to recoup increased regulatory expenses while also monitoring the revenue collected so that the ORF will not exceed such expenses, and (2) revise the

[4] *See* Securities Exchange Act Release No. 64400 (May 4, 2011), 76 FR 27118 (May 10, 2011) (SR–NYSEAmex–2011–27).

circumstances in which the Exchange will collect the ORF from ATP Holders. Transaction volumes across the industry have declined, thereby reducing ORF revenue, but the Exchange's regulatory expenses have not declined. The Exchange believes that revenue generated from the proposed ORF, when combined with all of the Exchange's other regulatory fees, will cover a material portion, but not all, of the Exchange's regulatory costs. The Exchange will continue to monitor the amount of revenue collected from the ORF so that, in combination with the Exchange's other regulatory fees and fines, it does not exceed regulatory costs. If the Exchange determines that regulatory revenues exceed regulatory costs, the Exchange will adjust the ORF by submitting a proposed rule change to the Commission.[5]

Additionally, the Exchange proposes to revise the manner in which it assesses the ORF. Currently, upon becoming an ATP Holder, a participant immediately becomes liable for the ORF. In certain instances, particularly at the outset of becoming an ATP Holder, a participant may be registered with the Exchange prior to obtaining the requisite technological certification needed to act as a Floor Broker, Market Maker, Clearing Member or Order Flow Provider. The Exchange believes that it is not equitable to assess the ORF on an ATP Holder that, prior to initially satisfying certain technology requirements, is not capable of availing itself of the benefits of its status as an ATP Holder.[6] The Exchange does not desire to assess the ORF on such ATP Holders until they have satisfied applicable technological requirements necessary to commence operations on the Exchange. The proposed change will have no effect on the assessment of fees for current ATP Holders that are fully certified to transact business on the Exchange, as described above. The Exchange notes that at least one other exchange has such a provision for assessing the options regulatory fee after satisfaction of applicable technology requirements.[7]

The Exchange notes that the proposed change is not otherwise intended to address any other issues surrounding the ORF and that the Exchange is not aware of any problems that ATP Holders would have in complying with the proposed change. The Exchange proposes to implement these changes on December 1, 2012.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[8] in general, and furthers the objectives of Section 6(b)(4) of the Act,[9] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities.

The Exchange believes that the proposal is reasonable because the Exchange's revenue from the collection of the ORF has declined due to a decrease in industry volume, but the Exchange's regulatory expenses have not declined. As described above, through the ORF the Exchange seeks to recover the costs of supervising and regulating ATP Holders, including performing routine surveillance and investigations, as well as policy, rulemaking, interpretive and enforcement activities. The proposed ORF increase will help to maintain the total revenue collected to offset these regulatory expenses, but would not exceed those regulatory costs. The Exchange further notes that another options exchange has raised its options regulatory fee to $0.0065 per contract, so the Exchange's proposed ORF of $0.005 per contract will still be below that level.[10]

The Exchange believes that the proposed ORF increase is equitable and not unfairly discriminatory because it is objectively allocated to all ATP Holders on all of their transactions that clear in the customer range at OCC. Moreover, the Exchange believes that the ORF is equitable and not unfairly discriminatory because it results in fees being charged to those ATP Holders that require more Exchange regulatory services based on the amount of customer options business they conduct. In this regard, regulating customer trading activity is more labor intensive and requires greater expenditure of human and technical resources than regulating non-customer trading activity. Surveillance and regulation of non-customer trading activity generally tends to be more automated and less labor intensive. As a result, the costs associated with administering the customer component of the Exchange's overall regulatory program are anticipated to be higher than the costs associated with administering the non-customer component of its regulatory program. As such, the Exchange proposes to continue to assess the ORF to those ATP Holders that will require more Exchange regulatory services based on the amount of customer options business they conduct.[11]

The Exchange believes that the ORF will continue to be equitable and not unfairly discriminatory because the fee increase is objectively allocated to all ATP Holders. The only ATP Holders that would not pay the fee will be those that have not yet achieved the technical certifications that are needed to actually begin acting as a Floor Broker, Market Maker, Clearing Member or Order Flow Provider on the Exchange. The Exchange believes that this exception is reasonable, equitable and not unfairly discriminatory. Not assessing the ORF on an ATP Holder that is not yet able to act in the capacity for which it is attempting to obtain certification is reasonable because the ATP Holder is not yet able to generate the revenue associated with serving in that capacity. In this respect, it is equitable and not unfairly discriminatory to not begin charging the ORF until the ATP Holder can generate the revenue to pay the fee. It is also equitable and not unfairly discriminatory because it will apply in an objective manner to all similarly situated ATP Holders.

As noted above, the Exchange will continue to monitor the amount of revenue collected from the ORF so that, in combination with its other regulatory fees and fines, it does not exceed regulatory costs. If the Exchange determines that regulatory revenues exceed regulatory costs, the Exchange will adjust the ORF by submitting a proposed rule change to the Commission.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose

[5] The Exchange notes that its regulatory responsibilities with respect to member compliance with options sales practice rules have been allocated to the Financial Industry Regulatory Authority, Inc. (''FINRA'') under an SEC Rule 17d–2 agreement. The ORF is not designed to cover the cost of options sales practice regulation. *See supra* note 4.

[6] The Exchange anticipates that any delay in satisfying applicable technological requirements necessary to commence operations on the Exchange would be brief.

[7] *See* Securities Exchange Act Release No. 62804 (August 31, 2010), 75 FR 54688 (September 8, 2010) (SR–BX–2010–060).

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(4).

[10] *See* Securities Exchange Act Release No. 67597 (August 6, 2012), 77 FR 47887 (August 10, 2012) (SR–CBOE–2012–065).

[11] The ORF is not charged for orders that clear in categories other than the customer range (e.g., market maker orders) because ATP Holders incur the costs of acquiring trading permits and through these permits are charged transaction fees, dues and other fees that go into the general funds of the Exchange, a portion of which is used to help pay the costs of regulation.

any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [12] of the Act and subparagraph (f)(2) of Rule 19b–4 [13] thereunder, because it establishes a due, fee, or other charge imposed by the NYSE MKT.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEMKT–2012–54 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEMKT–2012–54. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEMKT–2012–54, and should be submitted on or before December 6, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27716 Filed 11–14–12; 8:45 am]

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[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(2).

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68185; File No. SR–NYSE–2012–57]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing of Proposed Rule Change Deleting NYSE Rules 95(c) and (d) and Related Supplementary Material

November 8, 2012.

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 October 26, 2012, New York Stock Exchange LLC (the ''Exchange'' or ''NYSE'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to delete NYSE Rules 95(c) and (d) and related Supplementary Material. The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to delete NYSE Rules 95(c) and (d) and related Supplementary Material concerning restrictions on the ability of a Floor broker to engage in intra-day trading.[4]

Background

Rule 95(c) provides that:

If a Floor broker acquires a position for an account during a particular trading session while representing at the same time, on behalf of that account, market or limit orders at the minimum variation on both sides of the market, the broker may liquidate or cover the position established during that trading session only pursuant to a new order (a liquidating order) which must be time-recorded upstairs and upon receipt on the trading Floor.

As a related matter, Rule 95(d) requires that a Floor broker must execute the liquidating order entered pursuant to Rule 95(c) before the Floor broker can execute any other order for the same account on the same side of the market as that liquidating order. The Supplementary Material sets forth

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Exchange notes that parallel changes are proposed to be made to the rules of NYSE MKT LLC. *See* SR–NYSEMKT–2012–58.

examples illustrating the operation of Rules 95(c) and (d) along with examples indicating the type of buy and sell orders that a member may and may not represent for the same customer at the same time pursuant to Rule 95.

The Exchange adopted Rules 95(c) and (d) and related Supplementary Material .20 and .30 in 1994.[5] As noted in that filing, the Exchange adopted the rule to address ''intra-day trading'' by Floor brokers, the practice whereby a market participant places orders on both sides of the market and attempts to garner the spread by buying at the bid and selling at the offer. In particular, Rule 95(c) was meant to address situations where a Floor broker may have been perceived as having an advantage over other market participants, such as individual investors, because the Floor broker could trade on both sides of the market without leaving the Crowd.[6] Requiring the Floor broker to obtain a new liquidating order was designed, therefore, to reduce the immediacy with which a Floor broker could react to changing market conditions on behalf of an intra-day trading account by requiring him or her to leave the Crowd in order to receive a new liquidating order. The restriction was meant to ''enhance investors' confidence in the fairness and orderliness of the Exchange market.'' [7] The Commission specifically noted that the intra-day trading strategy employed by professionals ''provide[d] the perception that public customer orders [were] being disadvantaged by the time and place advantage of intra-day traders.'' [8] Notably, some public customers who used Floor brokers strongly criticized the restrictions of Rule 95(c) and (d) as favoring specialists because specialists were not subject to the restrictions.[9] As discussed below, the Exchange believes that the current prevalence of virtually instantaneous and fully automated executions both on and off the floor have diminished substantially any such advantage and rendered the new liquidating order requirements obsolete.

Proposed Rule Change

The Exchange proposes to delete NYSE Rules 95(c) and (d) and related Supplementary Material as outdated in today's market structure and an unnecessary restriction on the ability of Floor brokers to represent orders on behalf of their customers.

The Exchange believes that the rationale and approach underlying current Rules 95(c) and (d) no longer exists in today's trading environment. At the time Rules 95(c) and (d) were adopted, orders entered in the specialist's book experienced greater latency than did orders handled by Floor brokers. In particular, neither immediate limit order display nor auto execution existed at that time and, as a result, ''book'' orders could not be executed until the specialist manually executed them. Floor brokers in 1994, in other words, could stand at the point of sale and trade more quickly because of that position. Currently, incoming electronic orders are executed automatically in microseconds, and ''book'' orders receive immediate limit order display. Moreover, the passage of Floor broker orders through Floor systems today adds an additional layer of latency relative to the prior context. While the rationale for Rules 95(c) and (d) was that Floor broker customers could ''crowd-out small customer limit orders and delay or prevent their execution,'' [10] in the current market structure, it is more likely that electronic order flow would ''crowd-out'' Floor broker customer orders.

Additionally, since adopting the rule, the equities markets in general, and the Exchange in particular, have undergone market structure changes that obviate the need for this rule-based restriction on how a Floor broker represents orders on behalf of customers. For example, the Commission adopted Regulation NMS in 2005 [11] and in 2006, the Exchange adopted its ''Hybrid Market'' structure in part to meet the requirements of Regulation NMS that were implemented in July 2007.[12] Since that time, the Exchange has undergone a dramatic shift ''from a floor-based auction market with limited automated order interaction to a more automated market with limited floor-based auction market availability.'' [13]

Specifically, the changing role of the Floor broker can be seen in both the overall reduction in the Exchange's market share in its listed securities, as well as the decline in the Floor broker's share of Exchange volume and increased reliance on automatic execution. Prior to the adoption of the Hybrid Market, the Exchange had about an 80% market share in its listed securities and approximately 25% of that volume was from Floor broker transactions. Within a year of the approval of the Hybrid Market, automatic execution accounted for 82% of NYSE volume and Floor broker executions declined to 11% of overall Exchange volume.[14] Currently, the Exchange has approximately a 21% market share in its listed securities, and of that volume, Floor broker transactions represent approximately 9.8% of Exchange total volume. Less than 1% of those Floor broker transactions are represented in a manual, auction format. Furthermore, the average speed of execution has increased substantially to micro-second timing, which has significantly reduced the opportunities for Floor brokers to engage in manual transactions.

In addition, trading strategies have evolved since the enactment of Rule 95(c). Today one third of all equity trading takes place off-exchange and over 1,200 securities have more than 50% of their volume traded off-exchange, an increase of 143% in less than two years. Among other changes, off-Floor participants regularly engage in buy and sell side trading strategies, i.e., ''intra-day trading.'' In today's micro-second market, there is no longer a competitive advantage to being on the trading Floor when engaging in the type of intra-day trading addressed by Rules 95(c) and (d). Rather, due to the increase in the speed of trading, the increased fragmentation of the equity markets, and the dissemination of market information available to off-Floor participants, many off-Floor participants are able to synthesize market information across multiple markets faster than a Floor broker can do so from their physical presence on the Exchange trading Floor. Accordingly, to the extent there may still be a time and place advantage for Floor brokers by virtue of their presence on the Trading Floor, the Exchange believes that the type of information available to Floor brokers is no longer

[5] Securities Exchange Act Release No. 34363 (July 13, 1994), 59 FR 36808 (July 19, 1994) (''Rule 95(c) Adopting Release'').

[6] Rule 95(c)'s requirement that a liquidating order be ''new'' effectively required that a Floor broker leave the Crowd before entering a liquidating order (selling what had been bought, for example) because there was no way for the Floor broker to receive the new order (or otherwise communicate with a customer) from the Crowd.

[7] Rule 95(c) Adopting Release at 36809.

[8] *Id.* at 36810.

[9] *See, e.g.,* Letter from Daniel P. Barry, to Ms. Luka-Hopson, Branch Chief, Division of Market Regulation, Securities and Exchange Commission, dated November 11, 1993 (arguing that the proposed amendment to Rule 95 unfairly singled out ''the small public investor'' in its application of intra-day trading restrictions to Floor brokers alone).

[10] Rule 95(c) Adopting Release at 38611.

[11] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 Fed. Reg. 37496 (June 29, 2005) (''NMS Adopting Release'').

[12] *See* Securities Exchange Act Release No. 53539 (March 22, 2006), 71 Fed. Reg. 16353 (March 31, 2006).

[13] *Id.*

[14] *See Technology squeezes out real, live traders,* USA Today (July 12, 2007), *available at http://www.usatoday.com/money/markets/2007-07-11-nyse-traders_N.htm.*

the type of information that would provide Floor brokers with an advantage in connection with intra-day trading.

As a result of the above-discussed changes, Rules 95(c) and (d) are no longer operating to place Floor brokers on equal footing as other market participants, but instead are placing them at a disadvantage to other participants in the largely automatic market that has developed in the almost twenty years since the restrictions were put in place. Therefore, the Exchange believes it is appropriate to delete Rules 95(c) and (d) and related Supplementary Material. By deleting a trading restriction that was adopted in response to a specific market structure that has fundamentally changed since 2005, the Exchange believes that the proposed rule changes will serve to place Floor brokers on a more equal footing with other market participants utilizing automatic executions.

Furthermore, the Exchange notes that the manner that the current rule requires a Floor broker to comply with the rule is based on an auction market model where a rule-based speed bump that required a Floor broker to obtain a new time-stamped order from a customer was feasible.[15] In today's market structure, where Floor brokers compete with off-Floor participants that are entering orders on a micro-second basis on both the buy and sell side of the market, such a speed bump is not only a disadvantage to Floor brokers, but also does not serve its original purpose. In particular, the 1994 approval order notes that part of the rationale of implementing the speed bump for Floor brokers was to protect the public. However, even though the trading restrictions enacted by the 1994 rule changes will no longer be in effect, the public will still be protected. Floor brokers, through their normal course of business, act as agents for customers and, pursuant to Exchange and Commission rules, are required to act in the best interests of their customers.

In additional to the above-referenced changes, the Exchange proposes to delete Supplementary Material .20 and .30 to Rule 95, which were added as part of the addition of paragraphs (c) and (d) to Rule 95 in 1994. The Exchange proposes to keep Supplementary Material .10 to Rule 95.

[15] The Exchange notes that Exchange systems are not currently configured to accept the ''BC'' and ''SLQ'' order markings specified in Rule 95(c), as these are markings that were required to be included on manual order tickets that were completed by hand by a Floor broker rather than instructions submitted with electronic orders that customers transmit electronically to Floor brokers.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of Section 6(b) of the Act,[16] in general, and Section 6(b)(5) of the Act,[17] in particular, in that it is designed to remove impediments to and perfect the mechanism for a free and open market and a national market system and, in general, to protect investors and the public interest. In particular, the proposed rule change would further the ability of Floor brokers to carry out their Trading Floor functions and, as a result, is designed to remove impediments to and perfect the mechanism of a free and open market through the efficient operation of the Exchange, specifically by placing Floor brokers on equal footing with other market participants utilizing automatic executions.

The fundamental changes that the Exchange has undergone in the roughly twenty years since the adoption of Rules 95(c) and (d) have left the underlying rationale behind their adoption obsolete. The significant increase in market speed and the reduced role of Floor brokers have largely eliminated the concerns that Rules 95(c) and (d) were intended to address. By deleting a trading restriction that was adopted in response to a specific market structure that has fundamentally changed since 2005, the Exchange believes that the proposed rule changes will serve to place Floor brokers on a more equal footing with other market participants utilizing automatic executions.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(5).

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–NYSE–2012–57 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 Number SR–NYSE–2012–57. 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, on business days between the hours of 10 a.m. and 3 p.m., located at 100 F Street NE., Washington, DC 20549–1090. Copies of the filing will also be available for inspection and copying at the NYSE's principal office and on its Internet Web site at *www.nyse.com.* All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only

information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2012–57 and should be submitted on or before December 6, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27717 Filed 11–14–12; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68186; File No. SR–NYSEMKT–2012–58]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing of Proposed Rule Change Deleting NYSE MKT Rules 95(c) and (d)—Equities and Related Supplementary Material

November 8, 2012.

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 October 26, 2012, NYSE MKT LLC (the ''Exchange'' or ''NYSE MKT'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, 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 delete NYSE MKT Rules 95(c) and (d)—Equities and related Supplementary Material. The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to delete NYSE MKT Rules 95(c)—Equities and (d)—Equities and related Supplementary Material concerning restrictions on the ability of a Floor broker to engage in intra-day trading.[4]

Background

NYSE MKT Rule 95(c)—Equities provides that:

If a Floor broker acquires a position for an account during a particular trading session while representing at the same time, on behalf of that account, market or limit orders at the minimum variation on both sides of the market, the broker may liquidate or cover the position established during that trading session only pursuant to a new order (a liquidating order) which must be time-recorded upstairs and upon receipt on the trading Floor.

As a related matter, NYSE MKT Rule 95(d)—Equities requires that a Floor broker must execute the liquidating order entered pursuant to NYSE MKT Rule 95(c)—Equities before the Floor broker can execute any other order for the same account on the same side of the market as that liquidating order. The Supplementary Material sets forth examples illustrating the operation of NYSE MKT Rules 95(c)—Equities and (d)—Equities along with examples indicating the type of buy and sell orders that a member may and may not represent for the same customer at the same time pursuant to NYSE MKT Rule 95—Equities.

The New York Stock Exchange LLC (''NYSE'') adopted NYSE Rules 95(c) and (d) and related Supplementary Material .20 and .30 in 1994.[5] NYSE MKT Rule 95—Equities, an almost identical version of NYSE Rule 95, was adopted at the time of acquisition of The Amex Membership Corporation by NYSE Euronext.[6] Implicit in its mirroring, the rationale for the adoption of NYSE MKT Rules 95(c)—Equities and (d)—Equities was the same as the rationale for the adoption of NYSE Rules 95(c) and (d) in 1994. As noted in the NYSE filing, the NYSE adopted the rule to address ''intra-day trading'' by Floor brokers, the practice whereby a market participant places orders on both sides of the market and attempts to garner the spread by buying at the bid and selling at the offer. In particular, NYSE Rule 95(c) was meant to address situations where a Floor broker may have been perceived as having an advantage over other market participants, such as individual investors, because the Floor broker could trade on both sides of the market without leaving the Crowd.[7] Requiring the Floor broker to obtain a new liquidating order was designed, therefore, to reduce the immediacy with which a Floor broker could react to changing market conditions on behalf of an intra-day trading account by requiring him or her to leave the Crowd in order to receive a new liquidating order. The restriction was meant to ''enhance investors' confidence in the fairness and orderliness of the Exchange market.'' [8] The Commission specifically noted that the intra-day trading strategy employed by professionals ''provide[d] the perception that public customer orders [were] being disadvantaged by the time and place advantage of intra-day traders.'' [9] Notably, some public customers who used Floor brokers strongly criticized the restrictions of NYSE Rules 95(c) and (d) as favoring specialists because specialists were not subject to the restrictions.[10] As discussed below, the Exchange believes that the current prevalence of virtually instantaneous and fully automated executions both on and off the floor have diminished substantially any such advantage and rendered the new liquidating order requirements obsolete.

[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 Exchange notes that parallel changes are proposed to be made to the rules of New York Stock Exchange LLC. *See* SR–NYSE–2012–57.

[5] Securities Exchange Act Release No. 34363 (July 13, 1994), 59 FR 36808 (July 19, 1994) (''NYSE Rule 95(c) Adopting Release'').

[6] *See* Securities Exchange Act Release No. 58705 (October 1, 2008), 73 FR 58995 (October 8, 2008); Securities Exchange Act Release No. 58265 (July 30, 2008), 73 FR 46075 (August 7, 2008) (SR–Amex–2008–63).

[7] NYSE Rule 95(c)'s requirement that a liquidating order be ''new'' effectively required that a Floor broker leave the Crowd before entering a liquidating order (selling what had been bought, for example) because there was no way for the Floor broker to receive the new order (or otherwise communicate with a customer) from the Crowd.

[8] NYSE Rule 95(c) Adopting Release at 36809.

[9] *Id.* at 36810.

[10] *See, e.g.,* Letter from Daniel P. Barry, to Ms. Luka-Hopson, Branch Chief, Division of Market Regulation, Securities and Exchange Commission, dated November 11, 1993 (arguing that the proposed amendment to Rule 95 unfairly singled out ''the small public investor'' in its application of intra-day trading restrictions to Floor brokers alone).

Proposed Rule Change

The Exchange proposes to delete NYSE MKT Rules 95(c)—Equities and (d)—Equities and related Supplementary Material as outdated in today's market structure and an unnecessary restriction on the ability of Floor brokers to represent orders on behalf of their customers.

The Exchange believes that the rationale and approach underlying current NYSE MKT Rules 95(c)—Equities and (d)—Equities no longer exists in today's trading environment. At the time NYSE Rules 95(c) and (d) were adopted, orders entered in the specialist's book experienced greater latency than did orders handled by Floor brokers. In particular, neither immediate limit order display nor auto execution existed at that time and, as a result, ''book'' orders could not be executed until the specialist manually executed them. Floor brokers in 1994, in other words, could stand at the point of sale and trade more quickly because of that position. Currently, incoming electronic orders are executed automatically in microseconds, and ''book'' orders receive immediate limit order display. Moreover, the passage of Floor broker orders through Floor systems today adds an additional layer of latency relative to the prior context. While the rationale for NYSE Rules 95(c) and (d), and therefore also NYSE MKT Rules 95(c)—Equities and (d)—Equities, was that Floor broker customers could ''crowd-out small customer limit orders and delay or prevent their execution,'' [11] in the current market structure, it is more likely that electronic order flow would ''crowd-out'' Floor broker customer orders.

Additionally, since the adoption of NYSE Rules 95(c) and (d), the equities markets in general, and the Exchange in particular, have undergone market structure changes that obviate the need for this rule-based restriction on how a Floor broker represents orders on behalf of customers. For example, the Commission adopted Regulation NMS in 2005 [12] and in 2006, the NYSE adopted its ''Hybrid Market'' structure in part to meet the requirements of Regulation NMS that were implemented in July 2007.[13] Since that time, the NYSE, and because NYSE MKT has the same trading platform, has undergone a dramatic shift ''from a floor-based auction market with limited automated order interaction to a more automated market with limited floor-based auction market availability.'' [14]

Specifically, the changing role of the Floor broker can be seen in both the overall reduction in the Exchange's market share in its listed securities, as well as the decline in the Floor broker's share of Exchange volume and increased reliance on automatic execution. Prior to the adoption of the Hybrid Market, the NYSE had about an 80% market share in its listed securities and approximately 25% of that volume was from Floor broker transactions. Within a year of the approval of the Hybrid Market, automatic execution accounted for 82% of NYSE volume and Floor broker executions declined to 11% of overall Exchange volume.[15] Currently, the NYSE MKT has approximately a 14% market share in its listed securities, and of that volume, Floor broker transactions represent approximately 5% of Exchange total volume. Less than 1% of those Floor broker transactions are represented in a manual, auction format. Furthermore, the average speed of execution has increased substantially to micro-second timing, which has significantly reduced the opportunities for Floor brokers to engage in manual transactions.

In addition, trading strategies have evolved since the enactment of NYSE Rule 95(c). Today one third of all equity trading takes place off-exchange and over 1,200 securities have more than 50% of their volume traded off-exchange, an increase of 143% in less than two years. Among other changes, off-Floor participants regularly engage in buy and sell side trading strategies, i.e., ''intra-day trading.'' In today's micro-second market, there is no longer a competitive advantage to being on the trading Floor when engaging in the type of intra-day trading addressed by NYSE MKT Rules 95(c)—Equities and (d)—Equities. Rather, due to the increase in the speed of trading, the increased fragmentation of the equity markets, and the dissemination of market information available to off-Floor participants, many off-Floor participants are able to synthesize market information across multiple markets faster than a Floor broker can do so from their physical presence on the Exchange trading Floor. Accordingly, to the extent there may still be a time and place advantage for Floor brokers by virtue of their presence on the Trading Floor, the Exchange believes that the type of information available to Floor brokers is no longer the type of information that would provide Floor brokers with an advantage in connection with intra-day trading.

As a result of the above-discussed changes, NYSE MKT Rules 95(c)—Equities and (d)—Equities are no longer operating to place Floor brokers on equal footing as other market participants, but instead are placing them at a disadvantage to other participants in the largely automatic market that has developed in the almost twenty years since the restrictions were put in place. Therefore, the Exchange believes it is appropriate to delete NYSE MKT Rules 95(c)—Equities and (d)—Equities and related Supplementary Material. By deleting a trading restriction that was adopted in response to a specific market structure that has fundamentally changed since 2005, the Exchange believes that the proposed rule changes will serve to place Floor brokers on a more equal footing with other market participants utilizing automatic executions.

Furthermore, the Exchange notes that the manner that the current rule requires a Floor broker to comply with the rule is based on an auction market model where a rule-based speed bump that required a Floor broker to obtain a new time-stamped order from a customer was feasible.[16] In today's market structure, where Floor brokers compete with off-Floor participants that are entering orders on a micro-second basis on both the buy and sell side of the market, such a speed bump is not only a disadvantage to Floor brokers, but also does not serve its original purpose. In particular, the 1994 approval order for NYSE Rules 95(c) and (d) notes that part of the rationale of implementing the speed bump for Floor brokers was to protect the public. However, even though the trading restrictions first enacted by the 1994 rule changes will no longer be in effect, the public will still be protected. Floor brokers, through their normal course of business, act as agents for customers and, pursuant to Exchange and Commission rules, are required to act in the best interests of their customers.

In additional to the above-referenced changes, the Exchange proposes to delete Supplementary Material .20 and

[11] Rule 95(c) Adopting Release at 38611.

[12] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496 (June 29, 2005) (''NMS Adopting Release'').

[13] *See* Securities Exchange Act Release No. 53539 (March 22, 2006), 71 FR 16353 (March 31, 2006).

[14] *Id.*

[15] *See Technology squeezes out real, live traders,* USA Today (July 12, 2007), *available at http://www.usatoday.com/money/markets/2007-07-11-nyse-traders_N.htm.*

[16] The Exchange notes that Exchange systems are not currently configured to accept the ''BC'' and ''SLQ'' order markings specified in Rule 95(c), as these are markings that were required to be included on manual order tickets that were completed by hand by a Floor broker rather than instructions submitted with electronic orders that customers transmit electronically to Floor brokers.

.30 to NYSE MKT Rule 95—Equities. The Exchange proposes to keep Supplementary Material .10 to NYSE MKT Rule 95—Equities.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of Section 6(b) of the Act,[17] in general, and Section 6(b)(5) of the Act,[18] in particular, in that it is designed to remove impediments to and perfect the mechanism for a free and open market and a national market system and, in general, to protect investors and the public interest. In particular, the proposed rule change would further the ability of Floor brokers to carry out their Trading Floor functions and, as a result, is designed to remove impediments to and perfect the mechanism of a free and open market through the efficient operation of the Exchange, specifically by placing Floor brokers on equal footing with other market participants utilizing automatic executions.

The fundamental changes that have occurred in the roughly twenty years since the adoption of NYSE Rules 95(c) and (d) have left the underlying rationale behind their adoption obsolete, and subsequently, the rationale behind NYSE MKT Rules 95(c)—Equities and (d)—Equities is also obsolete. The significant increase in market speed and the reduced role of Floor brokers have largely eliminated the concerns that NYSE MKT Rules 95(c)—Equities and (d)—Equities were intended to address. By deleting a trading restriction that was originally adopted in response to a specific market structure that has fundamentally changed since 2005, the Exchange believes that the proposed rule changes will serve to place Floor brokers on a more equal footing with other market participants utilizing automatic executions.

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.

[17] 15 U.S.C. 78f(b).

[18] 15 U.S.C. 78f(b)(5).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEMKT–2012–58 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEMKT–2012–58. 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, on business days between the hours of 10 a.m. and 3 p.m., located at 100 F Street NE., Washington, DC 20549–1090. Copies of the filing will also be available for inspection and copying at the Exchange's principal office and on its Internet Web site at *www.nyse.com.* All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEMKT–2012–58 and should be submitted on or before December 6, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27718 Filed 11–14–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68190; File No. SR–NYSEArca–2012–95]

Self-Regulatory Organizations; NYSE Arca, Inc.; Order Granting Approval of Proposed Rule Change, as Modified by Amendment No. 1, To Amend Commentary .07 to NYSE Arca Options Rule 6.4 To Expand the Number of Expirations Available Under the Short Term Option Series Program (''STOS Program''), To Allow for the Exchange To Delist Series in the STOS Program That Do Not Have Open Interest, and To Expand the Number of Series in the STOS Program Under Limited Circumstances

November 8, 2012.

I. Introduction

On September 6, 2012, NYSE Arca, Inc. (''NYSE Arca'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend Commentary .07 to NYSE Arca Options Rule 6.4 (''Commentary .07'') to make certain modifications to the Exchange's Short Term Option Series Program (''STOS Program''). The proposed rule change was published for comment in the **Federal Register** on September 26,

[19] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

2012.[3] The Commission received no comment letters on the proposal. This order approves the proposed rule change, as modified by Amendment No. 1.

II. Description of the Proposal

The Exchange proposes to amend Commentary .07 to (i) expand the number of expirations available under the STOS Program; (ii) allow the Exchange to delist, in certain circumstances, series in the STOS program that do not have open interest; and (iii) allow the Exchange to list, in certain circumstances, additional series in the STOS program.

The proposed rule change allows the Exchange to open a maximum of five consecutive expirations under the STOS Program for trading on the Exchange. The Exchange notes that it will not add expirations in a STOS series if such expirations would coincide with an existing expiration of a monthly or quarterly series of an option in the same class of the STOS series.

The proposed rule change also amends the circumstances in which the Exchange may delist or list series in the STOS Program. Specifically, the proposed rule change provides that the Exchange will delist series in the STOS Program with no open interest in both the call and the put series having a: (i) Strike price higher than the highest strike price with open interest in the put and/or call series for a given expiration month; and (ii) strike price lower than the lowest strike price with open interest in the put and/or call series for a given month, so as to list series that are at least 10% but not more than 30% above or below the current price of the underlying security. The Exchange would also be permitted, under the proposed rule change, to list additional series in excess of the 30 series otherwise allowed [4] under Commentary .07 that are between 10% and 30% above or below the price of the underlying security. The Exchange will only be allowed to delist or list series in accordance with the proposed rule change in the event that the underlying security has moved so that there are no series that are at least 10% above or below the current price of the underlying security.

The Exchange asserts that the ability to list five consecutive expirations under the STOS Program is designed to meet increased customer demand and provide market participants with the ability to hedge in a greater number of option classes and series.[5] The Exchange also claims that the proposed amendments regarding delisting or listing STOS series are designed to provide investors flexibility by ensuring that there are series within the band of at least 10% but not more than 30% above or below the current price of the underlying security.[6]

III. Discussion and Commission Findings

After careful review of the proposed rule change, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[7] Specifically, the Commission finds that the proposal is consistent with Section 6(b)(5) of the Act,[8] which requires, among other things, that the rules of a national securities exchange be designed to promote just and equitable principles of trade, to prevent fraudulent and manipulative acts, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Commission believes that the proposed change may provide the investing public and other market participants with greater flexibility to closely tailor their investment and hedging decisions in a greater number of series, thus allowing investors to better manage their risk exposure.

In approving this proposal, the Commission notes that the Exchange has represented that it and OPRA have the necessary systems capacity to handle the potential additional traffic associated with opening of up to five consecutive expirations under the STOS Program.[9] The Commission expects the Exchange to monitor the trading volume associated with the additional options series listed as a result of this proposal and the effect of these additional series on market fragmentation and on the capacity of the Exchange's, OPRA's, and vendors' automated systems.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[10] that the proposed rule change, as modified by Amendment No. 1, (SR–NYSEArca–2012–95) be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27719 Filed 11–14–12; 8:45 am]

BILLING CODE 8011–01–P

[3] Securities Exchange Act Release No. 67898 (September 20, 2012), 77 FR 59233 (''Notice''). The Commission notes that on September 18, 2012, the Exchange submitted Amendment No. 1 to the proposed rule change to make certain amendments that, in part, clarified the circumstances in which the Exchange will delist series with no open interest.

[4] Commentary .07(a) provides, in part, that for each option class eligible for participation in the STOS Program, the Exchange may open up to 30 Short Term Option Series for each expiration date in that class.

[5] *See* Notice, *supra* note 3 at 59233.

[6] *See id.* at 59234.

[7] In approving this proposed rule change, the Commission considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[8] 15 U.S.C. 78f(b)(5).

[9] *See* Notice, *supra* note 3 at 59233.

[10] 15 U.S.C. 78s(b)(2).

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68191; File No. SR–NYSEMKT–2012–42]

Self-Regulatory Organizations; NYSE MKT LLC; Order Granting Approval of Proposed Rule Change, as Modified by Amendment No. 1, Amending Rule 903(h) and Related Commentary .10 To Expand the Number of Expirations Available Under the Short Term Option Series Program (''STOS Program''), To Allow for the Exchange To Delist Series in the STOS Program That Do Not Have Open Interest, and To Expand the Number of Series in the STOS Program Under Limited Circumstances

November 8, 2012.

I. Introduction

On September 6, 2012, NYSE MKT LLC (''NYSE MKT'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend Rule 903(h) and related Commentary .10 (''Commentary .10'') to make certain modifications to the Exchange's Short Term Option Series Program (''STOS Program''). The proposed rule change was published for comment in the **Federal Register** on September 26, 2012.[3] The Commission received no comment letters on the proposal. This order approves the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 67897 (September 20, 2012), 77 FR 59236 (''Notice''). The Commission notes that on September 18, 2012, the Exchange submitted Amendment No. 1 to the proposed rule change to make certain amendments that, in part, clarified the circumstances in which the Exchange will delist series with no open interest.

proposed rule change, as modified by Amendment No. 1.

II. Description of the Proposal

The Exchange proposes to amend Commentary .10 to (i) expand the number of expirations available under the STOS Program; (ii) allow the Exchange to delist, in certain circumstances, series in the STOS program that do not have open interest; and (iii) allow the Exchange to list, in certain circumstances, additional series in the STOS program.

The proposed rule change allows the Exchange to open a maximum of five consecutive expirations under the STOS Program for trading on the Exchange. The Exchange notes that it will not add expirations in a STOS series if such expirations would coincide with an existing expiration of a monthly or quarterly series of an option in the same class of the STOS series.

The proposed rule change also amends the circumstances in which the Exchange may delist or list series in the STOS Program. Specifically, the proposed rule change provides that the Exchange will delist series in the STOS Program with no open interest in both the call and the put series having a: (i) Strike price higher than the highest strike price with open interest in the put and/or call series for a given expiration month; and (ii) strike price lower than the lowest strike price with open interest in the put and/or call series for a given month, so as to list series that are at least 10% but not more than 30% above or below the current price of the underlying security. The Exchange would also be permitted, under the proposed rule change, to list additional series in excess of the 30 series otherwise allowed [4] under Commentary .10 that are between 10% and 30% above or below the price of the underlying security. The Exchange will only be allowed to delist or list series in accordance with the proposed rule change in the event that the underlying security has moved so that there are no series that are at least 10% above or below the current price of the underlying security.

The Exchange asserts that the ability to list five consecutive expirations under the STOS Program is designed to meet increased customer demand and provide market participants with the ability to hedge in a greater number of option classes and series.[5] The Exchange also claims that the proposed amendments regarding delisting or listing STOS series are designed to provide investors flexibility by ensuring that there are series within the band of at least 10% but not more than 30% above or below the current price of the underlying security.[6]

III. Discussion and Commission Findings

After careful review of the proposed rule change, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[7] Specifically, the Commission finds that the proposal is consistent with Section 6(b)(5) of the Act,[8] which requires, among other things, that the rules of a national securities exchange be designed to promote just and equitable principles of trade, to prevent fraudulent and manipulative acts, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Commission believes that the proposed change may provide the investing public and other market participants with greater flexibility to closely tailor their investment and hedging decisions in a greater number of series, thus allowing investors to better manage their risk exposure.

In approving this proposal, the Commission notes that the Exchange has represented that it and OPRA have the necessary systems capacity to handle the potential additional traffic associated with opening of up to five consecutive expirations under the STOS Program.[9] The Commission expects the Exchange to monitor the trading volume associated with the additional options series listed as a result of this proposal and the effect of these additional series on market fragmentation and on the capacity of the Exchange's, OPRA's, and vendors' automated systems.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[10] that the proposed rule change, as modified by Amendment No. 1, (SR–NYSEMKT–2012–42) be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27720 Filed 11–14–12; 8:45 am]

BILLING CODE 8011–01–P

[4] Commentary .10(a) provides, in part, that for each option class eligible for participation in the STOS Program, the Exchange may open up to 30 Short Term Option Series for each expiration date in that class.

[5] *See* Notice, *supra* note 3 at 59237.

[6] *See id.*

[7] In approving this proposed rule change, the Commission considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[8] 15 U.S.C. 78f(b)(5).

[9] *See* Notice, *supra* note 3 at 59237.

[10] 15 U.S.C. 78s(b)(2).

[11] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #13365 and #13366]

New York Disaster Number NY–00130

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of New York (FEMA–4085–DR), dated 10/30/2012.

Incident: Hurricane Sandy.

Incident Period: 10/27/2012 and continuing.

Effective Date: 11/02/2012.

Physical Loan Application Deadline Date: 12/31/2012.

EIDL Loan Application Deadline Date: 07/31/2013.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration Processing, And Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: The notice of the Presidential disaster declaration for the State of NEW YORK, dated 10/30/2012 is hereby amended to include the following areas as adversely affected by the disaster:

Primary Counties: (Physical Damage and Economic Injury Loans): Rockland, Westchester.

Contiguous Counties: (Economic Injury Loans Only):

Connecticut: Fairfield.

New Jersey: Passaic.

New York: Orange, Putnam.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2012–27781 Filed 11–14–12; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Notice of Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart B (Formerly Subpart Q) During the Week Ending October 27, 2012

The following Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits were filed under Subpart B (formerly Subpart Q) of the Department of Transportation's Procedural Regulations (See 14 CFR 301.201 *et seq.*). The due date for Answers, Conforming Applications, or Motions to Modify Scope are set forth below for each application. Following the Answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

Docket Number: DOT–OST–2012–0178.

Date Filed: October 22, 2012.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: November 12, 2012.

Description: Application of Scott Air, LLC (''SCA'') requesting a certificate of public convenience and necessity to the extent necessary to authorize SCA to engage in interstate scheduled air transportation of persons, property and mail utilizing small aircraft.

Docket Number: DOT–OST–2012–0180.

Date Filed: October 23, 2012.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: November 13, 2012.

Description: Application of Gama Charters Inc. (''Gama'') requesting a certificate of public convenience and necessity authorizing Gama to engage in the foreign charter air transportation of persons, property and mail with a Boeing Business Jet aircraft (''BBJ''). Gama also requests the Department exercise its discretionary authority to issue Gama an exemption pendente lite pending Department action on the instant certificate application.

Docket Number: DOT–OST–2012–0181.

Date Filed: October 23, 2012.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: November 13, 2012.

Description: Application of Gama Charters Inc. (''Gama'') requesting a certificate of public convenience and necessity authorizing Gama to engage in interstate charter air transportation of persons, property and mail with a Boeing Business Jet aircraft (''BBJ''). Gama also requests an exemption pendente lite to the extent necessary to allow it to conduct Part 135 services with BBJ aircraft pending Department action on the instant application.

Docket Number: DOT–OST–2010–0093.

Date Filed: October 24, 2012.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: November 14, 2012.

Description: Application of Open Joint Stock Company Transaero Airlines (''Transaero'') requesting to amend its foreign air carrier permit to include authority for Transaero to provide scheduled foreign air transportation of persons, property, and mail (i) from any point or points behind the Russian Federation, via any point or points in the Russian Federation and intermediate points, to San Francisco, California, and (ii) from San Francisco, California, to any point or points in the Russian Federation and beyond.

Barbara J. Hairston,

Acting Program Manager, Docket Operations, Federal Register Liaison.

[FR Doc. 2012–27800 Filed 11–14–12; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Notice of Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart B (Formerly Subpart Q) During the Week Ending October 20, 2012

The following Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits were filed under Subpart B (formerly Subpart Q) of the Department of Transportation's Procedural Regulations (See 14 CFR 301.201 *et. seq.*). The due date for Answers, Conforming Applications, or Motions to Modify Scope are set forth below for each application. Following the Answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or inappropriate cases a final order without further proceedings.

Docket Number: DOT–OST–2012–0182.

Date Filed: October 17, 2012.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: November 7, 2012.

Description: Application of Global Supply Systems Limited (''GSS'') requesting a new or amended foreign air carrier permit to enable GSS, consistent with the open skies, U.S.-European Union (''EU'') Air Transport Agreement, to provide: (i) Foreign scheduled and charter air transportation of property and mail from any point or points behind any Member State of the European Union, via any point or points in any Member State and via any intermediate points to any point or points in the United States and beyond; (ii) foreign scheduled and charter air transportation of property and mail between any point or points in the United States and any point or points in any member of the European Common Aviation Area; (iii) foreign scheduled and charter cargo air tansportation between any point or points in the United States and any point or points; (iv) other charters pursuant to the requirements set forth in the Department's regulations governing charters; and (v) transportation authorized by any additional route rights made available to European Union carriers in the future. GSS also requests (i) exemption authority, to the extent necessary and for an initial period of two years or until the requested permit is issued, to enable it to hold out and provide the service described above; and (ii) such additional or other relief as the Department may deem necessary or appropriate.

Barbara J. Hairston,

Acting Program Manager, Docket Operations, Federal Register Liaison.

[FR Doc. 2012–27801 Filed 11–14–12; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2012–1191]

Orders Limiting Operations at John F. Kennedy International Airport, LaGuardia Airport, and Newark Liberty International Airport; High Density Rule at Reagan Washington National Airport

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Limited Waiver of the Slot Usage Requirement.

SUMMARY: This action announces a limited waiver of the requirement to use Operating Authorizations (slots) at John F. Kennedy International Airport (JFK), LaGuardia Airport (LGA), and Newark

Liberty International Airport (EWR). This action also declines to grant a waiver of the requirement to use slots at Reagan Washington National Airport. This waiver is effective from October 28, 2012 through November 2, 2012.

DATES: Effective November 15, 2012.

FOR FURTHER INFORMATION CONTACT: Robert Hawks, Office of the Chief Counsel, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 267–7143; email: *rob.hawks@faa.gov*.

SUPPLEMENTARY INFORMATION:

Background

On October 29, 2012, Hurricane Sandy made landfall in southern New Jersey. Combined with another weather front, Hurricane Sandy transitioned to an extratropical storm that caused widespread power outages, severe flooding, and severe disruption of transportation systems in the northeastern and mid-Atlantic United States. This disruption included airport closures and mass cancellation of scheduled flights.

The degree of disruption and cancellations varied by airport across the region, and flight disruptions occurred at slot-controlled and non-slot-controlled airports. JFK and EWR were effectively closed on October 29 and 30 and had limited operational capacity on October 31. LGA was effectively closed from October 29 through October 31 and had limited operational capacity on November 1. DCA was effectively closed on October 29 and 30 and had reduced operational capacity on October 31. Recovery of normal operations took several days after the storm.

FAA Analysis

Under the FAA's High Density Rule at DCA and Orders limiting operations at LGA, JFK, and EWR, slots must be used at least 80 percent of the time. These rules are expected to accommodate routine weather and other cancellations under all but the most unusual circumstances. Slots not meeting the minimum usage requirement will be withdrawn or not receive historic precedence for the following scheduling season, depending on the airport.[1] The FAA may grant a waiver from the minimum usage requirement in highly unusual and unpredictable conditions that are beyond the control of the carrier and affect carrier operations for a period of five or more consecutive days (for LGA, JFK, and EWR) or of nine or more consecutive days (for DCA). However, the FAA does not routinely grant general waivers to the usage requirement except under the most unusual circumstances.

The FAA has granted waivers of the slot usage requirement in circumstances similar to those of Hurricane Sandy. The FAA generally considers the days of the weather event as well as a couple additional days to resume normal operations. For example, in February 2010, the FAA granted a general waiver because unusual snowstorms closed slot-controlled airports for multiple days and also caused mass cancellations resulting from reduced airport capacity.

For LGA, JFK, and EWR, the FAA has determined the unusual circumstances created by Hurricane Sandy meet the criteria for a limited waiver of the minimum slot usage requirement. Accordingly, the FAA will treat as used any slot or Operating Authorization held by a carrier from October 28 through November 2, 2012.

For DCA, the FAA has determined that overall operational disruption did not last for the required nine or more consecutive days. Operational data show normal operations largely had resumed by November 1, 2012.

Although the FAA has determined that a general waiver of the usage requirement is inappropriate for DCA, it acknowledges that some carriers operate flights between DCA and airports in the NYC area or northeastern U.S. affected by the storm. These circumstances may have created a unique hardship for those carriers justifying waiver relief. To assess that hardship and determine whether relief is warranted, the FAA requests that affected carriers submit an individual request for limited waiver. However, a carrier must demonstrate operational disruptions of scheduled flights that lasted nine or more consecutive days to be eligible for waiver relief.

FAA Decision

In consideration of the foregoing, the FAA GRANTS a limited waiver of the usage requirement for LGA, JFK, and EWR for the period from October 28 through November 2, 2012.

Issued in Washington, DC, on November 7, 2012.

Rebecca B. MacPherson,

Assistant Chief Counsel for International Law, Legislation, and Regulations.

[FR Doc. 2012–27844 Filed 11–14–12; 8:45 am]

BILLING CODE 4910–13–P

[1] 14 CFR 93.227 (DCA); 74 FR 51648 (Oct. 7, 2009) (EWR); 74 FR 51650 (Oct. 7, 2009) (JFK); 77 FR 30585 (May 23, 2012) (LGA).

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway in Indiana

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by FHWA and United States Army Corps of Engineers (USACE), DoD.

SUMMARY: This notice announces actions taken by the FHWA and the USACE that are final within the meaning of 23 U.S.C. 139(l)(1). The actions relate to proposed highway projects for a 26.7 mile segment of I–69 in the Counties of Greene and Monroe, State of Indiana, and grant licenses, permits, and approvals for the project.

DATES: By this notice, the FHWA is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1) and are final within the meaning of that law. A claim seeking judicial review of those Federal agency actions that are covered by this notice will be barred unless the claim is filed on or before April 14, 2013. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then the shorter time period applies.

FOR FURTHER INFORMATION CONTACT: For the FHWA: Ms. Michelle Allen, Federal Highway Administration, Indiana Division, 575 North Pennsylvania Street, Room 254, Indianapolis, IN 46204–1576; telephone: (317) 226–7344; email: *Michelle.Allen@dot.gov.* The FHWA Indiana Division Office's normal business hours are 7:30 a.m. to 4 p.m., e.t. For the USACE: Mr. Greg Mckay, Chief, North Section Regulatory Branch, Louisville District, United States Army Corps of Engineers, P.O. Box 59, Louisville, KY 40201–0059; telephone: (502) 315–6685; email: *gregory.a.mckay@usace.army.mil.* Normal business hours are 8 a.m. to 5 p.m., e.t. You may also contact Mr. Thomas Seeman, Project Manager, Indiana Department of Transportation (INDOT), 100 North Senate Avenue, Indianapolis, IN 46204; telephone: (317) 232–5336; email: *TSeeman@indot.IN.gov.* Normal business hours for the Indiana Department of Transportation are: 8 a.m. to 4:30 p.m., e.t.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the FHWA and other Federal agencies have taken final agency actions by issuing licenses, permits, and approvals for the highway project in the State of Indiana listed below. The

actions by the Federal agencies on the project, and the laws under which such actions were taken, are described in the Record of Decision (ROD), Reevaluation Documents to the final environmental impact statements (FEIS) issued in connection with the project, Section 404 Discharge of Dredged or Fill Material Permit, and in other documents in the FHWA administrative record for the project. The ROD and other documents from the FHWA administrative record files for the listed project are available by contacting the FHWA or the Indiana Department of Transportation (INDOT) at the addresses provided above. Project information may also be available through the INDOT I–69 Project Web site at *http://www.i69indyevn.org/.* People unable to access the Web site may contact FHWA or INDOT at the addresses listed above. This notice applies to all Federal agency decisions on the listed project as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to: 1. National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351]. 2. Endangered Species Act [16 U.S.C. 1531–1544]. 3. Federal-Aid Highway Act [23 U.S.C. 109 and 23 U.S.C. 128]. 4. Clean Air Act, 42 U.S.C. 7401–7671(q). 5. Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303]. 6. Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(f) *et seq.*]. 7. Bald and Golden Eagle Protection Act [16 U.S.C. 688–688d]. 8. Clean Water Act, 33 U.S.C. 1251–1377 (Section 404, Section 402, Section 401, Section 319). Previous actions taken by the USFWS for the Tier 1, I–69 project, pursuant to the Endangered Species Act, 16 U.S.C. 1531–1544, included its concurrence with the FHWA's determination that the I–69 project was not likely to adversely affect the eastern fanshell mussel (*Cyprogenia stegaria*) and that the project was likely to adversely affect, but not jeopardize, the bald eagle. The USFWS also concluded that the project was not likely to jeopardize the continued existence of the Indiana bat and was not likely to adversely modify the bat's designated Critical Habitat. These USFWS decisions were described in the Programmatic Biological Opinion issued on December 3, 2003, the Revised Programmatic Biological Opinion issued on August 24, 2006, and other documents in the Tier 1 project records. A Notice of Limitation on Claims for Judicial Review of these actions and decisions by the USFWS, DOI, was published in the **Federal Register** on April 17, 2007. The USFWS affirmed its decisions in the Amendment to the Revised Programmatic Biological Opinion issued on May 25, 2011. A Notice of Limitation on Claims for Judicial Review of these actions and decisions by the USFWS, DOI, was published in the **Federal Register** on July 20, 2011. A claim seeking judicial review of the Amendment to the Revised Programmatic Biological Opinion must have been filed by January 17, 2012, to avoid being barred under 23 U.S.C. 139(l).

The project subject to this notice is Section 4 of the I–69 highway project from Evansville to Indianapolis, which extends from U.S. 231 (near Crane Naval Surface Warfare Center) to near the intersection of State Road 37 and Victor Pike Road. Notice is hereby given that, subsequent to the earlier FHWA notice, the FHWA has taken final agency actions within the meaning of 23 U.S.C. 139(*l*)(1) by approving five (5) Reevaluations of the Tier 2, Section 4 Record of Decision issued on September 8, 2011. Section 4 of the I–69 project extends from U.S. 231 just north of the Crane Naval Surface Warfare Center to S.R. 37 south of the City of Bloomington. Section 4 is a new alignment, fully access-controlled highway. As approved in the Tier 1 ROD, the corridor is generally 2000-feet wide. The ROD selected Refined Preferred Alternative 2 for Section 4, as described in the I–69 Evansville to Indianapolis, Indiana, Tier 2 Final Environmental Impact Statement, Crane NSWC to Bloomington, Indiana (FEIS), available at *http://www.i69indyevn.org/section-4-feis.* The ROD also approved the locations of the interchanges, grade separations, and access roads (which include new roads, road relocations, and realignments). On September 29, 2011, the FHWA published a ''Notice of Limitation on Claims for Judicial Review of Actions by FHWA and United States Fish and Wildlife Service (USFWS), DOI'' in the **Federal Register** at (76 FR 60583–01) for the Section 4, 26.7 mile segment of I–69 in the Counties of Greene and Monroe. A claim seeking judicial review of the Tier 2, Section 4 decisions must have been filed by March 27, 2012, to avoid being barred under 23 U.S.C. 139(l). The five (5) Reevaluations of the Tier 2, Section 4 ROD include: (1) The November 4, 2011 Reevaluation, which was prepared to evaluate the impacts of additional temporary right-of-way areas (including temporary right-of-way required to accommodate demolition activities for building removal) made necessary based on final design that were not analyzed in the Tier 2 Section 4 ROD or FEIS (approved July 13, 2011); (2) the June 12, 2012 Reevaluation, which was prepared to evaluate the effects of additional right-of-way and improvements (including right-of-way required to decrease bank slopes in an area of inadequate soil conditions) made necessary based on final design that were not analyzed in the Tier 2 Section 4 ROD or FEIS (approved July 13, 2011); (3) the July 11, 2012 Reevaluation, which was prepared to evaluate the impacts of additional right-of-way areas (including temporary right-of-way required to accommodate demolition activities for building removal and filling the remaining portion of an impacted pond) made necessary based on final design that were not analyzed in the Tier 2 Section 4 ROD or FEIS (approved July 13, 2011); (4) the July 31, 2012 Reevaluation, which was prepared to evaluate the impacts of additional right-of-way areas (including temporary right-of-way required to accommodate demolition activities for building removal, temporary right-of-way required for construction of a private drive, and permanent right-of-way required for construction of a cul de sac.) made necessary based on final design that were not analyzed in the Tier 2 Section 4 ROD or FEIS (approved July 13, 2011); and (5) the October 11, 2012 Reevaluation, which was prepared to evaluate the impacts of additional right-of-way areas (including temporary right-of-way and permanent right-of-way required for construction a modified interchange) made necessary based on final design that was not analyzed in the Tier 2 Section 4 ROD or FEIS (approved July 13, 2011). The analysis in each of the Reevaluations supports the FHWA's conclusions that none of the changes examined will have impacts sufficient to require preparation of a Supplemental Environmental Impact Statement (SEIS) or an additional Draft Environmental Impact Statement (DEIS) for Section 4, and therefore that the Tier 2 Section 4 FEIS and ROD remain valid. The detailed analysis of the reevaluation documents along with the federal decision of minimal impact can be found on the project Web site at *http://www.i69indyevn.org/reevaluation-documents/.*

In addition, notice is hereby given that, subsequent to the earlier FHWA notice, the USACE has taken final agency actions within the meaning of 23 U.S.C. 139(*l*)(1) by issuing permits and approvals for the highway project. The actions by the USACE, related final actions by other Federal agencies, and the laws under which such actions were

taken, are described in the USACE decisions and its project records, referenced as Department of the Army (DA) Permit, Number LRL–2011–0041–djd. That information is available by contacting the USACE at the address provided above.

On September 22, 2011, INDOT filed an application with the USACE for authorization under Section 404 of the Clean Water Act, 33 U.S.C. 1344, to construct the 26.7 mile Section 4 I–69 project. On October 1, 2012, the USACE took final action in issuing the Department of the Army (DA) Permit for the Section 4 I–69 project, Number LRL–2011–0041–djd, as described in the USACE decision and its administrative record for the project. As part of the Section 4 project, which begins at the northern terminus of the Section 3 project in Greene County and terminates at S.R. 37 and Victor Pike Road in Monroe County, there are 18 crossings of water resources requiring individual permits from the USACE, including streams, open water and emergent, scrub-shrub and forested wetlands. Subject to the permit conditions, INDOT is permitted to discharge 34,154 cubic yards of fill material below the Ordinary Highway Water Mark of 88,462 linear feet of stream channels, and to discharge 190,215 cubic yards of fill material into 9.42 acres of open water and emergent, scrub-shrub, and forested wetlands in constructing these 18 crossings.

The actions by the Federal agencies on the project, and the laws under which such actions were taken, are described in the Reevaluation documents, the Department of the Army (DA) Permit (LRL–2011–0041–djd), and in other documents in the FHWA administrative record for the project. The ROD and other documents from the FHWA administrative record files for the Section 4 projects are available by contacting FHWA, USACE or INDOT at the addresses provided above. Project information may also be available through the INDOT I–69 Project Web site at *http://www.i69indyevn.org/*.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(*l*)(1)

Richard Marquis,

Acting Division Administrator, Indianapolis, Indiana.

[FR Doc. 2012–27617 Filed 11–14–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–1998–3637; FMCSA–2000–7006; FMCSA–2000–7165; FMCSA–2000–8203; FMCSA–2002–12294; FMCSA–2004–17984; FMCSA–2004–18885; FMCSA–2008–0266]

Qualification of Drivers; Exemption Applications; Vision

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

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew the exemptions from the vision requirement in the Federal Motor Carrier Safety Regulations for 11 individuals. FMCSA has statutory authority to exempt individuals from the vision requirement if the exemptions granted will not compromise safety. The Agency has concluded that granting these exemption renewals will provide a level of safety that is equivalent to or greater than the level of safety maintained without the exemptions for these commercial motor vehicle (CMV) drivers.

DATES: This decision is effective November 9, 2012. Comments must be received on or before December 17, 2012.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) numbers: Docket No. [FMCSA–1998–3637; 2000–7006; FMCSA–2000–7165; FMCSA–2000–8203; FMCSA–2002–12294; FMCSA–2004–17984; FMCSA–2004–18885; FMCSA–2008–0266], using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket number for this notice. Note that DOT posts all comments received without change to *http://www.regulations.gov*, including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

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

FOR FURTHER INFORMATION CONTACT: Elaine M. Papp, Chief, Medical Programs Division, 202–366–4001, *fmcsamedical@dot.gov*, FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may renew an exemption from the vision requirements in 49 CFR 391.41(b)(10), which applies to drivers of CMVs in interstate commerce, for a two-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The procedures for requesting an exemption (including renewals) are set out in 49 CFR part 381.

Exemption Decision

This notice addresses 11 individuals who have requested renewal of their exemptions in accordance with FMCSA procedures. FMCSA has evaluated these 11 applications for renewal on their

merits and decided to extend each exemption for a renewable two-year period. They are:

John W. Arnold (KY)
Jack E. Benjamin (NY)
Richard B. Eckert (NY)
Gary R. Evans (CT)
Harlan L. Gunter (VA)
David M. Hagadorn (NJ)
Danny L. Hillier (ND)
Gary L. Killian (NC)
Garry R. Setters (KY)
Jimmy E. Settle (MO)
Hubert Whittenburg (MO)

The exemptions are extended subject to the following conditions: (1) That each individual has a physical examination every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirements in 49 CFR 391.41(b)(10), and (b) by a medical examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) that each individual provides a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (3) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file and retains a copy of the certification on his/her person while driving for presentation to a duly authorized Federal, State, or local enforcement official. Each exemption will be valid for two years unless rescinded earlier by FMCSA. The exemption will be rescinded if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315.

Basis for Renewing Exemptions

Under 49 U.S.C. 31315(b)(1), an exemption may be granted for no longer than two years from its approval date and may be renewed upon application for additional two year periods. In accordance with 49 U.S.C. 31136(e) and 31315, each of the 11 applicants has satisfied the entry conditions for obtaining an exemption from the vision requirements (63 FR 196; 63 FR 30285; 65 FR 20245; 65 FR 33406; 65 FR 57230; 65 FR 57234; 65 FR 66293; 67 FR 46016; 67 FR 57266; 67 FR 57267; 67 FR 67234; 69 FR 33997; 69 FR 52741; 69 FR 53493; 69 FR 61292; 69 FR 62741; 69 FR 62742; 71 FR 55820; 71 FR 62147; 73 FR 51336; 73 FR 51689; 73 FR 61925; 73 FR 63047; 73 FR 74565; 75 FR 52061; 75 FR 59327; 75 FR 66423). Each of these 11 applicants has requested renewal of the exemption and has submitted evidence showing that the vision in the better eye continues to meet the requirement specified at 49 CFR 391.41(b)(10) and that the vision impairment is stable. In addition, a review of each record of safety while driving with the respective vision deficiencies over the past two years indicates each applicant continues to meet the vision exemption requirements.

These factors provide an adequate basis for predicting each driver's ability to continue to drive safely in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each renewal applicant for a period of two years is likely to achieve a level of safety equal to that existing without the exemption.

Request for Comments

FMCSA will review comments received at any time concerning a particular driver's safety record and determine if the continuation of the exemption is consistent with the requirements at 49 U.S.C. 31136(e) and 31315. However, FMCSA requests that interested parties with specific data concerning the safety records of these drivers submit comments by December 17, 2012.

FMCSA believes that the requirements for a renewal of an exemption under 49 U.S.C. 31136(e) and 31315 can be satisfied by initially granting the renewal and then requesting and evaluating, if needed, subsequent comments submitted by interested parties. As indicated above, the Agency previously published notices of final disposition announcing its decision to exempt these 11 individuals from the vision requirement in 49 CFR 391.41(b)(10). The final decision to grant an exemption to each of these individuals was made on the merits of each case and made only after careful consideration of the comments received to its notices of applications. The notices of applications stated in detail the qualifications, experience, and medical condition of each applicant for an exemption from the vision requirements. That information is available by consulting the above cited **Federal Register** publications.

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315, FMCSA will take immediate steps to revoke the exemption of a driver.

Issued on: November 8, 2012.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2012–27695 Filed 11–14–12; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2010–0201]

Qualification of Drivers; Exemption Applications; Vision

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

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew the exemptions from the vision requirement in the Federal Motor Carrier Safety Regulations for 12 individuals. FMCSA has statutory authority to exempt individuals from the vision requirement if the exemptions granted will not compromise safety. The Agency has concluded that granting these exemption renewals will provide a level of safety that is equivalent to or greater than the level of safety maintained without the exemptions for these commercial motor vehicle (CMV) drivers.

DATES: This decision is effective November 16, 2012. Comments must be received on or before December 17, 2012.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) numbers: Docket No. [FMCSA–2010–0201], using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the

docket number for this notice. Note that DOT posts all comments received without change to *http://www.regulations.gov,* including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

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

FOR FURTHER INFORMATION CONTACT: Elaine M. Papp, Chief, Medical Programs Division, 202–366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may renew an exemption from the vision requirements in 49 CFR 391.41(b)(10), which applies to drivers of CMVs in interstate commerce, for a two-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The procedures for requesting an exemption (including renewals) are set out in 49 CFR part 381.

Exemption Decision

This notice addresses 12 individuals who have requested renewal of their exemptions in accordance with FMCSA procedures. FMCSA has evaluated these 12 applications for renewal on their merits and decided to extend each exemption for a renewable two-year period. They are:

James B. Bierschbach (MN)
John P. Catalano (NJ)
Tyron O. Friese (MN)
Mark E. Lapp (PA)
David S. Matheny (WA)
Frank G. Merrill (OK)
Shannon L. Puckett (KY)
Leo S. Ruiz, Jr. (CA)
Ronald B. Shafer (MI)
Thomas M. Sharp (ME)
Kenneth M. Sova (IN)
Earl L. White, Jr. (NH)

The exemptions are extended subject to the following conditions: (1) That each individual has a physical examination every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirements in 49 CFR 391.41(b)(10), and (b) by a medical examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) that each individual provides a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (3) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file and retains a copy of the certification on his/her person while driving for presentation to a duly authorized Federal, State, or local enforcement official. Each exemption will be valid for two years unless rescinded earlier by FMCSA. The exemption will be rescinded if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315.

Basis for Renewing Exemptions

Under 49 U.S.C. 31315(b)(1), an exemption may be granted for no longer than two years from its approval date and may be renewed upon application for additional two year periods. In accordance with 49 U.S.C. 31136(e) and 31315, each of the 12 applicants has satisfied the entry conditions for obtaining an exemption from the vision requirements (75 FR 54958; 75 FR 70078). Each of these 12 applicants has requested renewal of the exemption and has submitted evidence showing that the vision in the better eye continues to meet the requirement specified at 49 CFR 391.41(b)(10) and that the vision impairment is stable. In addition, a review of each record of safety while driving with the respective vision deficiencies over the past two years indicates each applicant continues to meet the vision exemption requirements. These factors provide an adequate basis for predicting each driver's ability to continue to drive safely in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each renewal applicant for a period of two years is likely to achieve a level of safety equal to that existing without the exemption.

Request for Comments

FMCSA will review comments received at any time concerning a particular driver's safety record and determine if the continuation of the exemption is consistent with the requirements at 49 U.S.C. 31136(e) and 31315. However, FMCSA requests that interested parties with specific data concerning the safety records of these drivers submit comments by December 17, 2012.

FMCSA believes that the requirements for a renewal of an exemption under 49 U.S.C. 31136(e) and 31315 can be satisfied by initially granting the renewal and then requesting and evaluating, if needed, subsequent comments submitted by interested parties. As indicated above, the Agency previously published notices of final disposition announcing its decision to exempt these 12 individuals from the vision requirement in 49 CFR 391.41(b)(10). The final decision to grant an exemption to each of these individuals was made on the merits of each case and made only after careful consideration of the comments received to its notices of applications. The notices of applications stated in detail the qualifications, experience, and medical condition of each applicant for an exemption from the vision requirements. That information is available by consulting the above cited **Federal Register** publications.

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315, FMCSA will take immediate steps to revoke the exemption of a driver.

Issued on: November 8, 2012.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2012–27697 Filed 11–14–12; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–1998–3637, FMCSA–2000–7006, FMCSA–2000–7165, FMCSA–2000–7363, FMCSA–2004–17195, FMCSA–2004–18885, FMCSA–2008–0106, FMCSA–2008–0266, FMCSA–2008–0292, FMCSA–2010–0161, FMCSA–2010–0187, FMCSA–2010–0201]

Qualification of Drivers; Exemption Applications; Vision

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

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew the exemptions from the vision requirement in the Federal Motor Carrier Safety Regulations for 32 individuals. FMCSA has statutory authority to exempt individuals from the vision requirement if the exemptions granted will not compromise safety. The Agency has concluded that granting these exemption renewals will provide a level of safety that is equivalent to or greater than the level of safety maintained without the exemptions for these commercial motor vehicle (CMV) drivers.

DATES: This decision is effective December 8, 2012. Comments must be received on or before December 17, 2012.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) numbers: Docket No. [FMCSA–1998–3637, FMCSA–2000–7006, FMCSA–2000–7165, FMCSA–2000–7363, FMCSA–2004–17195, FMCSA–2004–18885, FMCSA–2008–0106, FMCSA–2008–0266, FMCSA–2008–0292, FMCSA–2010–0161, FMCSA–2010–0187, FMCSA–2010–0201], using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket number for this notice. Note that DOT posts all comments received without change to *http://www.regulations.gov,* including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments receive intoany of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act Statement for the FDMS published in the **Federal Register** on January 17, 2008 (73 FR 3316), or you may visit *http://edocket.access.gpo.gov/2008/pdf/E8–785.pdf.*

FOR FURTHER INFORMATION CONTACT: Elaine M. Papp, Chief, Medical Programs Division, 202–366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may renew an exemption from the vision requirements in 49 CFR 391.41(b)(10), which applies to drivers of CMVs in interstate commerce, for a two-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The procedures for requesting an exemption (including renewals) are set out in 49 CFR part 381.

Exemption Decision

This notice addresses 32 individuals who have requested renewal of their exemptions in accordance with FMCSA procedures. FMCSA has evaluated these 32 applications for renewal on their merits and decided to extend each exemption for a renewable two-year period. They are:

Henry W. Adams (AL)
Timothy S. Ballard (NC)
Larry W. Barnes (AR)
Delbert R. Bays (KY)
Larry D. Brown (MD)
Donald O. Clopton (AL)
Stephen R. Daugherty (IN)
Ronald W. Garner (WA)
Paul A. Gregerson (IA)
Herman Hicks (GA)
Nelson V. Jaramillo (MA)
Larry D. Johnson (IL)
James A. Jones (MD)
Bruce T. Loughary (AR)
Kenny Y. Louie (CA)
Wayne R. Mantela (KY)
Kenneth D. May (AL)
Carl M. McIntire (OH)
Duffy P. Metrejean, Jr. (LA)
Gordon L. Nathan (CA)
Bernice R. Parnell (NC)
Michael J. Paul (LA)
Stephen P. Preslopsky (FL)
Kevin L. Quastad (IA)
Melinda V. Salas (CA)
Patrick W. Shea (MA)
Ranjodh Singh (MA)
Mark A. Thornton (WA)
Roy F. Varnado, Jr. (LA)
Michael J. Welle (MN)
Eugene E. Wright (PA)
Rick A. Young (IN).

The exemptions are extended subject to the following conditions: (1) That each individual has a physical examination every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirements in 49 CFR 391.41(b)(10), and (b) by a medical examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) that each individual provides a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (3) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file and retains a copy of the certification on his/her person while driving for presentation to

a duly authorized Federal, State, or local enforcement official. Each exemption will be valid for two years unless rescinded earlier by FMCSA. The exemption will be rescinded if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315.

Basis for Renewing Exemptions

Under 49 U.S.C. 31315(b)(1), an exemption may be granted for no longer than two years from its approval date and may be renewed upon application for additional two year periods. In accordance with 49 U.S.C. 31136(e) and 31315, each of the 32 applicants has satisfied the entry conditions for obtaining an exemption from the vision requirements (69–FR–62741, 71–FR–62147, 63–FR–30285, 63–FR–54519, 65–FR–20245, 65–FR–33406, 65–FR–45817, 65–FR–57230, 65–FR–77066, 65–FR–77069, 67–FR–57266, 67–FR–71610, 69–FR–17263, 69–FR–31447, 69–FR–52741, 69–FR–53493, 69–FR–62742, 69–FR–64810, 71–FR–62148, 71–FR–66217, 73–FR–35194, 73–FR–48273, 73–FR–51689, 73–FR–60398, 73–FR–61922, 73–FR–61925, 73–FR–63047, 73–FR–74565, 75–FR–39725, 75–FR–44050, 75–FR–47883, 75–FR–54958, 75–FR–59327, 75–FR–61833, 75–FR–63255, 75–FR–70078, 75–FR–72868, 75–FR–77949). Each of these 32 applicants has requested renewal of the exemption and has submitted evidence showing that the vision in the better eye continues to meet the requirement specified at 49 CFR 391.41(b)(10) and that the vision impairment is stable. In addition, a review of each record of safety while driving with the respective vision deficiencies over the past two years indicates each applicant continues to meet the vision exemption requirements.

These factors provide an adequate basis for predicting each driver's ability to continue to drive safely in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each renewal applicant for a period of two years is likely to achieve a level of safety equal to that existing without the exemption.

Request for Comments

FMCSA will review comments received at any time concerning a particular driver's safety record and determine if the continuation of the exemption is consistent with the requirements at 49 U.S.C. 31136(e) and 31315. However, FMCSA requests that interested parties with specific data concerning the safety records of these drivers submit comments by December 17, 2012.

FMCSA believes that the requirements for a renewal of an exemption under 49 U.S.C. 31136(e) and 31315 can be satisfied by initially granting the renewal and then requesting and evaluating, if needed, subsequent comments submitted by interested parties. As indicated above, the Agency previously published notices of final disposition announcing its decision to exempt these 32 individuals from the vision requirement in 49 CFR 391.41(b)(10). The final decision to grant an exemption to each of these individuals was made on the merits of each case and made only after careful consideration of the comments received to its notices of applications. The notices of applications stated in detail the qualifications, experience, and medical condition of each applicant for an exemption from the vision requirements. That information is available by consulting the above cited **Federal Register** publications.

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315, FMCSA will take immediate steps to revoke the exemption of a driver.

Issued on: November 5, 2012.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2012–27693 Filed 11–14–12; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2012–0006–N–15]

Proposed Agency Information Collection Activities; Comment Request

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

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and its implementing regulations, the Federal Railroad Administration (FRA) hereby announces that it is seeking renewal of the following currently approved information collection activities. Before submitting these information collection requirements for clearance by the Office of Management and Budget (OMB), FRA is soliciting public comment on specific aspects of the activities identified below.

DATES: Comments must be received no later than January 14, 2013.

ADDRESSES: Submit written comments on any or all of the following proposed activities by mail to either: Mr. Robert Brogan, Office of Safety, Planning and Evaluation Division, RRS–21, Federal Railroad Administration, 1200 New Jersey Ave. SE., Mail Stop 25, Washington, DC 20590, or Ms. Kimberly Toone, Office of Information Technology, RAD–20, Federal Railroad Administration, 1200 New Jersey Ave. SE., Mail Stop 35, Washington, DC 20590. Commenters requesting FRA to acknowledge receipt of their respective comments must include a self-addressed stamped postcard stating, ''Comments on OMB Control Number 2130–0525'' and/or ''Comments on OMB Control Number 2130–0529.'' Alternatively, comments may be transmitted via facsimile to (202) 493–6216 or (202) 493–6170, or via email to Mr. Brogan at *Robert.Brogan@dot.gov,* or to Ms. Toone at *Kimberly.Toone@dot.gov.* Please refer to the assigned OMB control number in any correspondence submitted. FRA will summarize comments received in response to this notice in a subsequent notice and include them in its information collection submission to OMB for approval.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Brogan, Office of Planning and Evaluation Division, RRS–21, Federal Railroad Administration, 1200 New Jersey Ave. SE., Mail Stop 25, Washington, DC 20590 (telephone: (202) 493–6292) or Ms. Ms. Kimberly Toone, Office of Information Technology, RAD–20, Federal Railroad Administration, 1200 New Jersey Ave. SE., Mail Stop 35, Washington, DC 20590 (telephone: (202) 493–6132). (These telephone numbers are not toll-free.)

SUPPLEMENTARY INFORMATION: The Paperwork Reduction Act of 1995 (PRA), Public Law 104–13, § 2, 109 Stat. 163 (1995) (codified as revised at 44 U.S.C. 3501–3520), and its implementing regulations, 5 CFR Part 1320, require Federal agencies to provide 60-day notice to the public for comment on information collection activities before seeking approval for reinstatement or renewal by OMB. 44 U.S.C. 3506(c)(2)(A); 5 CFR 1320.8(d)(1),

1320.10(e)(1), 1320.12(a). Specifically, FRA invites interested respondents to comment on the following summary of proposed information collection activities regarding (i) whether the information collection activities are necessary for FRA to properly execute its functions, including whether the activities will have practical utility; (ii) the accuracy of FRA's estimates of the burden of the information collection activities, including the validity of the methodology and assumptions used to determine the estimates; (iii) ways for FRA to enhance the quality, utility, and clarity of the information being collected; and (iv) ways for FRA to minimize the burden of information collection activities on the public by automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (*e.g.,* permitting electronic submission of responses). *See* 44 U.S.C. 3506(c)(2)(A)(i)–(iv); 5 CFR 1320.8(d)(1)(i)–(iv). FRA believes that soliciting public comment will promote its efforts to reduce the administrative and paperwork burdens associated with the collection of information mandated by Federal regulations. In summary, FRA reasons that comments received will advance three objectives: (i) Reduce reporting burdens; (ii) ensure that it organizes information collection requirements in a ''user friendly'' format to improve the use of such information; and (iii) accurately assess the resources expended to retrieve and produce information requested. *See* 44 U.S.C. 3501.

Below are brief summaries of the two currently approved information collection activities that FRA will submit for clearance by OMB as required under the PRA:

Title: Certification of Glazing Materials.

OMB Control Number: 2130–0525.

Abstract: The collection of information is set forth under 49 CFR Part 223, which requires the certification and permanent marking of glazing materials by the manufacturer. The manufacturer is also responsible for making available test verification data to railroads and FRA upon request.

Form Number(s): N/A.

Affected Public: Businesses.

Respondent Universe: 5 Manufacturers.

CFR section	Respondent universe	Total annual responses	Average time per response	Total annual burden hours
223.17—Identification of Equipped Locomotives, Passenger Cars, and Caboose.	4 Manufacturers	200 stencilings or metal plates.	15 minutes	50
223.17—Appendix A—Requests for Glazing Certification.	5 Manufacturers	10 request	15 minutes	3
—Marking Individual Units of Glazing Material.	5 Manufacturers	25,000 pieces	480 pieces per hour	52
—Testing New Material and Providing Verification Data.	5 Manufacturers	1 test	14 hours	14

Frequency of Submission: On occasion.

Total Responses: 25,211.

Estimated Total Annual Burden: 119 hours.

Status: Extension of a currently approved collection.

Title: Disqualification Proceedings.

OMB Control Number: 2130–0529.

Abstract: Under 49 U.S.C. 20111(c), FRA is authorized to issue orders disqualifying railroad employees, including supervisors, managers, and other agents, from performing safety-sensitive service in the rail industry for violations of safety rules, regulations, standards, orders, or laws evidencing unfitness. FRA's regulations, 49 CFR Part 209, Subpart D, implement the statutory provision by requiring (i) a railroad employing or formerly employing a disqualified individual to disclose the terms and conditions of a disqualification order to the individual's new or prospective employing railroad; (ii) a railroad considering employing an individual in a safety-sensitive position to ask the individual's previous employing railroad whether the individual is currently serving under a disqualification order; and (iii) a disqualified individual to inform his new or prospective employer of the disqualification order and provide a copy of the same. Additionally, the regulations prohibit a railroad from employing a person serving under a disqualification order to work in a safety-sensitive position. This information serves to inform a railroad whether an employee or prospective employee is currently disqualified from performing safety-sensitive service based on the issuance of a disqualification order by FRA. Furthermore, it prevents an individual currently serving under a disqualification order from retaining and obtaining employment in a safety-sensitive position in the rail industry.

Form Number(s): N/A.

Affected Public: Railroad Employees.

Respondent Universe: 40,000 Locomotive Engineers.

Total Responses: 3.

Estimated Total Annual Burden: 5 hours.

Status: Extension of a currently approved collection.

Pursuant to 44 U.S.C. 3507(a) and 5 CFR 1320.5(b), 1320.8(b)(3)(vi), FRA informs all interested parties that it may not conduct or sponsor, and a respondent is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Authority: 44 U.S.C. 3501–3520.

Issued in Washington, DC, on November 8, 2012.

Rebecca Pennington,

Chief Financial Officer, Federal Railroad Administration.

[FR Doc. 2012–27790 Filed 11–14–12; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF THE TREASURY

Privacy Act of 1974, as Amended

AGENCY: Department of the Treasury.

ACTION: Notice of New Privacy Act System of Records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a, the Department of the Treasury gives notice to establish a new system of records entitled ''Treasury .014—Department of the Treasury User Profile Services.''

DATES: Comments must be received no later than December 17, 2012. This new system will be effective December 20, 2012 unless the Department of the Treasury receives comments that would result in a contrary determination.

ADDRESSES: Written comments should be submitted to Enterprise Content Management (ECM) c/o Office of Privacy, Transparency, and Records (PTR), Department of the Treasury, 1500

Pennsylvania Avenue NW., Washington, DC 20020. Comments can be faxed to (202) 622–4102 or emailed to *ecmpmo@treasury.gov.* The Department will make such comments available for public inspection and copying at the Department of the Treasury Library, 1500 Pennsylvania Avenue NW., Washington, DC 20020 on official business days between the hours of 9:00 a.m. and 5:00 p.m. Eastern Time. Persons wishing to inspect the comments submitted must request an appointment by telephoning (202) 622–0990. All comments, including attachments and other supporting materials, received are part of the public record and subject to public disclosure. You should submit only information that you wish to make available publicly.

FOR FURTHER INFORMATION CONTACT: For policy questions, contact Veronica Marco, Program Director for Privacy, Transparency, and Records at Department of the Treasury, 1500 Pennsylvania Avenue NW., Washington, DC 20020. For technical questions, contact Chakravarthy Susarla, Director of Applications & Support, at Department of the Treasury, 1500 Pennsylvania Avenue NW., Washington, DC 20020.

SUPPLEMENTARY INFORMATION: The adoption and implementation of SharePoint represents the Department of the Treasury's effort to create a system for Treasury employees, contractors, grantees, detailees, and interns with access to Treasury's Enterprise Content Management Environment to communicate in order to increase operational efficiencies. The User Profile service application stores information about users in a central location. Social computing features, such as tagging, and newsfeeds, use this information to facilitate productive interactions that enable users to collaborate efficiently. The department email directories (e.g., name, department, office phone number) auto-populate User Profile Services. In addition, the Profile Page feature gives individuals the option to provide additional information, such as skills and past projects.

The report of a new system of records, as required by 5 U.S.C. 552a(r), has been provided to the Committee on Oversight and Government Reform of the House of Representatives, the Committee on Homeland Security and Governmental Affairs of the Senate, and the Office of Management and Budget.

The proposed new system of records, entitled ''Treasury .014—Department of the Treasury SharePoint User Profile Services'' is published in its entirety below.

Dated: October 24, 2012.

Melissa Hartman,

Deputy Assistant Secretary for Privacy, Transparency, and Records.

Treasury/DO .014

SYSTEM NAME:

Department of the Treasury SharePoint User Profile Services

SYSTEM LOCATION:

These records are located in the Department of the Treasury's (Treasury) Office of Privacy, Transparency, and Records, and any other office within a Treasury bureau where the data was entered on the site. The locations at which the system is maintained are:

(1) a. Departmental Offices: 1500 Pennsylvania Ave. NW., Washington, DC 20220.

b. The Office of Inspector General: 740 15th Street NW., Washington, DC 20220.

c. Treasury Inspector General for Tax Administration: 1125 15th Street NW., Suite 700A, Washington, DC 20005.

d. Special Inspector General for the Troubled Asset Relief Program, 1801 L Street NW., Washington, DC 20036.

(2) Alcohol and Tobacco Tax and Trade Bureau: 1310 G Street NW., Washington, DC 20220.

(3) Office of the Comptroller of the Currency: 250 E Street NW., Washington, DC 20219–0001.

(4) Bureau of Engraving and Printing: 14th & C Streets SW., Washington, DC 20228.

(5) Fiscal Services: 401 14th Street SW., Washington, DC 20227.

(6) Internal Revenue Service: 1111 Constitution Avenue NW., Washington, DC 20224.

(7) United States Mint: 801 9th Street NW., Washington, DC 20220.

(8) Financial Crimes Enforcement Network: 2070 Chain Bridge Road, Vienna, VA 22183.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Treasury employees, detailees, contractors, and interns.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name; name of department/office/bureau; job title; office work and cell phone numbers; work email address; office fax number; office building location; assistant/alternate point of contact (optional); phonetic name (optional); skills/experience (optional); educational background (optional); status message (optional), and photograph (optional).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301.

PURPOSE(S):

The purpose of this system is to create a central platform through which Treasury and its bureaus' employees, detailees, contractors, and interns may collaborate and exchange information in order to increase operational efficiency.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

These records may be used to:

(1) Disclose pertinent information to appropriate federal, foreign, state, local, tribal, or other public authorities or self-regulatory organizations responsible for investigating or prosecuting the violations of, enforcing, or implementing, a statute, rule, regulation, order, or license, where the disclosing agency becomes aware of an indication of a violation or potential violation of civil or criminal law or regulation;

(2) Disclose information to a court, magistrate, or administrative tribunal in the course of presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, or settlement negotiations, in response to a court order, or in connection with criminal law proceedings or mediation/alternative dispute resolution;

(3) Provide information to a congressional office in response to an inquiry made at the request of the individual to whom the record pertains;

(4) Disclose information to the United States Department of Justice for the purpose of representing or providing legal advice to Treasury in a proceeding before a court, adjudicative body, or other administrative body before which Treasury is authorized to appear, when such proceeding involves:

(A) Treasury or any component thereof;

(B) Any employee of Treasury in his or her official capacity;

(C) Any employee of Treasury in his or her individual capacity where the Department of Justice or Treasury has agreed to represent the employee;

(D) The United States, when Treasury determines that litigation is likely to affect Treasury or any of its components.

(5) Disclose information to contractors and their agents, experts, consultants, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for Treasury, when necessary to accomplish an agency function related to this system of records;

(7) Provide information to appropriate agencies, entities, and persons when (a) the Department suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised; (b) the Department has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by the Department or another agency or entity) that rely upon the compromised information; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Department's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records in this system are stored electronically or on paper in secure facilities in a locked drawer behind a locked door. The electronic records are stored on magnetic disc, tape, digital media, and CD–ROM.

RETRIEVABILITY:

Records may be retrieved by name; department; name of office/bureau; job title; manager/supervisor; office work and cell phone; work email address; office fax number; office building location; assistant/alternate point of contact; phonetic name; skills/experience; educational background; and status message.

SAFEGUARDS:

Records in this system are safeguarded in accordance with applicable rules and policies, including all applicable Treasury automated systems security and access policies. Strict controls have been imposed to minimize the risk of compromising the information that is being stored. Access to the type and amount of data is governed by privilege management software and policies developed and enforced by federal government personnel and are determined by specific roles and responsibilities. Procedural and physical safeguards, such as personal accountability, will be utilized. Certified system management personnel are responsible for maintaining the system integrity and the data confidentiality.

RETENTION AND DISPOSAL:

To the extent there are records identified, they will be destroyed in accordance with the appropriate disposition schedule approved by the National Archives and Records Administration. Non-record material will be removed when no longer deemed necessary by the system owner.

SYSTEM MANAGER AND ADDRESS:

a. Deputy Assistant Secretary for Information Technology and Chief Information Officer, 1500 Pennsylvania Avenue NW., Washington, DC 20020;

b. Deputy Assistant Secretary for Privacy, Transparency, and Records, 1500 Pennsylvania Avenue NW., Washington, DC 20020.

NOTIFICATION PROCEDURE:

Individuals seeking notification and access to any record contained in this system of records, or seeking to contest its content, may inquire in writing in accordance with instructions appearing at 31 CFR part 1, Subpart C, Appendices A–M. Requests for information and specific guidance on where to send requests for records may be addressed to: Privacy Act Request, DO, Director, Disclosure Services, Department of the Treasury, 1500 Pennsylvania Avenue NW., Washington, DC 20220.

RECORD ACCESS PROCEDURES:

See ''Notification procedure'' above.

CONTESTING RECORD PROCEDURES:

See ''Notification procedure'' above.

RECORD SOURCE CATEGORIES:

Records are obtained from Active Directory, Treasury employees, detailees, contractors, and interns.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 2012–27698 Filed 11–14–12; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF THE TREASURY

Survey of U.S. Ownership of Foreign Securities as of December 31, 2012

AGENCY: Departmental Offices, Department of the Treasury.

ACTION: Notice of reporting requirements.

SUMMARY: By this Notice and in accordance with 31 CFR 129, the Department of the Treasury is informing the public that it is conducting a mandatory survey of ownership of foreign securities by U.S. residents as of December 31, 2012. This Notice constitutes legal notification to all United States persons (defined below) who meet the reporting requirements set forth in this Notice that they must respond to, and comply with, this survey. The reporting form SHCA (2012) and instructions may be printed from the Internet at: *http://www.treasury.gov/resource-center/data-chart-center/tic/Pages/forms-sh.aspx#shc.*

Definition: Pursuant to 22 USC § 3102 a United States person is any individual, branch, partnership, associated group, association, estate, trust, corporation, or other organization (whether or not organized under the laws of any State), and any government (including a foreign government, the United States Government, a State or local government, and any agency, corporation, financial institution, or other entity or instrumentality thereof, including a government-sponsored agency), who resides in the United States or is subject to the jurisdiction of the United States.

Who Must Report: The reporting panel for this survey is based upon the level of U.S. holdings of foreign securities reported on the December 2011 benchmark survey of U.S. holdings of foreign securities, and will consist primarily of the largest reporters on that survey. Entities required to report will be contacted individually by the Federal Reserve Bank of New York. Entities not contacted by the Federal Reserve Bank of New York have no reporting responsibilities.

What To Report: This report will collect information on holdings by U.S. residents of foreign securities, including equities, long-term debt securities, and short-term debt securities (including selected money market instruments).

How To Report: Completed reports can be submitted electronically or mailed to the Federal Reserve Bank of New York, Statistics Function, 4th Floor, 33 Liberty Street, New York, NY 10045–0001. Inquiries can be made to the survey staff of the Federal Reserve Bank of New York at (212) 720–6300 or email: *SHC.help@ny.frb.org.* Inquiries can also be made to Dwight Wolkow at (202) 622–1276, email: *comments2TIC@do.treas.gov.*

When To Report: Data must be submitted to the Federal Reserve Bank of New York, acting as fiscal agent for the Department of the Treasury, by March 1, 2013.

Paperwork Reduction Act Notice: This data collection has been approved by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act and assigned control number 1505–0146. An agency may not conduct or sponsor, and a person is not required to respond to, a

collection of information unless it displays a valid control number assigned by OMB. The estimated average annual burden associated with this collection of information is 48 hours per respondent for end-investors and custodians that file Schedule 3 reports covering their securities entrusted to U.S. resident custodians, 145 hours per respondent for large end-investors filing Schedule 2 reports, and 700 hours per respondent for large custodians of securities filing Schedule 2 reports. Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be directed to the Department of the Treasury, Attention Administrator, International Portfolio Investment Data Reporting Systems, Room 5422, Washington, DC 20220, and to OMB, Attention Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503.

Dwight Wolkow,

Administrator, International Portfolio Investment Data Reporting Systems.

[FR Doc. 2012–27808 Filed 11–14–12; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Designations of 4 Individuals Pursuant to Executive Order 13224 of September 23, 2001, ''Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten To Commit, or Support Terrorism''

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Treasury Department's Office of Foreign Assets Control (''OFAC'') is publishing the names of 4 individuals whose property and interests in property are blocked pursuant to Executive Order 13224 of September 23, 2001, ''Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten To Commit, or Support Terrorism.''

DATES: The designations by the Director of OFAC of the 4 individuals in this notice, pursuant to Executive Order 13224, are effective on November 8, 2012.

FOR FURTHER INFORMATION CONTACT: Assistant Director, Compliance Outreach & Implementation, Office of Foreign Assets Control, Department of the Treasury, Washington, DC 20220, tel.: 202/622–2490.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available from OFAC's web site (*www.treas.gov/ofac*) or via facsimile through a 24-hour fax-on-demand service, tel.: 202/622–0077.

Background

On September 23, 2001, the President issued Executive Order 13224 (the ''Order'') pursuant to the International Emergency Economic Powers Act, 50 U.S.C. 1701–1706, and the United Nations Participation Act of 1945, 22 U.S.C. 287c. In the Order, the President declared a national emergency to address grave acts of terrorism and threats of terrorism committed by foreign terrorists, including the September 11, 2001 terrorist attacks in New York, Pennsylvania, and at the Pentagon. The Order imposes economic sanctions on persons who have committed, pose a significant risk of committing, or support acts of terrorism. The President identified in the Annex to the Order, as amended by Executive Order 13268 of July 2, 2002, 13 individuals and 16 entities as subject to the economic sanctions. The Order was further amended by Executive Order 13284 of January 23, 2003, to reflect the creation of the Department of Homeland Security.

Section 1 of the Order blocks, with certain exceptions, all property and interests in property that are in or hereafter come within the United States or the possession or control of United States persons, of: (1) Foreign persons listed in the Annex to the Order; (2) foreign persons determined by the Secretary of State, in consultation with the Secretary of the Treasury, the Secretary of the Department of Homeland Security and the Attorney General, to have committed, or to pose a significant risk of committing, acts of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States; (3) persons determined by the Director of OFAC, in consultation with the Departments of State, Homeland Security and Justice, to be owned or controlled by, or to act for or on behalf of those persons listed in the Annex to the Order or those persons determined to be subject to subsection 1(b), 1(c), or 1(d)(i) of the Order; and (4) except as provided in section 5 of the Order and after such consultation, if any, with foreign authorities as the Secretary of State, in consultation with the Secretary of the Treasury, the Secretary of the Department of Homeland Security and the Attorney General, deems appropriate in the exercise of his discretion, persons determined by the Director of OFAC, in consultation with the Departments of State, Homeland Security and Justice, to assist in, sponsor, or provide financial, material, or technological support for, or financial or other services to or in support of, such acts of terrorism or those persons listed in the Annex to the Order or determined to be subject to the Order or to be otherwise associated with those persons listed in the Annex to the Order or those persons determined to be subject to subsection 1(b), 1(c), or 1(d)(i) of the Order.

On November 8, 2012, the Director of OFAC, in consultation with the Departments of State, Homeland Security, Justice and other relevant agencies, designated, pursuant to one or more of the criteria set forth in subsections 1(b), 1(c) or 1(d) of the Order, 4 individuals whose property and interests in property are blocked pursuant to Executive Order 13224.

The listings for these individuals on OFAC's list of Specially Designated Nationals and Blocked Persons appear as follows:

Individuals

1. AL-GHANIMI, Karim Ja'far Muhsin (a.k.a. AL–GHANIMI, Karim Mansur; a.k.a. AL–ZIRJAWI, Karim Jafar Hasan; a.k.a. ''ABU ISLAM, Karim''); DOB 1968; alt. DOB 1969; POB al-Amarah, Iraq; citizen Iraq (individual) [SDGT].
2. AL-MAKSUSI, Sayyid Salah Mahdi Hantush (a.k.a. AL–MUSAWI, Sayyid Salah; a.k.a. ''HAWRA, Abu''; a.k.a. ''SALAH, Sayyid''); DOB 1973; alt. DOB 1971; nationality Iraq (individual) [SDGT].
3. AL-HAMIDAWI, Riyad Yunis Jasim (a.k.a. ''TAQI, Abu''; a.k.a. ''TUQA, Abu''); DOB 16 Jan 1974; POB Baghdad, Iraq; Passport G1751672 expires 08 Feb 2016 (individual) [SDGT].
4. MINA'I, Mohammad (a.k.a. MINAEE, Muhamed); DOB 1964; POB Iran; citizen Iran (individual) [SDGT] [IRGC] [IFSR].

Dated: November 8, 2012.

Adam J. Szubin,

Director, Office of Foreign Assets Control.

[FR Doc. 2012–27831 Filed 11–14–12; 8:45 am]

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 416, 419, 476, et al.

Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Electronic Reporting Pilot; Inpatient Rehabilitation Facilities Quality Reporting Program; Revision to Quality Improvement Organization Regulations; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 416, 419, 476, 478, 480, and 495

[CMS–1589–FC]

RIN 0938–AR10

Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Electronic Reporting Pilot; Inpatient Rehabilitation Facilities Quality Reporting Program; Revision to Quality Improvement Organization Regulations

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) and the Medicare ambulatory surgical center (ASC) payment system for CY 2013 to implement applicable statutory requirements and changes arising from our continuing experience with these systems. In this final rule with comment period, we describe the changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. In addition, this final rule with comment period updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program, the ASC Quality Reporting (ASCQR) Program, and the Inpatient Rehabilitation Facility (IRF) Quality Reporting Program. We are continuing the electronic reporting pilot for the Electronic Health Record (EHR) Incentive Program, and revising the various regulations governing Quality Improvement Organizations (QIOs), including the secure transmittal of electronic medical information, beneficiary complaint resolution and notification processes, and technical changes. The technical changes to the QIO regulations reflect CMS' commitment to the general principles of the President's Executive Order on Regulatory Reform, Executive Order 13563 (January 18, 2011).

DATES: *Effective Date:* This final rule with comment period is effective on January 1, 2013.

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 must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on December 31, 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 1, 2013, 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–1589–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–1589–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–1589–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, (401) 786–4617, for issues related to new CPT and Level II HCPCS codes, exceptions to the 2 times rule, and new technology APCs.

Anita Bhatia, (410) 786–7236, Ambulatory Surgical Center Quality Reporting (ASCQR) Program—Program Administration and Reconsideration Issues.

Douglas Brown, (410) 786–0028, for issues related to Electronic Health Record (EHR) Incentive Program Electronic Reporting Pilot.

Carrie Bullock, (401) 786–0378, for issues related to blood products.

Erick Chuang, (410) 786–1816, for issues related to OPPS APC weights, mean calculation, copayments, wage index, outlier payments, and rural hospital payments.

Caroline Gallaher, (410) 786–8705, for issues related to Inpatient Rehabilitation Facility (IRF) Quality Reporting Program.

Shaheen Halim (410) 786–0641, Hospital Outpatient Quality Reporting Program (OQR)—Measures Issues and Publication of Hospital OQR Program Data, and Ambulatory Surgical Center Quality Reporting (ASCQR) Program—Measures Issues and Publication of ASCQR Program Data.

Twi Jackson, (410) 786–1159, for issues related to device-dependent APCs, no cost/full credit and partial credit devices, hospital outpatient visits, extended assessment and management composite APCs, and inpatient-only procedures.

Thomas Kessler, (401) 786–1991, for issues related to QIO regulations.

Marina Kushnirova, (410) 786–2682, for issues related to OPPS status indicators and comment indicators.

Barry Levi, (410) 786–4529, for issues related to OPPS pass-through devices, brachytherapy sources, intraoperative radiation therapy (IORT), brachytherapy composite APC, multiple imaging composite APCs, cardiac resynchronization therapy composite APC, and cardiac electrophysiologic evaluation and ablation composite APC.

Jana Lindquist, (410) 786–4533, for issues related to partial hospitalization and community mental health center (CMHC) issues.

Ann Marshall, (410) 786–3059, for issues related to hospital outpatient supervision, outpatient status, proton beam therapy, and the Hospital Outpatient Payment (HOP) Panel.

John McInnes, (410) 786–0378, for issues related to new technology intraocular lenses (NTIOLs) and packaged items/services.

James Poyer, (410) 786–2261, Hospital Outpatient Quality Reporting—Program Administration, Validation, and Reconsideration Issues.

Char Thompson, (410) 786–2300, for issues related to OPPS drugs, radiopharmaceuticals, biologicals, blood clotting factors, cost-to-charge ratios (CCRs), and ambulatory surgical center (ASC) payments.

Marjorie Baldo, (410) 786–4617, for all other issues related to hospital outpatient and ambulatory surgical center payments not previously identified.

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 4:00 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 in 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 OPPS/ASC proposed rule, all of the Addenda 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/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. The Addenda relating to the ASC payment system are available at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/index.html*. 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

AHA American Hospital Association
AMA American Medical Association
APC Ambulatory Payment Classification
ASC Ambulatory surgical center
ASCQR Ambulatory Surgical Center Quality Reporting
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
CASPER Certification and Survey Provider Enhanced Reporting
CAUTI Catheter associated urinary tract infection
CBSA Core-Based Statistical Area
CCI Correct Coding Initiative
CCN CMS Certification Number
CCR Cost-to-charge ratio
CDC Centers for Disease Control and Prevention
CEO Chief executive officer
CERT Comprehensive Error Rate Testing
CFR Code of Federal Regulations
CLFS Clinical Laboratory Fee Schedule
CMHC Community mental health center
CMS Centers for Medicare & Medicaid Services
CoP [Medicare] Condition of participation
CPI–U Consumer Price Index for All Urban Consumers
CPT Current Procedural Terminology (copyrighted by the American Medical Association)
CQM Clinical quality measure
CR Change request
CSAC Consensus Standards Approval Committee
CY Calendar year
DFO Designated Federal Official
DRA Deficit Reduction Act of 2005, Public Law 109–171
DRG Diagnosis-Related Group
DSH Disproportionate share hospital
EACH Essential access community hospital
eCQM Electronically specified clinical quality measure
ECT Electroconvulsive therapy
ED Emergency department
E/M Evaluation and management
EHR Electronic health record
ESRD End-stage renal disease
FACA Federal Advisory Committee Act, Public Law 92–463
FDA Food and Drug Administration
FFS [Medicare] Fee-for-service
FY Fiscal year
GAO Government Accountability Office
HAI Healthcare-associated infection
HCERA Health Care and Education Reconciliation Act of 2010, Public Law 111–152
HCPCS Healthcare Common Procedure Coding System
HCRIS Hospital Cost Report Information System
HEU Highly enriched uranium
HIPAA Health Insurance Portability and Accountability Act of 1996, Public Law 104–191
HITECH Health Information Technology for Economic and Clinical Health [Act] (found in the American Recovery and Reinvestment Act of 2009, Public Law 111–5)
HOP Hospital Outpatient Payment [Panel]
HOPD Hospital outpatient department
ICD–9–CM International Classification of Diseases, Ninth Revision, Clinical Modification
ICD Implantable cardioverter defibrillator
ICU Intensive care unit
IHS Indian Health Service
IMRT Intensity Modulated Radiation Therapy
I/OCE Integrated Outpatient Code Editor
IOL Intraocular lens
IOM Institute of Medicine
IORT Intraoperative radiation treatment
IPF Inpatient Psychiatric Facility
IPPS [Hospital] Inpatient Prospective Payment System
IQR [Hospital] Inpatient Quality Reporting
IRF Inpatient rehabilitation facility
IRF–PAI Inpatient Rehabilitation Facility-Patient Assessment Instrument

IRF QRP Inpatient Rehabilitation Facility Quality Reporting Program
LDR Low dose rate
LOS Length of Stay
LTCH Long-term care hospital
MAC Medicare Administrative Contractor
MAP Measure Application Partnership
MedPAC Medicare Payment Advisory Commission
MEI Medicare Economic Index
MFP Multifactor productivity
MGCRB Medicare Geographic Classification Review Board
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
MRA Magnetic resonance angiography
MRI Magnetic resonance imaging
MSA Metropolitan Statistical Area
NCCI National Correct Coding Initiative
NHSN National Healthcare Safety Network
NQF National Quality Forum
NTIOL New technology intraocular lens
NUBC National Uniform Billing Committee
OACT [CMS] Office of the Actuary
OBRA Omnibus Budget Reconciliation Act of 1996, Public Law 99–509
OIG [HHS] Office of the Inspector General
OMB Office of Management and Budget
OPD [Hospital] Outpatient Department
OPPS [Hospital] Outpatient Prospective Payment System
OPSF Outpatient Provider-Specific File
OQR [Hospital] Outpatient Quality Reporting
OT Occupational therapy
PCR Payment-to-cost ratio
PE Practice expense
PEPPER Program for Evaluating Payment Patterns Electronic Report
PHP Partial hospitalization program
PHS Public Health Service [Act], Public Law 96–88
PPI Producer Price Index
PPS Prospective payment system
PQRS Physician Quality Reporting System
PT Physical therapy
QDC Quality data code
QIO Quality Improvement Organization
RAC Recovery Audit Contractor
RFA Regulatory Flexibility Act
RTI Research Triangle Institute, International
RVU Relative value unit
SCH Sole community hospital
SCOD Specified covered outpatient drugs
SI Status indicator
SIR Standardized infection ratio
SLP Speech-language pathology
SNF Skilled Nursing Facility
SRS Stereotactic Radiosurgery
TEP Technical Expert Panel
TMS Transcranial Magnetic Stimulation Therapy
TOPs Transitional Outpatient Payments
UR Utilization review
USPSTF United States Preventive Services Task Force
UTI Urinary tract infection
VBP Value-based purchasing
WAC Wholesale acquisition cost

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I. Summary and Background

A. Executive Summary of This Final Rule With Comment Period

1. Purpose

In this final rule with comment period, we are updating the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments and Ambulatory Surgical Centers (ASCs) beginning January 1, 2013. Section 1833(t) of the Social Security Act (the Act) requires us to annually review and update the relative payment weights and the conversion factor for services payable under the Outpatient Prospective Payment System (OPPS). Under section 1833(i) of the Act, we annually review and update the ASC payment rates. We describe these and various other statutory authorities in the relevant sections of this final rule.

In addition to establishing payment rates for CY 2013, we are updating and implementing new requirements under the Hospital Outpatient Quality Reporting (OQR) Program, the Ambulatory Surgical Center Quality Reporting (ASCQR) Program, and the Inpatient Rehabilitation Facility (IRF) Quality Reporting Program. We are continuing the electronic reporting pilot for the Electronic Health Record (EHR) Incentive Program and making revisions to the regulations governing the Quality Improvement Organizations (QIOs), including the secure transmittal of electronic medical information, beneficiary complaint resolution and notification processes, and technical corrections. The technical changes to the QIO regulations that we are making to improve the regulations reflect CMS' commitment to the principles of the President's Executive Order on Regulatory Reform, Executive Order 13563 (January 18, 2011).

2. Summary of the Major Provisions

- *OPPS Update:* For CY 2013, we are increasing the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 1.8 percent. This increase is based on the final hospital inpatient market basket percentage increase of 2.6 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the multifactor productivity (MFP) adjustment of 0.7 percentage points, and minus a 0.1 percentage point adjustment required by the Affordable Care Act. Under this final rule with comment period, we estimate that total payments for CY 2013, including beneficiary cost-sharing, to the more than 4,000 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and community mental health centers (CMHCs)), will be approximately $48.1 billion, an increase of approximately $4.6 billion compared to CY 2012 payments, or $600 million excluding our estimated changes in enrollment, utilization, and case-mix.

We are continuing to implement the statutory 2.0 percentage point reduction in payments for hospitals failing to meet the hospital outpatient quality reporting requirements, by applying a reporting factor of 0.980 to the OPPS payments and copayments for all applicable services.

- *Geometric Mean-Based Relative Payment Weights:* CMS has discretion under the statute to set OPPS payments based upon either the estimated mean or median costs of services within an Ambulatory Payment Classification (APC) group, the unit of payment. To improve our cost estimation process, for

CY 2013 we are using the geometric mean costs of services within an APC to determine the relative payment weights of services, rather than the median costs that we have used since the inception of the OPPS. Our analysis shows that the change to means will have a limited payment impact on most providers, with a small number experiencing payment gain or loss based on their service-mix.

• *Rural Adjustment:* We are continuing the adjustment of 7.1 percent to the OPPS payments to certain rural sole community hospitals (SCHs), including essential access community hospitals (EACHs). This adjustment will apply to all services 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 cost.

• *Cancer Hospital Payment Adjustment:* For CY 2013, we are continuing our policy to provide additional payments to cancer hospitals so that the hospital's payment-to-cost ratio (PCR) with the payment adjustment is equal to the weighted average PCR for the other OPPS hospitals using the most recent submitted or settled cost report data. Based on those data, a target PCR of 0.91 will be used to determine the CY 2013 cancer hospital payment adjustment to be paid at cost report settlement. That is, the payment amount associated with the cancer hospital payment adjustment will be the additional payment needed to result in a PCR equal to 0.91 for each cancer hospital.

• *Payment Adjustment Policy for Radio-Isotopes Derived from Non-Highly Enriched Uranium Sources:* We are exercising our statutory authority to make payment adjustments necessary to ensure equitable payments in order to provide an adjustment for CY 2013 to cover the marginal cost of hospital conversion to the use of non-HEU sources of radio-isotopes used in medical imaging. The adjustment will cover the marginal cost of radio-isotopes produced from non-HEU sources over the costs of radio-isotopes produced by HEU sources.

• *Payment of Drugs, Biologicals, and Radiopharmaceuticals:* For CY 2013, payment for the acquisition and pharmacy overhead costs of separately payable drugs and biologicals that do not have pass-through status will be set at the statutory default of average sales price (ASP) plus 6 percent.

• *Supervision of Hospital Outpatient Therapeutic Services:* We are clarifying the application of the supervision regulations to physical therapy, speech-language pathology, and occupational therapy services that are furnished in OPPS hospitals and critical access hospitals (CAHs). In addition, in this final rule we note that we will extend the enforcement instruction one final year through CY 2013. This additional year, which we expect will be the final year of the extension, will provide additional opportunities for stakeholders to bring their issues to the Hospital Outpatient Payment Panel.

• *Outpatient Status:* We are concerned about recent increases in the length of time that Medicare beneficiaries spend as outpatients receiving observation services. In addition, hospitals continue to express concern about Medicare Part A to Part B rebilling policies when a hospital inpatient claim is denied because the inpatient admission was not medically necessary. In the CY 2013 OPPS/ASC proposed rule (77 FR 45155 through 45157), we provided an update on the Part A to Part B Rebilling Demonstration that is in effect for CY 2012 through CY 2014, which was designed to assist us in evaluating these issues. We also solicited public comments on potential clarifications or changes to our policies regarding patient status that may be appropriate, which we discuss in this final rule with comment period.

• *Ambulatory Surgical Center Payment Update:* For CY 2013, we are increasing payment rates under the ASC payment system by 0.6 percent. This increase is based on a projected CPI–U update of 1.4 percent minus a multifactor productivity adjustment required by the Affordable Care Act that is projected to be 0.8 percent. Based on this update, we estimate that total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix), for CY 2013 will be approximately $4.074 billion, an increase of approximately $310 million compared to estimated CY 2012 payments.

• *New Technology Intraocular Lenses:* We are revising the regulations governing payments for new technology intraocular lenses (NTIOLs) to require that the IOL's labeling, which must be approved by the FDA, contain a claim of a specific clinical benefit based on a new lens characteristic in comparison to currently available IOLs. We also are revising the regulations to require that any specific clinical benefit referred to in § 416.195(a)(2) must be supported by evidence that demonstrates that the IOL results in a measurable, clinically meaningful, improved outcome.

• *Ambulatory Surgical Center Quality Reporting (ASCQR) Program:* For the ASCQR Program, we address the public comments received as a result of our solicitation in the proposed rule on our approach for future measure selection and development as well as certain measures for future potential inclusion in the ASCQR Program measure set. We are finalizing our approach to future measure selection and development for the ASCQR Program. For the CY 2015 payment determination and subsequent years' payment determinations, we are adopting requirements for claims-based measures regarding the dates for submission and payment of claims and data completeness. We also are finalizing our policy regarding how the payment rates will be reduced in CY 2014 and in subsequent calendar years for ASCs that fail to meet program requirements, and we are clarifying our policy on updating measures.

• *Hospital Outpatient Quality Reporting (OQR) Program:* For the Hospital OQR Program, we are not establishing any new measures for CY 2013. We also are not specifying any new targeting criteria to select hospitals for validation of medical records. We are confirming the removal or suspension of data collection for specific measures. We are specifying that the criteria we will consider when determining whether to remove measures for the Hospital Inpatient Quality Reporting (IQR) Program will also apply to the Hospital OQR Program. We are providing that measures adopted in future rulemaking are automatically adopted for all subsequent year payment determinations unless we remove, suspend, or replace them. We are making changes to administrative forms used in the program. We are extending the deadline for submitting a notice of participation form and to enter structural measures data.

• *Electronic Health Record (EHR) Incentive Program:* For the EHR Incentive Program, we are extending the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs through 2013, exactly as finalized for 2012. We recently issued a final rule (77 FR 53968) for Stage 2 of the Medicare and Medicaid EHR Incentive Programs.

• *Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP):* We are: (1) Adopting updates on one (out of two) previously adopted measure for the IRF QRP that will affect annual prospective payment amounts for FY 2014; (2) adopting a nonrisk-adjusted version of an NQF-endorsed pressure ulcer measure for the IRF QRP, and we will not publicly report any pressure ulcer measure data until we begin risk adjustment of these data; (3) adopting a

policy that will provide that any measure that has been adopted for use in the IRF QRP will remain in effect until the measure is actively removed, suspended, or replaced; and (4) adopting policies regarding when notice-and-comment rulemaking will be used to update existing IRF QRP measures.

• *Revisions to the Quality Improvement Organization (QIO) Regulations:* We are revising the QIO program regulations to: (1) Give QIOs the authority to send and receive secure transmissions of electronic versions of medical information; (2) provide more detailed and improved procedures for QIOs when completing Medicare beneficiary complaint reviews and general quality of care reviews, including procedures related to a new alternative dispute resolution process called ''immediate advocacy''; (3) increase the information beneficiaries receive in response to QIO review activities; (4) convey to Medicare beneficiaries the right to authorize the release of confidential information by QIOs; and (5) make other technical changes that are designed to improve the regulations. The technical changes to the QIO regulations that we are making to improve the regulations reflect CMS' commitment to the principles of the President's Executive Order on Regulatory Reform, Executive Order 13563 (January 18, 2011).

3. Summary of Costs and Benefits

In sections XXII. and XXIII. of this final rule with comment period, we set forth a detailed analysis of the regulatory and federalism impacts that the changes will have on affected entities and beneficiaries. Key estimated impacts include the following:

a. Impacts of the OPPS Update

(1) Impacts of All OPPS Changes

Table 57 in section XXII. of this final rule with comment period displays the distributional impact all the OPPS changes on various groups of hospitals and CMHCs for CY 2013 compared to all estimated OPPS payments in CY 2012. We estimate that the policies in this final rule will result in a 1.9 percent overall increase in OPPS payments to providers. We estimate that the increase in OPPS expenditures, including beneficiary cost-sharing, will be approximately $600 million, not taking into account potential changes in enrollment, utilization, and case-mix. Taking into account estimated spending changes that are attributable to these factors, we estimate an increase of approximately $4.571 billion in OPPS expenditures, including beneficiary cost-sharing, for CY 2013 compared to CY 2012 OPPS expenditures. We estimate that total OPPS payments, including beneficiary cost-sharing, will be $48.1 billion for CY 2013.

We estimated the isolated impact of our OPPS policies on CMHCs because CMHCs are only paid for partial hospitalization services under the OPPS. Continuing the provider-specific structure that we adopted for CY 2011 and basing payment fully on the type of provider furnishing the service, we estimate a 4.4 percent decrease in CY 2013 payments to CMHCs relative to their CY 2012 payments.

(2) Impacts of Basing APC Relative Payment Weights on Geometric Mean Costs

We estimate that our final policy to base the APC relative payment weights on the geometric mean costs rather than the median costs of services within an APC will not significantly impact most providers. Payments to very low volume urban hospitals and to hospitals for which disproportionate share hospital (DSH) data are not available will increase by an estimated 2.5 and 4.3 percent, respectively. The hospitals for which DSH data are not available are largely non-IPPS psychiatric hospitals. In contrast, payments to CMHCs will decrease by an estimated 3.9 percent due to basing the relative payment weights on the geometric mean costs of services rather than the median costs of services.

(3) Impacts of the Updated Wage Indices

We estimate no significant impacts related to updating the wage indices and applying the frontier State wage index. Adjustments to the wage indices other than the frontier State wage adjustment will not significantly affect most hospitals. The updated wage indices will most affect urban hospitals in the Pacific and East South Central regions and rural hospitals in the Mountain and Pacific regions.

(4) Impacts of the Rural Adjustment and the Cancer Hospital Payment Adjustment

There are no significant impacts of our CY 2013 payment policies for hospitals that are eligible for the rural adjustment or for the cancer hospital payment adjustment. We are not making any change in policies for determining the rural and cancer hospital payment adjustments, and the adjustment amounts do not significantly impact the budget neutrality adjustments for these policies.

(5) Impacts of the OPD Fee Schedule Increase Factor

We estimate that, for most hospitals, the application of the OPD fee schedule increase factor of 1.8 percent to the conversion factor for CY 2013 will mitigate the small negative impacts of the budget neutrality adjustments. Certain low volume hospitals and hospitals for which DSH data are not available will experience larger increases ranging from 4.5 percent to 8.2 percent. As a result of the OPD fee schedule increase factor and other budget neutrality adjustments, we estimate that rural and urban hospitals will experience similar increases of approximately 1.8 percent for urban hospitals and 2.1 percent for rural hospitals. Classifying hospitals by teaching status or type of ownership suggests that these hospitals will receive similar increases.

b. Impacts of the ASC Payment Update

For impact purposes, the surgical procedures on the ASC list of covered procedures are aggregated into surgical specialty groups using CPT and HCPCS code range definitions. The percentage change in estimated total payments by specialty groups under the CY 2013 payment rates compared to estimated CY 2012 payment rates ranges between −3 percent for respiratory system procedures, integumentary system procedures, and cardiovascular system procedures and 3 percent for nervous system procedures.

c. Impacts of the Hospital OQR Program

We do not expect our CY 2013 policies to significantly affect the number of hospitals that do not receive a full annual payment update.

d. Impacts of the EHR Incentive Program Proposal

There are no changes from the 2012 OPPS/ASC final rule to the costs or impact for the 2013 Medicare EHR Incentive Program Electronic Reporting Pilot for Hospitals and CAHs.

e. Impacts of the ASCQR Program

We do not expect our CY 2013 final policies to significantly affect the number of ASCs that do not receive a full annual payment update beginning in CY 2014.

B. Legislative and Regulatory Authority for the Hospital OPPS

When Title XVIII of the Social Security 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 parts 410 and 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); the Medicare and Medicaid Extenders Act of 2010 (MMEA, Pub. L. 111–309); the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA, Pub. L. 112–78), enacted on December 23, 2011; and most recently the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA, Pub. L. 112–96), enacted on February 22, 2012.

Under the OPPS, we pay for hospital outpatient services on a rate-per-service basis that varies according to the 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. The OPPS includes payment for most hospital outpatient services, except those identified in section I.C. 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 CMHCs), and certain inpatient hospital services designated by the Secretary that are furnished to inpatients who are entitled to Part A and have exhausted their Part A benefits, or who are not so entitled.

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 (or mean cost, if elected by the Secretary) 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 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 clinical information and cost 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.

C. 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 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 IPPS. We set forth the services that are excluded from payment under the OPPS in regulations at 42 CFR 419.22.

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; CAHs; hospitals located outside of the 50 States, the District of Columbia, and Puerto Rico; and Indian Health Service (IHS) hospitals.

D. 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/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

E. Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel), Formerly Named the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel)

1. Authority of the 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 external advisory panel of experts to annually review the clinical integrity of the payment groups and their weights under the OPPS. In CY 2000, based on section 1833(t)(9)(A) of the Act and section 222 of the Public Health Service (PHS) Act, the Secretary established the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel) to fulfill this requirement. In CY 2011, based on section 222 of the PHS Act which gives discretionary authority to the Secretary to convene advisory councils and committees, the Secretary expanded the panel's scope to include the supervision of hospital outpatient therapeutic services in addition to the APC groups and weights. To reflect this new role of the panel, the Secretary changed the panel's name to the Advisory Panel on Hospital Outpatient Payment (the HOP Panel, or the Panel). The Panel is not restricted to using data compiled by CMS, and in conducting its review it may use data collected or developed by organizations outside the Department.

2. Establishment of the Panel

On November 21, 2000, the Secretary signed the initial charter establishing the HOP Panel, at that time named the APC Panel. This expert panel, which may be composed of up to 19 appropriate representatives of providers (currently employed full-time, not as consultants, in their respective areas of expertise), reviews clinical data and advises CMS about the clinical integrity of the APC groups and their payment weights. Since CY 2012, the Panel also is charged with advising the Secretary on the appropriate level of supervision for individual hospital outpatient therapeutic services. The 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 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 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 charter was amended on November 15, 2011 and the Panel was renamed to reflect expanding the Panel's authority to include supervision of hospital outpatient therapeutic services and therefore to add CAHs to its membership.

The current Panel membership and other information pertaining to the 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. Panel Meetings and Organizational Structure

The Panel has held multiple meetings, with the last meeting taking place on August 27–28, 2012. Prior to each meeting, we publish a notice in the **Federal Register** to announce the meeting and, when necessary, to solicit nominations for Panel membership and to announce new members.

The Panel has established an operational structure that, in part, currently includes the use of three subcommittees to facilitate its required 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 Panel and for recommending options for resolving them. The Visits and Observation Subcommittee reviews and makes recommendations to the Panel on all technical issues pertaining to observation services and hospital outpatient visits paid under the OPPS (for example, APC configurations and APC relative 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 APC placement of HCPCS codes regarding services for which separate payment is made.

Each of these subcommittees was established by a majority vote from the full Panel during a scheduled Panel meeting, and the Panel recommended that the subcommittees continue at the August 2012 Panel meeting. We accepted this recommendation.

Discussions of the other recommendations made by the Panel at the February 2012 and August 2012 Panel meetings are included in the sections of this final rule that are specific to each recommendation. For discussions of earlier Panel meetings and recommendations, we refer readers to previously published 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*.

F. Public Comments Received in Response to the CY 2013 OPPS/ASC Proposed Rule

We received approximately 668 timely pieces of correspondence on the CY 2013 PPS/ASC proposed rule that appeared in the **Federal Register** on July 30, 2012 (77 FR 45061). We note that we received some public comments that were outside the scope of the proposed rule and that are not addressed in this 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 subject-matter headings.

G. Public Comments Received on the CY 2012 OPPS/ASC Final Rule With Comment Period

We received approximately 61 timely pieces of correspondence on the CY 2012 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on November 30, 2011 (76 FR 74122), some of which contained 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. Summaries of these public comments on topics that were open to comment and our responses to them are set forth in various sections of this final rule with comment period under the appropriate subject-matter headings.

II. Updates Affecting OPPS Payments

A. Recalibration of APC Relative Payment 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 2013 OPPS/ASC proposed rule (77 FR 45071), for the CY 2013 OPPS, we proposed to recalibrate the APC relative payment weights for services furnished on or after January 1, 2013, and before January 1, 2014 (CY 2013), using the same basic methodology that we described in the CY 2012 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 2013, we used approximately 141 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, 2011, and before January 1, 2012. For this final rule with comment period, for the purpose of recalibrating the final APC relative payment weights for CY 2013, we used approximately 153 million final action claims (claims for which all disputes and adjustments have been resolved and payment has been made) for HOPD services furnished on or after January 1, 2011, and before January 1, 2012. 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/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

Of the approximately 153 million final action claims for services provided in hospital outpatient settings used to calculate the final CY 2013 OPPS payment rates for this final rule with comment period, approximately 121 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 approximately 121 million claims, approximately 5 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 116 million claims, we created approximately 120 million single records, of which approximately 81 million were ''pseudo'' single or ''single session'' claims (created from approximately 39 million multiple procedure claims using the process we discuss later in this section). Approximately 1 million claims were trimmed out on cost or units in excess of ±3 standard deviations from the geometric mean, yielding approximately 120 million single bills for ratesetting. 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 payment 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 2013 ratesetting some portion of approximately 95 percent of the CY 2011 claims containing services payable under the OPPS.

The final APC relative weights and payments for CY 2013 in Addenda A and B to this final rule with comment period (which are available via the Internet on the CMS Web site) were calculated using claims from CY 2011 that were processed through June 30, 2012. While we have historically based the payments on median hospital costs for services in the APC groups, we proposed in the CY 2013 OPPS/ASC proposed rule (77 FR 45071) to establish the cost-based relative payment weights of the CY 2013 OPPS using geometric mean costs, as discussed in section II.A.2.f. of this final rule with comment period. Therefore, on the CMS Web site, along with Addenda A and B, we provided a file that presented payment information for the proposed CY 2013 OPPS payments based on geometric mean costs compared to those based on median costs. Under this methodology, 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 relative costs underpinning the APC relative payment weights and the CY 2013 payment rates.

b. Use of Single and Multiple Procedure Claims

For CY 2013, in general, we proposed to continue to use single procedure claims to set the costs on which the APC relative payment weights are based. We generally use single procedure claims to set the estimated 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 enables 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 2012 OPPS/ASC final rule with comment period (76 FR 74132 through 74134). In addition, for CY 2008 (72 FR 66614 through 66664), we increased packaging and created the first composite APCs, and continued

those policies through CY 2012. Increased packaging and creation of composite APCs also increased the number of bills that we were able to use for ratesetting 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 in developing the OPPS relative weights on which payments are based. We have continued the composite APCs for multiple imaging services through CY 2012. We did not receive any public comments on this policy, and therefore, we are finalizing our proposal to continue this policy for CY 2013. We refer readers to section II.A.2.e. of this final rule with comment period for a discussion of the use of claims in modeling the 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 2013 OPPS. This methodology enabled us to create, for this final rule with comment period, approximately 81 million ''pseudo'' single procedure claims, including multiple imaging composite ''single session'' bills (we refer readers to section II.A.2.e.(5) of this final rule with comment period for further discussion), to add to the approximately 39 million ''natural'' single procedure claims. For this final rule with comment period, ''pseudo'' single procedure and ''single session'' procedure bills represented approximately 67 percent of all single procedure bills used for ratesetting purposes.

For CY 2013, we proposed to bypass 480 HCPCS codes that were identified in Addendum N to the CY 2013 OPPS/ASC proposed rule (which was 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 2013, data available for the February 27, 2012 meeting of the Advisory Panel on Hospital Outpatient Payment (the Panel) from CY 2011 claims processed through September 30, 2011, and CY 2010 claims data processed through June 30, 2011, used to model the payment rates for CY 2012) to determine whether it would be appropriate to add additional codes to the previous year's bypass list. For CY 2013, we proposed to continue to bypass all of the HCPCS codes on the CY 2012 OPPS bypass list, with the exception of HCPCS codes that we proposed to delete for CY 2013, which are listed in Table 1 of the proposed rule. We also proposed to remove HCPCS codes that are not separately paid under the OPPS because the purpose of the bypass list is to obtain more data for those codes relevant to ratesetting. In addition, we proposed to add to the bypass list for CY 2013 HCPCS codes not on the CY 2012 bypass list that, using either the CY 2012 final rule data (CY 2010 claims) or the February 27, 2012 Panel data (first 9 months of CY 2011 claims), met the empirical criteria for the bypass list that are summarized below. Finally, to remain consistent with the CY 2013 final policy to develop OPPS relative payment weights based on geometric mean costs, we proposed that the median cost of packaging criterion instead be based on the geometric mean cost of packaging. The entire list proposed for CY 2013 (including the codes that remain on the bypass list from prior years) was open to public comment in the CY 2013 OPPS/ASC proposed rule. 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. As we proposed, the criteria for the bypass list are:

- 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 geometric mean 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.

We note that, in the CY 2013 OPPS/ASC proposed rule (77 FR 45072), we proposed to establish the CY 2013 OPPS relative payment weights based on geometric mean costs. To remain consistent in the metric used for identifying cost patterns, we proposed to use the geometric mean cost of packaging to identify potential codes to add to the bypass list. The development of the CY 2013 OPPS relative payment weights based on geometric mean costs is discussed in greater detail in section II.A.2.f. of this final rule with comment period.

In response to public comments on 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. Based on the same rationale described for the CY 2012 OPPS/ASC final rule with comment period (76 FR 74133), we proposed for CY 2013 to continue to update the packaged cost threshold by the market basket increase. By applying the final CY 2012 market basket increase of 1.9 percent to the prior non-rounded dollar threshold of $52.76 (76 FR 74133), we determined that the threshold remains for CY 2013 at $55 ($53.76 rounded to $55, the nearest $5 increment). Therefore, we proposed to set the geometric mean packaged cost threshold on the CY 2011 claims at $55 for a code to be considered for addition to the CY 2013 OPPS bypass list.

- The code is not a code for an unlisted service. Unlisted codes do not describe a specific service, and thus their costs would not be appropriate for bypass list purposes.

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 2013 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 certain HCPCS codes on the bypass list 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 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 costs. ''Overlap bypass codes'' that are members of the multiple imaging composite APCs are identified by asterisks (*) in Addendum N to this final rule with comment period (which is available via the Internet on the CMS Web site).

Addendum N to this final rule with comment period includes the list of bypass codes for CY 2013. The list of bypass codes contains codes that were reported on claims for services in CY 2011 and, therefore, includes codes that were in effect in 2011 and used for billing but were deleted for CY 2012. We retained these deleted bypass codes on the CY 2013 bypass list because these codes existed in CY 2011 and were covered OPD services in that period, and CY 2011 claims data are used to calculate CY 2013 payment rates. Keeping these deleted bypass codes on the bypass list potentially allows us to create more ''pseudo'' single procedure claims for ratesetting purposes. ''Overlap bypass codes'' that were members of the proposed multiple imaging composite APCs are identified by asterisks (*) in the third column of Addendum N to this final rule with comment period. HCPCS codes that we are adding for CY 2013 are identified by asterisks (*) in the fourth column of Addendum N. Table 1 of the proposed rule contained the list of codes that we proposed to remove from the CY 2013 bypass list for CY 2013 (77 FR 45073).

Comment: One commenter supported the proposal to include CPT codes 76881 (Ultrasound, extremity, nonvascular, real-time with image documentation; complete) and 76882 (Ultrasound, extremity, nonvascular, real-time with image documentation; limited, anatomic specific) on the CY 2013 OPPS bypass list.

Response: We appreciate the commenter's support.

Comment: Several commenters expressed appreciation for our efforts to include multiple procedure claims in the ratesetting process through processes such as the bypass list and date of service stratification, which are used to create ''pseudo'' single claims. However, the commenters remained concerned about the limited number of claims used to model brachytherapy APCs 0312 (Radioelement Applications), 0651 (Complex Interstitial Radiation Source Application), and 8001 (LDR Prostate Brachytherapy Composite) and encouraged CMS to continue exploring potential methodologies through which more claims data could be used in OPPS ratesetting.

Response: We appreciate the commenters' support of our efforts to include more appropriate claims data for ratesetting purposes. As discussed above, one of the challenges in modeling the APC costs on which the OPPS/ASC relative payment weights are based is appropriately allocating the packaged cost associated with a service, when multiple separately payable procedures appear on the claim. However, recognizing the challenges associated with obtaining additional information, we will continue to explore potential methodologies through which we would be able to derive accurate cost data from the multiple major procedure claims made available to us.

After consideration of the public comments we received, we are adopting as final the proposed ''pseudo'' single claims process and the final CY 2013 bypass list of 480 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 2013 bypass list because these codes were either deleted from the HCPCS before CY 2011 (and therefore were not covered OPD services in CY 2011) or were not separately payable codes under the CY 2013 OPPS because these codes are not used for ratesetting (and therefore would not need to be bypassed). None of these deleted codes are ''overlap bypass'' codes.

TABLE 1.—HCPCS CODES REMOVED FROM THE CY 2013 BYPASS LIST

HCPCS Code	HCPCS Short Descriptor
76880	Us exam, extremity
86903	Blood typing, antigen screen
92135	Ophth dx imaging post seg
93231	Ecg monitor/record, 24 hrs
93232	ECG monitor/report, 24 hrs
93236	ECG monitor/report, 24 hrs

c. Calculation and Use of Cost-to-Charge Ratios (CCRs)

In the CY 2013 OPPS/ASC proposed rule (77 FR 45073), for CY 2013, we proposed to continue to use the hospital-specific overall ancillary and departmental cost-to-charge ratios (CCRs) to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk. To calculate the APC costs on which the proposed CY 2013 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 2011 claims data from the most recent available hospital cost reports, in most cases, cost reports beginning in CY 2010. For the CY 2013 OPPS proposed rates, we used the set of claims processed during CY 2011. 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/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

To ensure the completeness of the revenue code-to-cost center crosswalk, we reviewed changes to the list of revenue codes for CY 2011 (the year of the claims data we used to calculate the proposed CY 2013 OPPS payment rates) and found that the National Uniform Billing Committee (NUBC) did not add any new revenue codes to the NUBC 2011 Data Specifications Manual.

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, as detailed in the CY 2007 OPPS/ASC final rule with comment period, is the calculation of blood costs, as discussed in section II.A.2.d.(2) of 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 hospitals that filed outpatient claims in CY 2011 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 2010. For the proposed rule, we used the most recently submitted cost reports to calculate the CCRs to be used to calculate costs for the proposed CY 2013 OPPS payment rates. If the most recently 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 above for all purposes that require use of an overall ancillary CCR. We proposed to continue this longstanding methodology for the calculation of costs for CY 2013.

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. This issue was evaluated in a report by Research Triangle Institute, International (RTI). 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 (73 FR 48458 through 45467). Specifically, we created one cost center for ''Medical Supplies Charged to Patients'' and one cost center for ''Implantable Devices Charged to Patients,'' essentially splitting the then current cost center for ''Medical

Supplies Charged to Patients'' into one cost center for low-cost medical supplies and another cost center for high-cost implantable devices in order to mitigate some of the effects of charge compression. In determining the items that should be reported in these respective cost centers, we adopted commenters' recommendations that hospitals should use revenue codes established by the AHA's NUBC to determine the items that should be reported in the ''Medical Supplies Charged to Patients'' and the ''Implantable Devices Charged to Patients'' cost centers. 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.

The cost center for ''Implantable Devices Charged to Patients'' has been available for use for cost reporting periods beginning on or after May 1, 2009. As discussed in the CY 2013 OPPS/ASC proposed rule (77 FR 45074), 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. In preparation for the CY 2013 proposed rule, we assessed the availability of data in the ''Implantable Devices Charged to Patients'' cost center using cost reports in the December 31, 2011 quarter ending update of HCRIS, which was the latest upload of the cost report data that we could use for the CY 2013 proposed rule. We determined that 2,063 hospitals, out of approximately 3,800 hospitals, utilized the ''Implantable Devices Charged to Patients'' cost center. Because we believe that this is a sufficient amount of data from which to generate a meaningful analysis, we proposed to use data from the ''Implantable Devices Charged to Patients'' cost center to create a distinct CCR for use in calculating the OPPS relative payment weights for CY 2013.

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 and CY 2009 OPPS/ASC proposed and final rules, RTI also found that the costs and charges of CT scans, MRIs, and cardiac catheterization differ significantly from the costs and charges of other services included in the standard associated cost center. RTI concluded that both the IPPS and the OPPS relative payment weights would better estimate the costs of those services if CMS were to add standard costs centers for CT scans, MRIs, and cardiac catheterization in order for hospitals to report separately the costs and charges for those services and in order for CMS to calculate unique CCRs to estimate the 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, MRIs, and cardiac catheterization. The new standard cost centers for CT scans, MRIs, and cardiac catheterization are effective for cost report periods beginning on or after May 1, 2010, on the revised cost report Form CMS–2552–10. However, because cost reports that were filed on the revised cost report Form CMS–2552–10 are not currently accessible in the HCRIS, we were unable to calculate distinct CCRs for CT scans, MRIs, and cardiac catheterization using the new standard cost centers for these services. We believe that we will have cost report data available for an analysis of creating distinct CCRs for CT scans, MRIs, and cardiac catheterization for the CY 2014 OPPS rulemaking.

Comment: Many commenters supported CMS' proposal to use data from the ''Implantable Devices Charged to Patients'' cost center to create a distinct CCR for use in calculating the OPPS relative payment weights for CY 2013. The commenters also encouraged CMS to continue to engage in educational efforts related to the use of the new cost center so that hospitals understand how to accurately report data in the new cost center. In addition, the commenters suggested that the Medicare administrative contractors (MACs) develop an audit program that would identify hospitals that have not reported data for the new cost center.

Response: We appreciate the commenters' support of our proposal to use data from the ''Implantable Devices Charged to Patients'' cost center to create a distinct CCR. We agree with commenters 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 under the new Medicare cost report form CMS–2552–10. The new cost report form also facilitates greater audit scrutiny from the MACs. Line 121 of Worksheet S–2, Part I, of cost report form CMS–2552–10 asks ''Did this facility incur and report costs for implantable devices charged to a patient? Enter in column 1 'Y' for yes and 'N' for no.''

Comment: Two commenters recommended that CMS wait until CY 2014 OPPS rulemaking to determine if the ''Implantable Devices Charged to Patients'' cost center should be used to create a distinct CCR. The commenters did not believe that data from 2,063 hospitals provide a meaningful representation of all of the hospitals subject to the OPPS from which to base the proposal to use the new cost center for CY 2013.

Response: We disagree with the commenters and believe that data from the 2,063 hospitals that utilized the ''Implantable Devices Charged to Patients'' cost center, out of approximately 3,800 hospitals, are sufficient and appropriate for creating a distinct CCR to use in the calculation of the CY 2013 OPPS relative payment weights.

Comment: Commenters expressed disappointment that, because the revised cost report Form CMS–2552–10 was not accessible in the HCRIS at the time of the proposed rule, CMS was not able to create distinct CCRs for CT scans, MRIs, and cardiac catheterization services for use in the calculation of the CY 2013 OPPS relative payment weights. The commenters urged CMS to analyze the data in the new CT scan, MRI, and cardiac catheterization cost centers when the data are available and utilize the new cost centers in the development of the OPPS relative payment weights as soon as possible.

Response: We expect that we will have sufficient and appropriate cost report data available for an analysis of creating distinct CCRs for CT scans, MRIs, and cardiac catheterization for the CY 2014 rulemaking. If so, as was done for the ''Implantable Devices Charged to Patients'' cost center for the CY 2013 OPPS/ASC proposed rule, we expect to provide an impact analysis in the CY 2014 OPPS/ASC proposed rule that will enable the public to assess the full impact of the use of the new CCRs specific to CT scans, MRIs, and cardiac catheterization on payments for all services.

Comment: One commenter recommended that CMS require the use of the new nonstandard cost center for cardiac rehabilitation instead of making its use optional.

Response: We created the new nonstandard cost center for cardiac rehabilitation because we believed that

this would facilitate more accurate cost reporting for these services. The nonstandard cost centers are additional common cost centers available to hospitals for reporting when preparing their Medicare hospital cost report. To the extent hospitals provide services captured by nonstandard cost centers, they should report the relevant nonstandard cost centers as well. However, we do not specify a revenue code-to-cost center crosswalk that hospitals must adopt to prepare the cost report and, therefore, we do not believe that we should require hospitals to use the nonstandard cost center for cardiac rehabilitation.

After consideration of the public comments we received, we are finalizing our proposal to use data from the ''Implantable Devices Charged to Patients'' cost center to create a distinct CCR for use in calculating the OPPS relative payment weights for CY 2013.

2. Data Development Process and Calculation of Costs Used for Ratesetting

In this section of this final rule with comment period, we discuss the use of claims to calculate OPPS payment rates for CY 2013. The Hospital OPPS page on the CMS Web site on which this final rule with comment period is posted (*http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*) provides an accounting of claims used in the development of the final payment rates. 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. The CMS Web site, *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*, 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 2011 claims that were used to calculate the final payment rates for the CY 2013 OPPS.

In the history of the OPPS, we have traditionally established the scaled relative weights on which payments are based using APC median costs, which is a process most recently described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74188). However, as discussed in more detail in section II.A.2.f. of this final rule with comment period, we proposed to use geometric mean costs to calculate the relative weights on which the CY 2013 OPPS payment rates are based. While this policy changes the cost metric on which the relative payments are based, the data process in general remains the same, under the methodologies that we use to obtain appropriate claims data and accurate cost information in determining estimated service cost.

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 costs we used to establish the relative weights used in calculating the OPPS payment rates for CY 2013 shown in Addenda A and B to this final rule with comment period (which are available via the Internet on the CMS Web site). For the proposed rule, we provided a comparison file so that the public could provide meaningful comment on our proposal to base the CY 2013 OPPS relative payment weights on geometric mean costs. We refer readers to section II.A.4. of this final rule with comment period for a discussion of the conversion of APC costs to scaled payment weights.

Comment: Commenters expressed concern with respect to the volatility of the OPPS payment rates from year to year. The commenters suggested a ''stability policy'' and suggested that the 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 2012 OPPS/ASC final rule with comment period (76 FR 74139), there are a number of factors that contribute to cost 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 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, we believe that implementing the policy suggested by the commenters would make payments less reflective of the true service costs, which would be contrary to a purpose of our proposed CY 2013 policy of establishing relative payment weights based on geometric mean 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.

a. Claims Preparation

For this final rule with comment period, we used the CY 2011 hospital outpatient claims processed through June 30, 2012, to calculate the geometric mean costs of APCs that underpin the relative payment weights for CY 2013. To begin the calculation of the relative payment weights for CY 2013, we pulled all claims for outpatient services furnished in CY 2011 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 121 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 on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. Revenue codes that we do not use in establishing relative costs 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 only influenza and pneumococcal pneumonia (PPV) vaccines. Influenza and PPV vaccines are paid at reasonable cost; 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 arithmetic and geometric mean and median cost and a per day arithmetic and geometric 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 past several years, we have developed payment policy for nonpass-through separately paid drugs and biologicals based on a redistribution methodology that accounts for pharmacy overhead by allocating cost from packaged drugs to separately paid drugs. This typically would have required us to reduce the cost associated with packaged coded and uncoded drugs in order to allocate that cost. However, for CY 2013, as we proposed, we are paying for separately payable drugs and biologicals under the OPPS at ASP + 6 percent, based upon the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. Therefore, under this policy, we do not redistribute the packaged cost. 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 in CY 2013.

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 removed from the inpatient list for CY 2012 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 2013, as we proposed, we are continuing the policy we implemented for CY 2012 to exclude line-item data for pass-through drugs and biologicals (status indicator ''G'' for CY 2011) and nonpass-through drugs and biologicals (status indicator ''K'' for CY 2011) 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 2012 OPPS/ASC final rule with comment period (76 FR 74141) 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 data used for ratesetting purposes.

b. Splitting Claims and Creation of ''Pseudo'' Single Procedure Claims

(1) Splitting Claims

For the CY 2013 OPPS, 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 are presented below.) For CY 2013, as we proposed, we are continuing 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 2013, as we proposed, we are continuing to assign 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. As we proposed, we are treating these codes in the same manner for data purposes for CY 2013 as we have treated them since CY 2008. Specifically, we are continuing 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 geometric mean 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, as we proposed, 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.

(2) Creation of ''Pseudo'' Single Procedure Claims

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 procedure claim).

We also use the bypass codes listed in Addendum N to this final rule with comment period (which is available via the Internet on our 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 final CY 2013 ''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. If 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.

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. If 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 costs on which the CY 2013 OPPS payments are based. 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, we also examine 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 2012 relative payment 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 2012 relative payment weight to create a ''pseudo'' single procedure claim for that code: Additional units of the status indicator ''Q1'' HCPCS code with the highest CY 2012 relative payment 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 geometric mean cost for the status indicator ''Q1'' HCPCS code.

Similarly, if 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 2012 relative payment weight 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 ''Q2'' HCPCS code that had the highest CY 2012 relative payment weight to create a ''pseudo'' single procedure claim for that code: Additional units of the status indicator ''Q2'' HCPCS code with the highest CY 2012 relative payment 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.

If 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 payment weight for CY 2012 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 2012 relative payment 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 selected status indicator ''Q2'' HCPCS codes instead of ''Q1'' HCPCS codes because ''Q2'' HCPCS codes have higher CY 2012 relative payment weights. If a status indicator ''Q1'' HCPCS code had a higher CY 2011 relative payment weight, it became 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, if they met the criteria for single procedure claims. Conditionally packaged codes are identified using status indicators ''Q1'' and ''Q2,'' and are described in section XII.A. of this final rule with comment period.

Lastly, 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 costs.

After consideration of the public comments we received, we are finalizing our proposals to continue to apply the methodology described above for the purpose of creating ''pseudo'' single procedure claims for the CY 2013 OPPS.

c. Completion of Claim Records and Geometric Mean Cost Calculations

(1) General Process

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 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, and as we proposed, we are continuing to compare the final list of packaged revenue codes that we are adopting for CY 2013 to the revenue codes that the I/OCE will package for CY 2013 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 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 on the CY 2010 proposed list of packaged revenue codes.

For CY 2013, as we did for CY 2012, we reviewed the changes to revenue codes that were effective during CY 2011 for purposes of determining the charges reported with revenue codes but without HCPCS codes that we are packaging for CY 2013. 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 2013, we proposed to continue 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 geometric mean costs on which the final CY 2013 OPPS/ASC payment rates 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 (77 FR 45079 through 45081), we are finalizing the proposed packaged revenue codes for CY 2013, 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 2011, the year of the claims data on which the final CY 2013 OPPS payment rates are based.

BILLING CODE 4120–01–P

TABLE 2.—CY 2013 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

Revenue Code	Description
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
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

Revenue Code	Description
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

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In accordance with our longstanding policy, we proposed to continue 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 payment 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 proposed to continue these processes for the CY 2013 OPPS.

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 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 geometric mean costs.

In accordance with our longstanding practice, we also proposed to exclude 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 116 million claims were left. Using these approximately 116 million claims, we created approximately 120 million single and ''pseudo'' single procedure claims, of which we used slightly more than 120 million single bills (after trimming out approximately 1 million claims as discussed in section II.A.1.a. of this final rule with comment period) in the CY 2013 geometric mean cost development and ratesetting.

As discussed above, the OPPS has historically developed the relative weights on which APC payments are based using APC median costs. For the CY 2013 OPPS, we proposed to calculate the APC relative payment weights using geometric mean costs; therefore, the following discussion of the 2 times rule violation and the development of the relative payment weight refers to geometric means. For more detail about the CY 2013 OPPS/ASC policy to calculate relative payment weights based on geometric means, we refer readers to section II.A.2.f. of this final rule with comment period.

We proposed to use these claims to calculate the CY 2013 geometric mean costs for each separately payable HCPCS code and each APC. The comparison of HCPCS code-specific and APC geometric mean costs 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 shall not be treated as 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 within 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 (the 2 times rule). While we have historically applied the 2 times rule based on median costs, as part of the CY 2013 policy to develop the OPPS relative payment weights based on geometric mean costs, we also are applying the 2 times rule based on geometric mean costs. For a detailed discussion of the CY 2013 policy to develop the APC relative payment weights based on geometric mean costs, we refer readers to section II.A.2.f. of this final rule with comment period.

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 geometric mean cost to be significant. 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 120 million single procedure or single session claims we use for establishing geometric mean 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 geometric mean. We note that this method of identifying significant HCPCS codes within an APC for purposes of the 2 times rule was used in prior years under the median-based cost methodology. Under our CY 2013 policy to base the relative payment weights on geometric mean costs, we believe that this same consideration for identifying significant HCPCS codes should apply because the principles are consistent with their use in the median-based cost methodology. 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 geometric mean. Finally, we reviewed the geometric mean costs for the services for which we 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 geometric mean costs and for other reasons. The APC geometric means were recalculated after we reassigned the affected HCPCS codes. Both the HCPCS code-specific geometric means and the APC geometric means were weighted to account for the inclusion of multiple units of the bypass codes in the creation of ''pseudo'' single procedure claims.

Comment: Some commenters asked that CMS provide an adjustment for medical education costs under the OPPS. These commenters stated that CMS indicated that it would study the costs and payment differential among different classes of providers in the April 7, 2000 OPPS final rule but has not done so. The commenters requested that CMS conduct its own analysis and that, if that analysis showed a difference in their payment to cost ratios (similar to the comparison study performed to calibrate the cancer hospital payment adjustment) due to the unique missions of teaching hospitals, CMS should add a teaching payment adjustment under the OPPS.

Response: Unlike payment under the IPPS, the law does not specifically provide for payment for direct or indirect graduate medical education costs to be made under the OPPS. Section 1833(t)(2)(E) of the Act states that the Secretary shall establish, in a budget neutral manner ''* * * other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals.'' We have not found such an adjustment to be necessary to ensure equitable payments to teaching hospitals and, therefore, have not developed such an adjustment. As the commenters recognized, the cancer hospital payment adjustment discussed in section II.F. of this final rule with comment period was established based on section 1833(t)(18) of the Act. Similarly, those hospitals were permanently held harmless and continued to receive TOPs under section 1833(t)(7)(d)(ii) of the Act. Furthermore, in this final rule with comment period, we have developed OPPS relative payment weights that we believe provide appropriate and adequate payment for the complex medical services, such as new technology services and device-dependent procedures, which we understand are furnished largely by teaching hospitals. The impacts of the final CY 2013 policies, by class of hospital, are displayed in Table 57 in section XXII. of this final rule with comment period.

After consideration of the public comments we received, we are finalizing our proposed CY 2013 methodology for calculating the costs upon which the CY 2013 OPPS payment rates are based.

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 geometric mean 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 geometric mean costs. Section II.A.2.e. of this final rule with comment period discusses the calculation of composite APC criteria-based geometric mean costs. Section VIII.B. of this final rule with comment period addresses the methodology for calculating the geometric mean costs for partial hospitalization services.

(2) Recommendations of the Advisory Panel on Hospital Outpatient Payment Regarding Data Development

At the August 27–28, 2012 meeting of the Advisory Panel on Hospital Outpatient Payment (the Panel), we provided the Data Subcommittee with a list of all APCs fluctuating by greater than 10 percent when comparing the CY 2013 OPPS/ASC proposed rule costs based on CY 2011 claims processed through June 30, 2012, to those based on CY 2012 OPPS/ASC final rule data (CY 2010 claims processed through June 30, 2011). The Data Subcommittee reviewed the fluctuations in the APC costs and their respective weights.

At the August 27–28, 2012 Panel meeting, the Panel made a number of recommendations related to the data process. The Panel's recommendations and our responses follow.

Recommendation: The Panel recommends that the work of the Data Subcommittee continue.

CMS Response: We are accepting this recommendation.

Recommendation: The Panel recommends that Traci Rabine serve as the acting chair of the Data Subcommittee for the August 2012 HOP Panel meeting.

CMS Response: We are accepting this recommendation.

Recommendation: The Panel recommends that CMS continue to provide a list of APCs fluctuating by more than 10 percent in costs.

CMS Response: We are accepting this recommendation.

d. Calculation of Single Procedure APC Criteria-Based 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 2013 OPPS/ASC proposed rule (77 FR 45081 through 45082), we proposed for CY 2013 to use the standard methodology for calculating costs for device-dependent APCs that was finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74148 through 74151). This methodology utilizes claims data that generally represent the full cost of the required device and the most recent cost report data. Specifically, we proposed to calculate the costs for device-dependent APCs for CY 2013 using only the subset of single procedure claims from CY 2011 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, 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 costs for device-dependent APCs gives us the most appropriate costs for device-dependent APCs in which the hospital incurs the full cost of the device. In Table 4A of the proposed rule, we listed the APCs for which we proposed to use our standard device-dependent APC ratesetting methodology for CY 2012.

Subsequent to the publication of the CY 2013 OPPS/ASC proposed rule, the AMA's CPT Editorial Panel created several new CPT codes describing services related to device-dependent APCs, to be effective beginning January 1, 2013. Our standard process for dealing with new CPT codes effective on January 1 for the upcoming calendar year is to assign each 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'' in Addendum B to the final rule with comment period 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 for 60 days following the publication of the final rule with comment period. As with all new CPT codes, we encourage interested stakeholders to review those codes identified with the ''NI'' in Addendum B and assigned to device-dependent APCs and submit public comments on those assignments.

Our interim assignment of some of the new CPT codes for CY 2013 to device-dependent APCs prompted us to change the titles of two APCs to reflect more accurately the clinical configurations of those APCs for CY 2013. Specifically, we assigned, on an interim basis, the following codes to device-dependent APC 0107, currently titled ''Insertion of Cardioverter-Defibrillator'': CPT code 0319T (Insertion or replacement of subcutaneous implantable defibrillator system with subcutaneous electrode), 0321T (Insertion of subcutaneous implantable defibrillator pulse generator only with existing subcutaneous electrode), and 0323T (Removal of subcutaneous implantable defibrillator pulse generator with replacement of subcutaneous implantable defibrillator pulse generator only). We note that the title of APC 0108 is currently ''Insertion/Replacement/Repair of AICD Leads, Generator and Pacing Electrode.'' In order to streamline and simplify the titles of APCs 0107 and 0108, which both contain procedures for the implantation of cardioverter-defibrillator pulse generators, leads, and electrodes, we are revising their titles to reflect the insertion of cardioverter-defibrillators without specifying the component pieces involved. Specifically, we are revising the title of APC 0107 to read ''Level I Implantation of Cardioverter-Defibrillator'' and the title of APC 0108 to read ''Level II Implantation of Cardioverter-Defibrillator.''

The creation of new CPT codes involving intracoronary stent placement procedures for CY 2013 also requires us to create nine new HCPCS C-codes and to delete two existing HCPCS G-codes in order to maintain the correct implementation of existing OPPS policy for CY 2013. Specifically, since CY 2003, under the OPPS, we assign coronary stent placement procedures to separate APCs based on the use of nondrug-eluting or drug-eluting stents (APC 0104 (Transcatheter Placement of Intracoronary Stents) or APC 0656 (Transcatheter Placement of Intracoronary Drug-Eluting Stents), respectively). In order to effectuate this policy, we created HCPCS G-codes G0290 (Transcatheter placement of a drug eluting intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method; single vessel) and G0291 (Transcatheter placement of a drug eluting intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method; each additional vessel) for drug-eluting intracoronary stent placement procedures that parallel existing CPT codes 92980 (Transcatheter placement of an intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method; single vessel) and 92981 (Transcatheter placement of an intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method; each additional vessel), which are used to describe nondrug-eluting intracoronary stent placement procedures. CPT codes 92980 and 92981 are assigned to APC 0104, while HCPCS codes G0290 and G0291 are assigned to APC 0656. We refer readers to the CY 2003 OPPS final rule with comment period (67 FR 66732 through 66734) for more information regarding the initial implementation of this policy.

Effective January 1, 2013, the AMA's CPT Editorial Panel is deleting CPT codes 92980 and 92981 and replacing them with the following new CPT codes:

- CPT code 92928 (Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch), 92929 (Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (List separately in addition to code for primary procedure));
- CPT code 92933 (Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch);
- CPT code 92934 (Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (List separately in addition to code for primary procedure));
- CPT code 92937 (Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel);
- CPT code 92938 (Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (List separately in addition to code for primary procedure));
- CPT code 92941 (Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel);
- CPT code 92943 (Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of

intracoronary stent, atherectomy and angioplasty; single vessel); and

• CPT code 92944 (Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (List separately in addition to code for primary procedure)).

In order to maintain the existing policy of differentiating payment for intracoronary stent placement procedures involving nondrug-eluting and drug-eluting stents, we are deleting HCPCS codes G0290 and G0291 and replacing them with the following new HCPCS C-codes to parallel the new CPT codes:

• HCPCS code C9600 (Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch);

• HCPCS code C9601 (Percutaneous transcatheter placement of drug-eluting intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (List separately in addition to code for primary procedure));

• HCPCS code C9602 (Percutaneous transluminal coronary atherectomy, with drug eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch);

• HCPCS code C9603 (Percutaneous transluminal coronary atherectomy, with drug-eluting intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (List separately in addition to code for primary procedure));

• HCPCS code C9604 (Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel);

• HCPCS code C9605 (Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (List separately in addition to code for primary procedure));

• HCPCS code C9606 (Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel);

• HCPCS code C9607 (Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; single vessel); and

• HCPCS code C9608 (Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (List separately in addition to code for primary procedure)).

The interim APC assignment for CPT codes 92928, 92933, 92929, 92934, 92937, 92938, 92941, 92943, and 92944 is APC 0104, and the interim APC assignment for HCPCS codes C9600, C9601, C9602, C9603, C9604, C9605, C9606, C9607, and C9608 is APC 0656 for CY 2013.

Comment: One commenter requested that CPT code 0304T (Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; device only) be placed in APC 0107 (Level I Implantation of Cardioverter-Defibrillators (ICDs)), rather than APC 0090 (Insertion/Replacement of Pacemaker Pulse Generator), because CPT code 0304T describes the insertion or removal and replacement of a device, which is similar to other CPT codes assigned to APC 0107, such as CPT code 33262 (Removal of pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; single lead system). The commenter also stated that 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 existing generator) is better aligned with APC 0107 than with its current APC assignment of APC 0655 (Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing Electrode).

Response: We disagree with the commenter's assertion that CPT codes 0304T and 33224 should be placed in APC 0107. APC 0107 includes procedures involving the insertion of a cardioverter-defibrillator, and CPT codes 0304T and 33224 do not describe such procedures.

Comment: One commenter suggested that CMS consider the assignment of different APCs for upgrades to a pacemaker or cardioverter-defibrillator based on the number of leads inserted, which can result in cost differences among procedures.

Response: The commenter did not provide specific CPT codes for pacemaker or cardioverter-defibrillator insertion procedures for us to consider. Generally speaking, however, we believe that our standard ratesetting methodology for device-dependent APCs would appropriately capture hospitals' varying costs based on the number of leads inserted during these procedures because we use data from hospital claims and cost reports that would reflect any such differences in costs.

Comment: Commenters expressed appreciation for the proposed increase in payment for the cochlear implant procedure, described by CPT code 69930 (Cochlear device implantation, with or without mastoidectomy) which is assigned to APC 0259 (Level VII ENT Procedures). However, the commenters also expressed concern that the increase does not reflect the actual cost of the procedure and device. The commenters indicated potential coding errors by major hospital facilities where claims for less expensive osseointegrated auditory device implant procedures (such as those assigned to APC 0425 (Level II Arthroplasty or Implantation with Prosthesis)) were included in the dataset used for calculation of cochlear implants, and requested that CMS review the APC 0259 source data and remove the claims that were inadvertently included as part of the original dataset to ensure the appropriate payment.

Response: We employ procedure-to-device and device-to-procedure edits to ensure that the appropriate procedures and devices are correctly billed together and those same edits are again used in modeling the OPPS payment rates for the respective device-dependent APCs. Only claims containing the appropriate procedure and device code pairings are used to model the estimated APC cost for device-dependent APCs. We also note that the cochlear implant procedure and the osseointegrated

auditory device implant procedures are in different APCs; therefore, only single claims containing one of these procedures would be used to model the estimated APC cost for their respective APCs. Further, claims with multiple major procedures generally are not entered into the dataset used for calculating estimated APC costs. Therefore, we do not believe that the inclusion of claims containing both cochlear implant procedures and osseointegrated auditory device implant procedures would result in inaccurate procedure or APC cost estimations.

Comment: Some commenters pointed out an apparent discrepancy between the listed proposed payment rate for APC 0425 in Addendum B to the CY 2013 OPPS/ASC proposed rule when compared to the listed proposed payment rate for APC 0425 in the data file entitled ''CY 2013 OPPS Comparison Between Proposed Geometric Mean and Median-Based Payments.'' Commenters requested that CMS review its proposed payment rates and determine which proposed payment rate reflects the correct geometric mean cost for APC 0425 for use in CY 2013 OPPS ratesetting.

Some commenters also requested that CMS reconfigure APC 0425 to ensure the procedures in the APC are similar from both a cost and clinical cohesion perspective and thereby facilitate Medicare hospital outpatient payment rates that are more in line with hospitals' actual costs for orthopedic arthroplasty procedures. Specifically, the commenters argued that the osseointegrated auditory device implant procedures assigned to APC 0425, such as the procedure described by CPT code 69714 (Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy), are not related to the orthopaedic joint replacement procedures also assigned to APC 0425. The commenters also stated the proposed composition of APC 0425 violated the 2 times rule because CPT code 69717 (Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy) has a proposed mean cost of $5,382 and CPT code 25446 (Arthroplasty with prosthetic replacement; distal radius and partial or entire carpus (total wrist)) has a proposed mean cost of $15,020.

Response: We recognize the discrepancy between the proposed payment rate for APC 0425 in Addendum B to the CY 2013 OPPS/ASC proposed rule and the proposed payment rate for APC 0425 listed in the ''CY 2013 OPPS Comparison Between Proposed Geometric Mean and Median-Based Payments'' data file. The cost statistics used in the generation of the ''CY 2013 OPPS Comparison Between Proposed Geometric Mean and Median-Based Payments'' data file did not reflect the final configuration of the proposed CY 2013 OPPS relative payment weights; thus, the proposed payment rate reflected in that data file was inaccurate.

We believe that the current configuration of APC 0425 is appropriate as all procedures within the APC share clinical and resource similarity. Specifically, we disagree with the commenters who asserted that the osseointegrated auditory device implant procedures assigned to APC 0425 are not related to the orthopaedic joint replacement procedures also assigned to APC 0425. As we have stated in the past (73 FR 68539), all procedures assigned to APC 0425, including the osseointegrated auditory device implant procedures, involve the implantation of a prosthetic device into bone. We also note the assignments of CPT codes 69717 and 25446 to APC 0425 do not violate the 2 times rule as the commenters claimed. As discussed in section III.B.2. of the proposed rule and this final rule with comment period, we consider only those HCPCS codes that are significant, based on the number of claims, in making this determination. 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 cost to be significant. CPT codes 69717 and 25446 do not meet this criteria and their inclusion in the same APC, therefore, does not violate the 2 times rule because they are not considered significant.

Comment: One commenter stated that CMS should study further the claims for any device-dependent APC for which the calculated proposed payment reduction would be greater than 10 percent and take action to correct issues that may artificially reduce these payments.

Response: We routinely examine all APCs with a greater than 10 percent fluctuation in costs as part of our annual rulemaking process.

Comment: Commenters supported CMS' determination that urology procedures in APCs 0385 (Level I Prosthetic Urological Procedures), 0386 (Level II Prosthetic Urological Procedures), and 0674 (Prostate Cryoablation) should be categorized as device-dependent APCs. The commenters also requested the mandatory reporting of all HCPCS device C-codes on hospital claims for services involving devices and asserted that CMS should require complete and correct coding for packaged services. The commenters urged CMS to continue to promote device coding edits, while encouraging hospitals to remain vigilant in reporting the costs of performing device related services, and educating hospitals on the importance of accurate coding for devices, supplies, and other technologies.

Response: We appreciate the commenters' support and will continue to promote device coding edits, as well as encourage hospitals to report all costs in performing device related services. As we have stated in the past (73 FR68535 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. As we stated in the CY 2009 OPPS/ASC final rule with comment period (73 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.

After consideration of the public comments we received, we are finalizing our proposed policy to use the standard methodology for calculating costs for device-dependent APCs for CY 2013 that was finalized in the CY 2012 OPPS/ASC final rule with comment period.

Table 3 below lists the APCs for which we used our standard device-dependent APC ratesetting methodology for CY 2013. 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 payment rates for these device-dependent APCs for CY 2013.

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TABLE 3.—CY 2013 DEVICE-DEPENDENT APCs

CY 2013 APC	CY 2013 Status Indicator	CY 2013 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	Level I Implantation of Cardioverter-Defibrillator
0108	T	Level II Implantation of Cardioverter-Defibrillator
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
0385	S	Level I Prosthetic Urological Procedures
0386	S	Level II Prosthetic Urological Procedures
0425	T	Level II Arthroplasty or Implantation with Prosthesis

CY 2013 APC	CY 2013 Status Indicator	CY 2013 APC Title
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

(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 2013 OPPS/ASC proposed rule (77 FR 45082 through 45083), we proposed to continue for CY 2013 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 costs upon which the proposed CY 2013 payment rates for blood and blood products were 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. We noted that we used geometric mean unit costs for each blood and blood product to calculate the proposed payment rates, consistent with the methodology we proposed for other items and services, discussed in section II.A.2.f. of the proposed rule and this final rule with comment period.

We stated in the proposed rule that 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 stated in the proposed rule that we believe that it yields more accurate estimated costs for these products.

Comment: Some commenters expressed concern that the proposed APC payment rates for some blood products are less than the acquisition costs of those products, citing a published study of a national survey of blood acquisition and overhead costs. According to the commenters, the safety and availability of blood may be jeopardized without adequate payment. The commenters asked that CMS formally consider and evaluate potential alternative methodologies for setting APC payment rates for blood products, preferably by seeking input from affected stakeholders. The commenters also stated that the use of the geometric mean methodology to calculate blood costs would result in lower payment rates compared to the use of median costs to calculate the payment rates for blood and blood products and urged CMS to use the median cost instead.

Response: As we have stated in the past (75 FR 71838 through 71839 and 76 FR 74152), we continue to believe that using blood-specific CCRs applied to hospital claims data results in payment that appropriately reflect hospitals' relative costs of providing blood and blood products as reported to us by

hospitals. We will consider any information presented to us from affected stakeholders regarding alternative ratesetting methodologies. We address the use of geometric mean costs to calculate blood payment rates in section II.A.2.c. of this final rule with comment period.

Comment: One commenter expressed concern regarding coding and payment for pre-storage pooled, leukocyte reduced platelets. According to the commenter, hospitals currently bill for pre-storage pooled, leukocyte reduced platelets using HCPCS code P9031 (Platelets, leukocytes reduced, each unit) based on the number of platelet concentrates (PCs) that are combined to create one unit of the blood product. The commenter stated that because the number of PC units used to make a therapeutic dose of pre-storage pooled, leukocyte reduced platelets is variable, blood centers must notify hospitals of the number of PCs in each therapeutic dose for the hospital's billing purposes, even though it does not affect the cost of the product to the hospital.

According to the commenter, a new technology exists that can make a unit of pre-storage pooled, leukocyte reduced platelets out of fewer PCs. However, the commenter expressed concern that the current coding and payment based on the use of HCPCS code P9031 unfairly and inappropriately disadvantages the use of this technology. The commenter indicated that where a greater number of PCs are needed to make a unit of pre-storage pooled, leukocyte reduced platelets, the hospital may end up being paid at a rate that significantly exceeds the cost of the product. However, according to the commenter, where the blood center can make the pre-storage pooled, leukocyte reduced platelets using fewer PCs, the hospital may end up receiving payment that is not sufficient to cover the cost of the product.

The commenter stated that a separate code will be necessary to differentiate pre-storage pooled, leukocyte reduced platelets from other platelet products, and that an application for a unique HCPCS code is currently pending. The commenter urged CMS, for OPPS purposes, to take action to ensure appropriate payment for pre-storage pooled, leukocyte reduced platelets, regardless of whether a new HCPCS code is created.

Response: The outcome of the commenter's application for a unique HCPCS code for pre-storage pooled, leukocyte reduced platelets is beyond the scope of OPPS rulemaking. We note that it is an expected and appropriate outcome of a prospective payment system that hospitals would receive payments that are less than their costs in some cases and exceed their costs in other cases, as the commenter described is occurring in the case of pre-storage pooled, leukocyte reduced platelets. Therefore, we do not believe that it is necessary for us to take action to ensure appropriate payment for pre-storage pooled, leukocyte reduced platelets at this time. However, we are interested in hearing from other stakeholders regarding the current incentives and disincentives that exist in the marketplace for pre-storage pooled, leukocyte reduced platelets and invite public comment on payment for the blood product described by HCPCS code P9031 in this final rule with comment period.

After consideration of the public comments we received, we are finalizing our proposed policy, without modification, 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, for CY 2013. We continue to believe that this methodology in CY 2013 will result in 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.

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 2013 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) Brachytherapy Sources

Section 1833(t)(2)(H) of the Act, as added by section 621(b)(2)(C) of Public Law 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 must include separate groups for palladium-103 and iodine-125 sources. For the history of OPPS payment for brachytherapy sources, we refer readers to prior OPPS proposed and final rules. As we have stated previously (72 FR 66780, 73 FR 41502, 74 FR 60533 through 60534, 75 FR 71978, and 76 FR 74160), 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 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 averaging the extremely high and low values, in contrast to 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, has provided 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.

Therefore, in the CY 2013 OPPS/ASC proposed rule (77 FR 45087), we proposed to use the costs from CY 2011 claims data for setting the proposed CY 2013 payment rates for brachytherapy sources, as we proposed for most other items and services that will be paid under the CY 2013 OPPS. We based the proposed rates for brachytherapy sources using geometric mean unit costs for each source, consistent with the methodology proposed for other items and services, discussed in section II.A.2.f. of the proposed rule. 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). 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 and CY 2012, 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 specified at 42 CFR 419.43(d). In addition, implementation of prospective payment for brachytherapy sources provides opportunities for eligible hospitals to receive additional payments in CY 2013 under certain circumstances through the 7.1 percent rural adjustment, as described in section II.E. of the proposed rule and this final rule with comment period.

We referred readers to Addendum B to the proposed rule (which was available via the Internet on the CMS Web site) for the proposed CY 2013 payment rates for brachytherapy sources, identified with status indicator ''U.'' We invited public comment on this proposed policy and also requested recommendations for new HCPCS codes to describe new brachytherapy sources consisting of a radioactive isotope, including a detailed rationale to support recommended new sources. In the proposed rule, we provided an appropriate address for receipt of these recommendations; the address is repeated at the end of this section. We indicated that we will continue to add new brachytherapy source codes and descriptors to our systems for payment on a quarterly basis.

Comment: A number of commenters opposed our proposal to base the payment for brachytherapy sources on geometric mean costs, while other commenters supported the proposal. Commenters also addressed other payment issues related to brachytherapy:

First, some commenters claimed that there are longstanding problems with OPPS claims data for brachytherapy source payment. For example, commenters stated that high dose rate (HDR) sources can be used to treat multiple patients because they decay over a 90-day period. The commenters stated that, as a result, the per source cost depends on the number of patients treated as well as the number of treatments and the intensity of the treatments within the 90-day period, making adequate payment for all hospitals difficult. Commenters asserted, as further examples of problems with our claims data, that our claims data continue to show a huge variation in unit costs on claims across hospitals; that more than half of the brachytherapy APCs have proposed payment rates based on 50 or fewer hospitals; and that our claims data contain rank order anomalies between high-activity palladium-103 (HCPCS code C2635) and low-activity palladium-103 sources (HCPCS codes 2640 and C2641), claiming that high-activity palladium-103 always costs more than low-activity palladium-103.

Second, commenters stated that brachytherapy source payments proposed for CY 2013 are unstable and fluctuate significantly from CY 2012 levels. They expressed concern about unpredictable changes in payment rates for brachytherapy sources from year to year, stating that proposed rates for some sources would change significantly, ranging from a decrease of 14.2 percent for HCPCS code C2643 (Brachytherapy source, non-stranded, cesium-131, per source) to an increase of 216 percent for HCPCS code C1716 (Brachytherapy source, non-stranded, gold-198, per source).

Response: In response to the commenters' concerns regarding the proposal to base payment for brachytherapy sources on geometric mean cost, we refer readers to section II.A.2.f. of this final rule with comment period, where we address the use of the geometric means methodology for determining OPPS payments for brachytherapy sources for CY 2013.

We disagree with the commenters who stated that the CY 2013 proposed payment rates for brachytherapy sources based on geometric mean cost would change payment levels significantly from the CY 2012 payment rates. While the commenters are correct that the proposed CY 2013 payment rate changes range from −14.2 to 216 percent, when we compare the CY 2013 proposed payment rates to the CY 2012 final payment rates, we find that 10 of the 16 brachytherapy source codes will receive increases or decreases of less than 10 percent, indicating stability for the majority of the brachytherapy sources. Moreover, when we compare the CY 2013 proposed payment rates to the CY 2012 final payment rates, we find that 10 of the 16 brachytherapy source codes will receive increased payment amounts per source, while 6 of the 16 codes will receive decreased payments per source.

With regard to the commenters who articulated concerns about perceived longstanding problems such as variability of brachytherapy source payment rates (which they have repeatedly opined in prior years), we are pleased that, unlike in past years, the commenters did not express objection to prospective payment for brachytherapy sources. As we stated previously (72 FR 66782, 74 FR 60534, 75 FR 71979, and 76 FR 74161), 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, and 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 in costs for other component items and services and because relative weights are typically estimated using a smaller set of claims.

As we have stated previously (75 FR 71979 and 76 FR 74161), 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, some sources may have costs and payment rates based on 50 or fewer hospitals 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 hospitals using particular low-volume sources, for which we are required to pay separately by statute. Further, our methodology for estimating 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 believe that prospective payment rates based on claims from those hospitals furnishing a particular source appropriately reflect the cost of that source for hospitals.

In the case of high and low activity iodine-125 sources, our claims data show that the hospitals' relative costs for the high activity source as reported on hospital claims and in cost report data are greater than the low activity sources, as we have noticed in the past. However, this relationship is reversed for palladium-103 sources, as a few commenters pointed out. As we have stated in the past (75 FR 71979 and 76 FR 74162), we do not have any 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 8 hospitals reported this service in CY 2010, compared to 139 and 203 hospitals for low-activity palladium-103 sources described by HCPCS codes C2640 and C2641, respectively. As we stated regarding this issue in the CYs 2010, 2011, and 2012 OPPS/ASC final rules with comment period (74 FR 60535, 75 FR 71979, and 76 FR 74162, respectively), it is clear that fewer hospitals furnished high-activity palladium-103 sources than low-activity palladium-103 sources, and we expect that the hospital cost distribution for those hospitals could be different than the cost distribution of the large number of hospitals reporting the low-activity sources. These varied cost distributions clearly contribute to the observed relationship in 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 will not yield valid costs for those hospitals furnishing the different brachytherapy sources upon which CY 2013 prospective payments rates are based.

As we indicated in the CYs 2011 and 2012 OPPS/ASC final rules with comment period (75 FR 71980 and 76 FR 74162, respectively), we agree that high dose rate (HDR) brachytherapy sources such as HDR iridium-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-192, 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, and 76 FR 74162). For most of these OPPS services, our practice is to establish prospective payment rates based on the costs from hospitals' claims data to provide incentives for efficient and cost effective delivery of these services.

Comment: One commenter requested that CMS establish appropriate payment for HCPCS code A9527 (Iodine, I-125, sodium iodide solution, therapeutic, per millicurie (mCi)), claiming that the source has not been available for patients from June 2010 to July 2012, when it became available for purchase by providers. The commenter stated that the claims from two hospitals that reported HCPCS code A9527 are erroneous. The commenter requested that CMS use external data based upon actual hospital invoices to assign payment for HCPCS code A9527, which, according to the commenter, cost hospitals in CY 2012 $28.00 per millicurie (mCi), which is above the proposed payment rate of $20.86.

Response: We have been paying for I-125 brachytherapy solution since 2003, both as HCPCS code A9527 and its predecessor code in the OPPS, C2632 (Brachytherapy solution, iodine-125, per mCi). Our claims data over the period of 2004 through 2011 show a consistent range of costs of $16.83 to $29.42 per mCi, with several thousand units of claims in most of those years. The claims data for HCPCS code A9527 reflect claims for 8 providers, rather than 2 as indicated by the commenter. Therefore, we believe that we are obtaining adequate and consistent data on HCPCS code A9527. We will maintain our use of claims data for HCPCS code A9527 in our OPPS ratesetting for CY 2013.

Comment: One commenter requested that CMS add a new C-code and APC for a high-activity cesium-131 brachytherapy source, which is designed to generate isotropic emission of therapeutic radiation and to be used primarily for the treatment of head and neck and eye cancer.

Response: We appreciate the commenter informing us of a new high-activity cesium-131 source. However, our evaluation process of new sources for addition to our set of codes is beyond the scope of this rulemaking. As we state elsewhere in this final rule with comment period, and in previous rules, such as the CY 2012 OPPS/ASC final rule with comment period (76 FR 74163), we ask 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. We suggest to the commenter to send its recommendation for this new brachytherapy source, along with the detailed rationale to support the new source, to the address provided at the end of this section. We will continue to add new brachytherapy source codes and descriptors to our systems on a quarterly basis.

Comment: One commenter supported CMS' proposal to continue the policy of paying for new sources for which we have no claims data, with prospective payment rates based on the consideration of external data as well as other relevant information. The commenter expressed appreciation for CMS' efforts to establish appropriate payment rates for brachytherapy sources in a timely manner, and recommended that CMS finalize this proposal.

Response: We appreciate the support and recognition of our efforts to provide appropriate and timely payment. We are finalizing our proposal to pay for new sources using external data and other relevant information.

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 geometric mean costs for CY 2013. We refer readers to Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*) for the final CY 2013 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 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 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 relative weights to scaling for purposes of budget neutrality.

As stated in the proposed rule (77 FR 45087), 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 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 necessary, high quality care and 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 policies for extended assessment and management services, low dose rate (LDR) prostate brachytherapy, cardiac electrophysiologic evaluation and ablation services, mental health services, multiple imaging services, and cardiac resynchronization therapy 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) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74163) for more recent background.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45087 through 45094), we proposed for CY 2013 to continue our composite policies for extended assessment and management services, LDR prostate brachytherapy, cardiac electrophysiologic evaluation and ablation services, mental health services, multiple imaging services, and cardiac resynchronization therapy 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), II.A.2.e.(5), and II.A.2.e.(6), respectively, of the proposed rule.

Comment: One commenter encouraged CMS to create payments that drive hospitals to develop low cost deliveries of care instead of rewarding them for excess deliveries of care, such as beneficiaries receiving up to three CT scans in a single emergency department visit.

Response: We agree with the commenter that it is important to create payment methodologies that encourage efficiency. As we have stated in the past, we believe that composite APCs enable hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves. With respect to CT scans in particular, as we discuss in section II.A.2.e.(5) of this final rule with comment period, we provide a single payment each time a hospital bills more than one CT on the same date of service.

The final composite policies for extended assessment and management services, LDR prostate brachytherapy, cardiac electrophysiologic evaluation and ablation services, mental health services, multiple imaging services, and cardiac resynchronization therapy services are discussed in the following sections (II.A.2.e.(1), II.A.2.e.(2), II.A.2.e.(3), II.A.2.e.(4), II.A.2.e.(5), and II.A.2.e.(6), respectively) of this final rule with comment period.

(1) Extended Assessment and Management Composite APCs (APCs 8002 and 8003)

In the CY 2013 OPPS/ASC proposed rule (77 FR 45088), 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 2013. Beginning in 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 the two composite APCs as appropriate. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74163 through 74165) for a full discussion of this longstanding policy.

For CY 2013, we proposed to continue the extended assessment and management composite APC payment methodology and criteria for APCs 8002 and 8003 that we finalized for CYs 2009 through 2012. 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 also proposed to calculate the costs for APCs 8002 and 8003 using the same methodology that we used to calculate the costs for composite APCs 8002 and 8003 for the CY 2008 OPPS (72 FR 66649). That is, we proposed to use all single and ''pseudo'' single procedure claims from CY 2011 that met the criteria for payment of each composite APC and apply the standard packaging and trimming rules to the claims before calculating the CY 2013 costs. The proposed CY 2013 cost resulting from this methodology for composite APC 8002 was approximately $446, which was calculated from 17,072 single and ''pseudo'' single claims that met the required criteria. The proposed CY 2013 cost for composite APC 8003 was approximately $813, which was calculated from 255,231 single and ''pseudo'' single claims that met the required criteria.

We did not receive any public comments on this proposal. We are finalizing our proposed policy, without modification, to calculate the costs for APCs 8002 and 8003 using the same

methodology that we used to calculate the costs for composite APCs 8002 and 8003 for the CY 2008 OPPS (72 FR 66649). The final CY 2013 cost resulting from this methodology for composite APC 8002 is approximately $453, which was calculated from 19,028 single and ''pseudo'' single claims that met the required criteria. The final CY 2013 cost for composite APC 8003 is approximately $821, which was calculated from 284,861 single and ''pseudo'' single claims that met the required criteria.

At its August 2012 meeting, the Advisory Panel on Hospital Outpatient Payment (the Panel) recommended that CMS continue to report clinic/emergency department visit and observation claims data and, if CMS identifies changes in patterns of utilization or cost, that CMS bring those issues to the Visits and Observation Subcommittee. Additionally, the Panel recommended that CMS examine the costs and frequency for Level I and Level II Extended Assessment and Management Composite APCs associated with greater than 24 hours of observation, if available, and report the findings to the Visits and Observation Subcommittee. The Panel recommended that Scott Manaker, M.D., Ph.D., be named the chair of the Visits and Observation Subcommittee. The Panel recommended that the work of the Visits and Observation Subcommittee continue. We are accepting these recommendations and will provide the requested data to the Panel at a future meeting.

(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), which are generally present together on claims for the same date of service in the same operative session. 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 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. 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 2013 OPPS/ASC proposed rule (77 FR 45088 through 45089), we proposed for CY 2013 to continue to pay for LDR prostate brachytherapy services using the composite APC methodology proposed and implemented for CY 2008 through CY 2012. That is, we proposed to use CY 2011 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 2012 practice, we proposed not to use the claims that met these criteria in the calculation of the costs for APC 0163 (Level IV Cystourethroscopy and Other Genitourinary Procedures) and APC 0651 (Complex Interstitial Radiation Source Application), the APCs to which CPT codes 55875 and 77778 are assigned, respectively. We proposed to continue to calculate the costs for APCs 0163 and 0651 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 stated that we continue to believe that data from claims reporting both services required for LDR prostate brachytherapy provide the most accurate cost upon which to base the composite APC payment rate.

Using a partial year of CY 2011 claims data available for the CY 2013 proposed rule, we were able to use 650 claims that contained both CPT codes 55875 and 77778 to calculate the cost upon which the proposed CY 2013 payment for composite APC 8001 was based. The proposed cost for composite APC 8001 for CY 2013 was approximately $3,362.

Comment: A few commenters supported the proposed payment methodology and policy for APC 8001. The commenters also supported the continued use of the LDR prostate brachytherapy composite APC methodology and the proposed increase in payment for CY 2013.

Response: We appreciate the commenters' support.

We are finalizing, without modification, our proposed policy for composite APC 8001. Using a full year of CY 2011 claims data available for this CY 2013 final rule with comment period, we were able to use 677 claims that contained both CPT codes 55875 and 77778 to calculate the cost upon which the final CY 2013 payment for composite APC 8001 is based. The final cost for composite APC 8001 for CY 2013 is approximately $3,348.

(3) Cardiac Electrophysiologic Evaluation and Ablation Composite APC (APC 8000)

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. 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)). Calculating a composite APC for these services allowed us to utilize many more claims than were available to establish the individual APC costs for these services, and advanced our stated goal of promoting hospital efficiency through larger payment bundles. In order to calculate the 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 CPT 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 2013 OPPS/ASC proposed rule (77 FR 45089), we proposed for CY 2013 to continue to pay for cardiac electrophysiologic evaluation and ablation services using the composite APC methodology proposed and implemented for CY 2008 through CY 2012. We stated that we continue to believe that the cost for these services 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. Consistent with our practice since CY 2008, we proposed not to use the claims that met the composite payment criteria in the calculation of the costs for APCs 0085 and 0086, to which the CPT codes in both Groups A and B for composite APC 8000 are otherwise assigned. We proposed that the costs for APCs 0085 and 0086 would continue to be calculated using single procedure claims. For CY 2013, using a partial year of CY 2011 claims data available for the proposed rule we were able to use 11,358 claims containing a combination of Group A and Group B CPT codes to calculate a proposed cost of approximately $11,458 for composite APC 8000.

Subsequent to the publication of the CY 2013 OPPS/ASC proposed rule, the AMA's CPT Editorial Panel created five new CPT codes describing cardiac electrophysiologic evaluation and ablation services, to be effective January 1, 2013. These five new codes are:

- CPT code 93653 (Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with right atrial pacing and recording, right ventricular pacing and recording, His recording with intracardiac catheter ablation of arrhythmogenic focus; with treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry);
- CPT code 93654 (Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with right atrial pacing and recording, right ventricular pacing and recording, His recording with intracardiac catheter ablation of arrhythmogenic focus; with treatment of ventricular tachycardia or focus of ventricular ectopy including intracardiac electrophysiologic 3D mapping, when performed, and left ventricular pacing and recording, when performed);
- CPT code 93655 (Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia (List separately in addition to code for primary procedure));
- CPT code 93656 (Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with atrial recording and pacing, when possible, right ventricular pacing and recording, His bundle recording with intracardiac catheter ablation of arrhythmogenic focus, with treatment of atrial fibrillation by ablation by pulmonary vein isolation); and
- CPT code 93657 (Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation (List separately in addition to code for primary procedure)).

The CPT Editorial Panel also deleted two electrophysiologic ablation codes, CPT code 93651 (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) and CPT code 93652 (Intracardiac catheter ablation of arrhythmogenic focus; for treatment of ventricular tachycardia), effective January 1, 2013.

Our standard process for dealing with new CPT codes effective on January 1 for the upcoming calendar year is to assign each 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'' in Addendum B to the final rule with comment period to identify it as a new interim APC assignment for the new year and the APC assignment for the new CPT codes is then open to public comment for 60 days following the publication of the final rule with comment period.

New CPT codes 93653, 93654, and 93656 are primary electrophysiologic services that encompass evaluation as well as ablation, while new CPT codes 93655 and 93657 are add-on codes. Because CPT codes 93653, 93654, and 93656 already encompass both evaluation and ablation services, we are assigning them to composite APC 8000 with no further requirement to have another electrophysiologic service from either Group A or Group B furnished on the same date of service, and we are assigning them interim status indicator ''Q3'' (Codes that may be paid through a composite APC) in Addendum B to this final rule with comment period. To facilitate implementing this policy, we are assigning CPT codes 93653, 93654, and 93656 to a new Group C, which will be paid at the composite APC 8000 payment rate. (We note that we will use single and ''pseudo'' single claims for CPT codes 93653, 93654, and 93656 when they become available for calculating the costs upon which the payment rate for APC 8000 will be based in future ratesetting.) Because CPT codes 93655 and 93657 are dependent services that may only be performed as ancillary services to the primary CPT codes 93653, 93654, and 93656, we believe that packaging CPT codes 93655 and 93657 with the primary procedures is appropriate, and we are assigning them interim status indicator ''N.'' Because the CPT Editorial Panel deleted CPT codes 93651 and 93652, effective January 1, 2013, we are deleting them from the Group B code list, leaving only CPT 93650 (Intracardiac catheter ablation of atrioventricular node function, atrioventricular conduction for creation of complete heart block, with or without temporary pacemaker placement) in Group B at this time.

As is our usual practice for new CPT codes that were not available at the time of the proposed rule, our treatment of new CPT codes 93653, 93654, 93655, 93656, and 93657 is open to public comment for a period of 60 days following the publication of this final rule with comment period.

We did not receive any public comments on our proposal to continue to pay for cardiac electrophysiologic evaluation and ablation services using the composite APC methodology. We are finalizing our proposed policy for CY 2013 to continue to pay for cardiac

electrophysiologic evaluation and ablation services using the composite APC methodology proposed and implemented for CY 2008 through CY 2012. We note that we are modifying our proposal for CY 2013 to reflect the CPT coding changes as discussed above. For CY 2013, using a full year of CY 2011 claims data available for this final rule with comment period, we were able to use 12,235 claims containing a combination of Group A and Group B CPT codes to calculate a final cost of approximately $11,466 for composite APC 8000.

Table 4 below lists the groups of procedures upon which we will base composite APC 8000 for CY 2013.

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TABLE 4.—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, or At Least One in Group C	CY 2013 CPT Code	Single Code CY 2013 APC	CY 2013 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
Group C			
Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with right atrial pacing and recording, right ventricular pacing and recording, His recording with intracardiac catheter ablation of arrhythmogenic focus; with treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry	93653	8000	Q3

Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with right atrial pacing and recording, right ventricular pacing and recording, His recording with intracardiac catheter ablation of arrhythmogenic focus; with treatment of ventricular tachycardia or focus of ventricular ectopy including intracardiac electrophysiologic 3D mapping, when performed, and left ventricular pacing and recording, when performed	93654	8000	Q3
Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with atrial recording and pacing, when possible, right ventricular pacing and recording, His bundle recording with intracardiac catheter ablation of arrhythmogenic focus, with treatment of atrial fibrillation by ablation by pulmonary vein isolation	93656	8000	Q3

(4) Mental Health Services Composite APC (APC 0034)

(a) Mental Health Services Composite Policy

In the CY 2013 OPPS/ASC proposed rule (77 FR 45090), we proposed for CY 2013 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 provided by a hospital, which we consider to be the most resource-intensive of all outpatient mental health treatments for CY 2013. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18452 to 18455) for the initial discussion of this longstanding policy and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74168) for more recent background.

Specifically, we proposed that 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 for a hospital, those specified mental health services would be assigned to APC 0034 (Mental Health Services Composite). We proposed to continue to set the payment rate for APC 0034 at the same rate as we pay for APC 0176 (Level II Partial Hospitalization (4 or more services) for Hospital-Based PHPs), which is the maximum partial hospitalization per diem payment for a hospital, and that the hospital would continue to be paid one unit of APC 0034. Under this policy, the I/OCE would continue to determine whether to pay for these specified mental health services individually or 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.

We did not receive any public comments on this proposal. Therefore, we are finalizing our CY 2013 proposal, without modification, to continue our longstanding policy of limiting the aggregate payment for specified less resource-intensive mental health services furnished on the same date by a hospital to the payment for APC 0176, which is the maximum partial hospitalization per diem payment for a hospital for CY 2013.

(b) Coding Changes

Subsequent to the publication of the CY 2013 OPPS/ASC proposed rule, the AMA's CPT Editorial Panel deleted 16 psychotherapy and psychiatric diagnostic evaluation CPT codes to which the mental health services composite APC methodology applies, and replaced them with 12 new CPT codes, to be effective January 1, 2013. The new and deleted CPT codes are included in Table 5 below. Our standard process for addressing new CPT codes effective on January 1 for the upcoming calendar year is to assign each 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'' in Addendum B to the final rule with comment period 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 for 60 days following the publication of the final rule with comment period.

Because the new mental health CPT codes in Table 5 replace CPT codes that are subject to the mental health composite APC, and because all of the HCPCS codes in the respective APCs to which these codes are assigned for CY 2013 are subject to the mental health composite APC, the new separately payable mental health CPT codes also will be assigned to composite APC 0034 with an interim status indicator of ''Q3'' (Codes that may be paid through a composite APC) in Addendum B to this final rule with comment period. The single code APC assignment, the composite APC assignment, and the interim status indicator assignment for each of these new CPT codes are included in Table 5 below. As discussed above for new CPT codes that were not available at the time of the proposed rule, our treatment of these new mental health CPT codes is open to public comment for a period of 60 days following the publication of this final rule with comment period. The current single code APC assignments for all of the HCPCS codes to which the mental health composite APC policy applies, along with their composite APC assignment and their APC assignments when the composite methodology does not apply, can be found in Addendum M to this final rule with comment period (which is available via the Internet on the CMS Web site).

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TABLE 5.--NEW AND DELETED PSYCHOTHERAPY AND PSYCHIATRIC DIAGNOSTIC EVALUATION CPT CODES FOR CY 2013

Deleted CY 2012 Psychotherapy and Psychiatric Diagnostic Evaluation CPT Codes					
HCPCS Code	**CY 2012 Short Descriptor**	**CY 2012 CI**	**CY 2012 SI**	**CY 2012 Single Code APC Assignment**	**CY 2012 Composite APC Assignment**
90801	Psy dx interview		Q3	0323	0034
90802	Intac psy dx interview		Q3	0323	0034
90804	Psytx office 20-30 min		Q3	0322	0034
90805	Psytx off 20-30 min w/e&m		Q3	0322	0034
90806	Psytx off 45-50 min		Q3	0323	0034
90807	Psytx off 45-50 min w/e&m		Q3	0323	0034
90808	Psytx office 75-80 min		Q3	0323	0034
90809	Psytx off 75-80 w/e&m		Q3	0323	0034
90810	Intac psytx off 20-30 min		Q3	0322	0034
90811	Intac psytx 20-30 w/e&m		Q3	0322	0034
90812	Intac psytx off 45-50 min		Q3	0323	0034
90813	Intac psytx 45-50 min w/e&m		Q3	0323	0034
90814	Intac psytx off 75-80 min		Q3	0323	0034
90815	Intac psytx 75-80 w/e&m		Q3	0323	0034
90857	Intac group psytx		Q3	0325	0034
90862	Medication management		Q3	0605	0034
New CY 2013 Psychotherapy And Psychiatric Diagnostic Evaluation CPT Codes					
HCPCS Code	**CY 2013 Short Descriptor**	**CY 2013 CI**	**CY 2013 SI**	**CY 2013 Single Code APC Assignment**	**CY 2013 Composite APC Assignment**
90785	Psytx complex interactive	NI	N	N	n/a
90791	Psych diagnostic evaluation	NI	Q3	0323	0034
90792	Psych diag eval w/med srvcs	NI	Q3	0323	0034
90832	Psytx pt&/family 30 minutes	NI	Q3	0322	0034
90833	Psytx pt&/fam w/e&m 30 min	NI	N	n/a	n/a

90834	Psytx pt&/family 45 minutes	NI	Q3	0323	0034
90836	Psytx pt&/fam w/e&m 45 min	NI	N	n/a	n/a
90837	Psytx pt&/family 60 minutes	NI	Q3	0323	0034
90838	Psytx pt&/fam w/e&m 60 min	NI	N	n/a	n/a
90839	Psytx crisis initial 60 min	NI	Q3	0323	0034
90840	Psytx crisis ea addl 30 min	NI	N	n/a	n/a
90863	Pharmacologic mgmt w/psytx	NI	N	n/a	n/a

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(5) Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)

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, in order to reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session (73 FR 41448 through 41450). 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 8 of the CY 2012 OPPS/ASC final rule with comment period (76 FR 74171 through 74175).

While there are three imaging families, there are five multiple imaging composite APCs due to the statutory requirement under 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.

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).

In the CY 2013 OPPS/ASC proposed rule (77 FR 45090), we proposed to continue for CY 2013 to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology. We stated that we continue to believe that this policy would reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session. The proposed CY 2013 payment rates for the five multiple imaging composite APCs (APC 8004, APC 8005, APC 8006, APC 8007, and APC 8008) were based on costs calculated from a year of CY 2011 claims available for the CY 2013 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 costs, we used the same methodology that we used to calculate the final CY 2012 costs for these composite APCs, as described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74169). The imaging HCPCS codes that we removed from the bypass list for purposes of calculating the proposed multiple imaging composite APC costs, pursuant to our established methodology (76 FR 74169), appeared in Table 11 of the proposed rule.

We were able to identify approximately 1.0 million ''single session'' claims out of an estimated 1.5 million potential composite cases from our ratesetting claims data, more than half of all eligible claims, to calculate the proposed CY 2013 costs for the multiple imaging composite APCs.

Comment: One commenter supported the proposed payment rate for APC 8004, while acknowledging the increased proposed payment rate for the ultrasound composite and for other standard (non-composite) ultrasound procedures.

Response: We appreciate the commenter's support.

Comment: Several commenters supported CMS' decision not to propose any new multiple imaging composite APCs, and requested that CMS analyze the potential impact on utilization and access for any newly proposed multiple imaging composite APCs, and to provide notice and seek comment for any new proposals.

Response: We appreciate the feedback regarding the multiple imaging composite APCs. As is our usual practice, we will analyze our claims data and provide public notice and seek comment for any new proposals through our annual rulemaking process.

After consideration of the public comments we received, we are finalizing our proposed policy, without modification, to calculate multiple imaging composite APC costs for CY 2013 pursuant to our established methodology. For this final rule with comment period, we were able to identify approximately 1.0 million ''single session'' claims out of an

estimated 1.6 million potential composite cases from our ratesetting claims data, more than half of all eligible claims, to calculate the final CY 2013 costs for the multiple imaging composite APCs.

Table 6 below lists the HCPCS codes that will be subject to the multiple imaging composite policy and their respective families and approximate composite APC costs for CY 2013. Table 7 below lists the OPPS imaging family services that overlap with HCPCS codes on the CY 2013 bypass list. We note that we mistakenly did not include CPT code 70547 (Magnetic resonance angiography, neck; without contrast material(s)) on this list in the proposed rule. We are adding it to this list for the final rule with comment period because it is part of the MRI and MRA with and without contrast imaging family and is also on the CY 2013 bypass list.

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TABLE 6.—OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCs

Family 1 – Ultrasound	
CY 2013 APC 8004 (Ultrasound Composite)	**CY 2013 Approximate APC Cost = $202**
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 2013 APC 8005 (CT and CTA without Contrast Composite)*	**CY 2013 Approximate APC Cost = $412**
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 2013 APC 8006 (CT and CTA with Contrast Composite)	**CY 2013 Approximate APC Cost = $702**
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 2013 APC 8007 (MRI and MRA without Contrast Composite)*	**CY 2013 Approximate APC Cost = $727**
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 2013 APC 8008 (MRI and MRA with Contrast Composite)	**CY 2013 Approximate APC Cost = $1,069**
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

70547	Mr angiography neck w/o 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 7.-OPPS IMAGING FAMILY SERVICES OVERLAPPING WITH HCPCS CODES ON THE CY 2013 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

70547	Mr angiography neck w/o dye
70551	Mri brain w/o dye
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
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

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(6) Cardiac Resynchronization Therapy Composite APC (APC 0108)

Cardiac resynchronization therapy (CRT) uses electronic devices to sequentially pace both sides of the heart to improve its output. CRT utilizing a pacing electrode implanted in combination with an implantable cardioverter defibrillator (ICD) is known as CRT–D. Hospitals commonly report the implantation of a CRT–D system using 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) (List separately in addition to code for primary procedure)) and CPT code 33249 (Insertion or repositioning of electrode lead(s) for single or dual chamber pacing cardioverter-defibrillator and insertion of pulse generator). As described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74176), over the past several years, stakeholders have pointed out significant fluctuations in the payment rate for CPT code 33225 and 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 claims upon which to calculate an accurate cost. In response to these concerns, we established a policy beginning in CY 2012 to recognize CPT codes 33225 and 33249 as a single, composite service when the procedures are performed on the same day and to assign them to APC 0108 (Insertion/Replacement/Repair of AICD Leads, Generator, and Pacing Electrodes) when they appear together on a claim with the same date of service. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74176 through 74182) for a full description of how we developed this policy.

As described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74182), hospitals continue to use the same CPT codes to report CRT–D implantation services, 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 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 is also 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 is assigned to APC 0655.

In order to ensure that hospitals correctly code for CRT services in the future, we also finalized a policy in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74182) 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 one of the following procedures to insert an ICD or pacemaker, as specified by the AMA in the CPT codebook:

- 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 the CY 2013 OPPS/ASC proposed rule (77 FR45094), we proposed to continue for CY 2013 to recognize CRT–D as a single, composite service as described above and finalized in the CY 2012 OPPS/ASC final rule with comment period. 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, which, because of its add-on code status, is always performed in conjunction with another procedure and, therefore, to address the inherent ratesetting challenges associated with CPT code 33225. We also noted 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 decision making based on individual patient's clinical needs rather than financial considerations. In calculating the costs upon which the proposed payment rate for APC 0108 was based for CY 2013, for the proposed rule, 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 9,790 single claims from the CY 2013 proposed rule claims data to calculate a proposed cost of approximately $31,491 for APC 0108. Because CPT codes 33225 and 33249 may be treated as a composite service for payment purposes, we proposed to continue to assign them status indicator ''Q3'' (Codes that may be paid through a composite APC) in Addendum B to the proposed rule. The assignment of CPT codes 33225 and 33249 to APC 0108 when treated as a composite service was also reflected in Addendum M to the proposed rule (which is available via the Internet on the CMS Web site).

As we noted in the proposed rule (77 FR 45094), we revised the claims processing edits in place for CPT code 33225 due to revised guidance from the AMA in the CPT code book specifying the codes that should be used in conjunction with CPT code 33225. Specifically, on February 27, 2012, the AMA posted a correction as errata to the CY 2012 CPT code book on the AMA Web site at *http://www.ama-assn.org/resources/doc/cpt/cpt-corrections.pdf*. This correction removed CPT code 33222 (Revision or relocation of skin pocket for pacemaker) as a service that should be provided in conjunction with CPT code 33225, and added CPT codes 33228 (Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator; dual lead system), 33229 (Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator; multiple lead system), 33263 (Removal of pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; dual lead system), and 33264 (Removal of pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; multiple lead system). In accordance with this revised guidance, we deleted CPT code 33222 as a code that can satisfy the claims processing edit for CPT code 33225, and added CPT codes 33228, 33229, 33263, and 33264 as codes that can satisfy this edit beginning in CY 2012.

Comment: One commenter requested that CMS delay the status indicator change from ''T'' to ''Q3'' for CPT code 33225, stating that CMS does not have sufficient cost data to allow a composite payment for this procedure. The commenter also asked that CPT code 33225 be assigned to APC 0655 while CMS carries out further analysis.

Response: We disagree with the commenter that we do not have sufficient cost data to allow a composite payment for the procedure described by CPT code 33225. For this final rule with comment period, we were able to use 3,413 single claims containing the CRT–D composite service, defined as the combination of CPT codes 33225 and 33249 with the same date of service, to calculate the cost of APC 0108. We note that we did not propose to change the status indicator for CPT code 33225 from ''T'' to ''Q3'' for CY 2013 as the commenter indicated; rather, we proposed to continue to apply the ''Q3'' status indicator to CPT code 33225 in accordance with the status indicator and policy for this code finalized in the CY 2012 OPPS/ASC final rule with comment period. We also note that, when not performed on the same day as the service described by CPT code 33249, the service described by CPT code 33225 is assigned to APC 0655 and not paid as a composite service.

After consideration of the public comment we received, we are finalizing our proposed policy, without modification, to continue to recognize CRT–D as a single, composite service as described above and finalized in the CY 2012 OPPS/ASC final rule with comment period. In calculating the costs upon which the final payment rate for APC 0108 is based for CY 2013, 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 11,251 single claims from the CY 2013 final rule claims data to calculate a final cost of approximately $31,561 for APC 0108. Because CPT codes 33225 and 33249 may be treated as a composite service for payment purposes, we are continuing to assign them status indicator ''Q3'' (Codes that may be paid through a composite APC) in Addendum B to this final rule with comment period.

f. Geometric Mean-Based Relative Payment Weights

As we discussed in the CY 2013 OPPS/ASC proposed rule (77 FR 45094 through 45098), when the Medicare program was first implemented, payment for hospital services (inpatient and outpatient) was based on hospital-specific reasonable costs attributable to furnishing services to Medicare beneficiaries. Although payment for most Medicare hospital inpatient services became subject to a PPS under section 1886(d) of the Act in 1983, Medicare hospital outpatient services continued to be paid based on hospital-specific costs. This methodology for payment provided little incentive for hospitals to furnish such outpatient services efficiently and in a cost effective manner. At the same time, advances in medical technology and changes in practice patterns were bringing about a shift in the site of medical care from the inpatient setting to the outpatient setting.

In the Omnibus Budget Reconciliation Act of 1986 (OBRA 1986) (Pub. L. 99–509), the Congress paved the way for development of a PPS for hospital outpatient services. Section 9343(g) of OBRA 1986 mandated that fiscal intermediaries require hospitals to report claims for services under the Healthcare Common Procedure Coding System (HCPCS). Section 9343(c) of OBRA 1986 extended the prohibition against unbundling of hospital services under section 1862(a)(14) of the Act to include outpatient services as well as inpatient services. The codes under the HCPCS enabled us to determine which specific procedures and services were billed, while the extension of the prohibition against unbundling ensured that all nonphysician services provided to hospital outpatients were reported on hospital bills and captured in the hospital outpatient data that were used to develop an outpatient PPS.

The brisk increase in hospital outpatient services further led to an interest in creating payment incentives to promote more efficient delivery of hospital outpatient services through a Medicare outpatient PPS. Section 9343(f) of OBRA 1986 and section 4151(b)(2) of the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990) (Pub. L. 101–508) required that we develop a proposal to replace the hospital outpatient payment system with a PPS and submit a report to the Congress on the proposed system. The statutory framework for the OPPS was established by the Balanced Budget Act (BBA) of 1997 (Pub. L. 105–33) with section 4523 amending section 1833 of

the Act by adding subsection (t), which provides for a PPS for hospital outpatient department services and the BBRA of 1999 (Pub. L. 106–113), with section 201 further amending section 1833(t) of the Act. The implementing regulations for these statutory authorities were codified at 42 CFR part 419, effective for services furnished on or after August 1, 2000.

Section 1833 of the Act sets forth the methodological requirements for developing the PPS for hospital outpatient services (the OPPS). At the onset of the OPPS, there was significant concern over observed increases in the volume of outpatient services and corresponding rapidly growing beneficiary coinsurance. Accordingly, much of the focus was on finding ways to address those issues. Section 1833(t)(2)(C) of the Act initially provided that relative payment weights for covered outpatient department services be established based on median costs under section 4523(a) of the BBA of 1997. Later, section 201(f) of the BBRA of 1999 amended section 1833(t)(2)(C) of the Act to allow the Secretary the discretion to base the establishment of relative payment weights on either median or mean hospital costs. Since the OPPS was initially implemented, we have established relative payment weights based on the median hospital costs for both statistical reasons and timely implementation concerns. The proposed rule for the OPPS was published prior to the passage of the BBRA of 1999, which amended the Act to permit the use of mean costs. At that time, we noted that making payment for hospital outpatient services based on the median cost of each APC was a way of discouraging upcoding that occurs when individual services that are similar have disparate median costs, as well as associating services for which there are low claims volume into the appropriate classifications based on clinical patterns and their resource consumption (63 FR 47562).

As discussed in the CY 2000 OPPS final rule with comment period (65 FR 18482 through 18483), initial implementation of the payment system for hospital outpatient services was delayed due to multiple extensions of the proposed rule comment period, Year 2000 (Y2K) system concerns, and other systems challenges in developing the OPPS. Even though the BBRA of 1999 passed during that period of time, and provided the Secretary with the discretion to establish relative payment weights under the OPPS based on mean hospital costs, we determined that reconstructing the database to evaluate the impact of using mean costs would have postponed implementation of the OPPS further. There were important challenges at the time, including being responsive to stakeholder comments regarding the initial OPPS and addressing implementation issues so that the payment and claims processing systems would work correctly. To do so in a timely manner was critical; therefore, median costs were selected as an appropriate metric on which to base payment relativity, both based on the statistical reasons noted above and practical implementation concerns.

In addition to the reasons discussed above, developing relative payment weights based on median costs was a way of attenuating the impact of cost outlier cases. In an environment where facility coding practices were still in their infancy, median costs served to minimize the impact of any coding errors. Using median costs to establish service cost relativity served the same function as any measure of central tendency (including means), ensuring that the relative payment weights used in the OPPS would, in general, account for the variety of costs associated with providing a service.

Since the beginning of the OPPS and throughout its development, we have striven to find ways to improve our methods for estimating the costs associated with providing services. The dialogue with the public regarding these issues, the meaningful information and recommendations that the Panel (previously the APC Panel) has provided, and the policies we have established to better derive the costs on which OPPS payment is calculated have contributed to improving cost estimation. However, challenges remain in our continuing effort to better estimate the costs associated with providing services. These challenges include our limited ability to obtain more meaningful information from the claims and cost report data available and ensuring that the approach used to calculate the payments for services accurately captures the relative costs associated with providing the services. Over the years, we have implemented many changes to the OPPS cost modeling process to help address these challenges.

To obtain more information from the claims data we have available, we first began bypassing codes from the standard process to develop ''pseudo'' single claims in CY 2003 (67 FR 66746). In CY 2006, this concept later evolved into the bypass list (and its corresponding criteria for addition) which allows us to extract more cost information from claims that would otherwise be unusable for modeling service cost (70 FR 68525). In CY 2008, we examined clinical areas where packaging of services was appropriate, which allows us to use more claims in modeling the payments for primary procedures and encourage providers to make cost efficient choices where possible (72 FR 66610 through 66649). In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66590), we noted that this packaging approach increased the number of ''natural'' single bills, while simultaneously reducing the universe of codes requiring single bills for ratesetting. Beginning in CY 2008, we also established composite APCs for services that are typically provided together in the same encounter, allowing us to use even more previously unusable claims (due to containing multiple separately payable major codes) for modeling service cost, as well as develop APCs that reflect the combined encounter (72 FR 66650 through 66658). We have implemented many steps to obtain more information from the claims and cost report data available to us, and continue to examine ways in which we can derive more meaningful information on service costs for use in ratesetting.

In our experience in working with the OPPS, we also have implemented many processes to ensure that the cost information we derive from cost reports and claims data is accurate. In the beginning of the OPPS, we implemented a cost trim of three standard deviations outside the geometric mean cost, similar to the cost data trim in the IPPS, because it would ensure that the most aberrant data were removed from ratesetting (65 FR 18484). We also have implemented similar trims to the hospital departmental CCR and claims based unit data related to the services (71 FR 67985 through 67987).

During the CY 2008 rulemaking cycle, we contracted with Research Triangle Institute, International (RTI) to examine possible improvements to the OPPS cost estimation process after RTI had investigated similar issues in the IPPS setting (72 FR 66659 through 66602). There was significant concern that charge compression, which results from 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, was influencing the cost estimates on which the OPPS relative payment weights are based. Based on RTI's recommendations in its July 2008 report, available on the Web site at: *http://www.rti.org/reports/cms/HHSM-500-2005-0029I/PDF/Refining_Cost_to_Charge_Ratios_200807_Final.pdf*, in CY 2009, we finalized

modifications to the Medicare cost report form to create an ''Implantable Medical Devices Charged to Patients'' cost center to address public commenters' concerns related to charge compression in the ''Medical Supplies Charged to Patients'' cost center (73 FR 48458 through 48467). These modifications helped to address potential issues related to hospital mark-up practices and how they are reflected in the CCRs on the Medicare hospital cost reporting form.

In CY 2010, we incorporated a line item trim into our data process that removed lines that were eligible for OPPS payment in the claim year but received no payment, presumably because of a line item rejection or denial due to claims processing edits (74 FR 60359). This line item trim was developed with the goal of using additional lines to model prospective payment.

In addition to these process changes that were designed to include more accurate cost data in ratesetting, we have developed a number of nonstandard modeling processes to support service or APC specific changes. For example, in the device-dependent APCs, we have incorporated edits into the cost estimation process to ensure that the full cost of the device is incorporated into the primary procedure.

While we have already implemented numerous changes to the data process in order to obtain accurate resource cost estimates associated with providing a procedure, we continue to examine possible areas of improvement. In the past, commenters have expressed concern over the degree to which payment rates reflect the costs associated with providing a service, believing that, in some cases, high cost items or services that might be packaged are not accordingly reflected in the payment weights (72 FR 66629 through 66630 and 66767). As mentioned above, in the CY 2008 OPPS/ASC final rule with comment period, we developed a packaging policy that identified a number of clinical areas where services would be commonly performed in a manner that was typically ancillary and supportive to other primary procedures. Packaging for appropriate clinical areas provides an incentive for efficient and cost-effective delivery of services. In that final rule with comment period, we recognized that there were strengths and weaknesses associated with using median costs as the metric for developing the OPPS relative payment weights (72 FR 66615). Medians are generally more stable than means because they are less sensitive to extreme observations, but they also do not reflect subtle changes in cost distributions. As a result, the use of medians rather than means under the OPPS usually results in relative payment weight estimates being less sensitive to packaging decisions, as well as changes in the cost model due to factors such as the additional claims processed between the proposed rule and the final rule.

The OPPS, like other prospective payment systems, relies on the concept of averaging, where the payment may be more or less than the estimated costs of providing a service or package of services for a particular patient (73 FR 68570). Establishing the cost-based relative payment weights based on a measure of central tendency, such as means or medians, ensures that the payments for the package of services should generally account for the variety of costs associated with providing those services. Prospective payments are ultimately adjusted for budget neutrality and updated by an OPD update factor, which affects the calculated payments, but the accuracy of the cost-based weights is critical in ensuring that the relative payment weights are adjusted appropriately.

We recognize that median costs have historically served and may continue to serve as an appropriate measure on which to establish relative payment weights. However, as discussed above, the metric's resistance to outlier observations is balanced by its limited ability to be reflective of changes to the dataset used to model cost or changes beyond the center of the dataset. While there was significant concern in the initial years of the OPPS regarding outlier cost values and the possible introduction of potentially aberrant values in the cost modeling, hospital experience in coding under the system, the data modeling improvements we have made to obtain more accurate cost information while removing erroneous data, and other changes in our experience with the system have all lessened the potential impact of error values (rather than actual, accurate cost outliers). As noted above, over the history of the OPPS, we have made multiple refinements to the data process to better capture service costs, respond to commenter concerns regarding the degree to which OPPS relative payment weights accurately reflect service cost and APC payment volatility from year to year, and better capture the variety of resource cost associated with providing a service as provided under section 1833(t)(2)(C) of the Act. In the CY 2013 OPPS/ASC proposed rule (77 FR 45098), we proposed for CY 2013 to shift the basis for the CY 2013 APC relative payment weights that underpin the OPPS from median costs to geometric mean-based costs.

Geometric means better encompass the variation in costs that occur when providing a service because, in addition to the individual cost values that are reflected by medians, geometric means reflect the magnitude of the cost measurements, and are thus more sensitive to changes in the data. We believe developing the OPPS relative payment weights based on geometric mean costs would better capture the range of costs associated with providing services, including those cases involving high-cost packaged services, and those cases where very efficient hospitals have provided services at much lower costs. The use of geometric mean-based costs also would allow us to detect changes in the cost of services earlier, because changes in cost often diffuse into the industry over time as opposed to impacting all hospitals equally at the same time. Medians and geometric means both capture the impact of uniform changes, that is, those changes that influence all providers, but only geometric means capture cost changes that are introduced slowly into the system on a case-by-case or hospital-by-hospital basis.

We stated that an additional benefit of this proposed policy relates to the 2 times rule, described in section III.B. of the proposed rule, which is our primary tool for identifying clinically similar services that have begun to deviate in terms of their financial resource requirements. We stated that basing HCPCS projections on geometric mean costs would increase the sensitivity of this tool as we configure the APC mappings because it would allow us to detect differences when higher costs occur in a subset of services even if the number of services does not change. This information would allow us to better ensure that the practice patterns associated with all the component codes appropriately belong in the same APC.

In addition to better incorporating those cost values that surround the median and, therefore, describing a broader range of clinical practice patterns, we stated in the proposed rule that basing the relative payment weights on geometric mean costs may also promote better stability in the payment system. In the short term, geometric mean-based relative payment weights would make the relative payment weights more reflective of the service costs. Making this change also may promote more payment stability in the long term by including a broader range of observations in the relative payment

weights, making them less susceptible to gaps in estimated cost near the median observation and also making changes in the relative payment weight a better function of changes in estimated service costs.

We noted that this proposed change would bring the OPPS in line with the IPPS, which utilizes hospital costs derived from claims and cost report data to calculate prospective payments, and specifically, mean costs rather than median costs to form the basis of the relative payment weights associated with each of the payment classification groups. We stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74181) our intent 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 based on financial considerations rather than clinical needs. By adopting a means cost-based approach to calculating relative payment weights under the OPPS, we stated that we expect to achieve greater consistency between the methodologies used to calculate payment rates under the IPPS and the OPPS, which would put us in a better position from an analytic perspective to make cross-system comparisons and examine issues of payment parity.

For the reasons described above, in the CY 2013 OPPS/ASC proposed rule (77 FR 45098), we proposed to establish the CY 2013 OPPS relative payment weights based on geometric mean costs. While this would involve a change to the metric used to develop the relative payment weights, the use of claims would not be affected. We proposed to continue to subset claims using the data processes for modeling the standard APCs and the criteria-based APCs described in section II.A.2. of the proposed rule, where appropriate. The reasoning behind implementing modeling edits or changes in the criteria-based APCs would not be affected because the process of developing the relative payment weights based on a measure of central tendency is the last step of the modeling process, and occurs only once the set of claims used in ratesetting has been established.

One important step that occurs after the development of relative payment weights is the assignment of individual HCPCS codes (services) to APCs. In our analysis of the impacts of a process conversion to geometric means, we determined that the change to means would not significantly influence the application of the 2 times rule. Very few services would need to be shifted to new APCs because of 2 times rule violations because the use of geometric means would resolve some violations that would exist under the use of medians, even as it creates other violations due to new cost projections. The net impact of the proposed change results in seven more violations of the 2 times rule created by the entire rebasing process than would exist if median-based values were used.

During the development of this proposed policy, we also determined that the cumulative effect of data shifts over the 12 years of OPPS introduced a number of inconsistencies in the APC groupings based on clinical and resource homogeneity. We believe that a shift to payments derived from geometric means would improve our ability to identify resource distinctions between previously homogenous services, and we intend to use this information over the next year to reexamine our APC structure and assignments to consider further ways of increasing the stability of payments for individual services over time.

We noted that this proposed policy to establish all OPPS relative payment weights using geometric mean costs would apply to all APCs that would have previously been paid based on median costs. In addition, we proposed to calculate the relative payment weights for line item based payments such as brachytherapy sources, which were discussed in section II.A.2.d.(6) of the proposed rule, as well as blood and blood products, which were discussed in section II.A.2.d.(2) of the proposed rule, based on their proposed geometric mean costs for the CY 2013 OPPS.

We indicated that the CY 2013 proposed policy to base relative payment weights on geometric mean costs would specifically include the CMHC and hospital-based partial hospitalization program APCs, which were previously based on median per diem costs. Their estimated payments would continue to be included in the budget neutral weight scaling process, and their treatment is similar to other nonstandard APCs discussed in section II.A. of the proposed rule. The process for developing a set of claims that is appropriate for modeling these APCs would continue to be the same as in recent years, with the only proposed difference being that a geometric mean per diem cost would be calculated rather than a median per diem cost. The proposed CY 2013 partial hospitalization payment policies were described in section VIII. of the proposed rule.

In the proposed rule, we stated that we believe it is important to make the transition from medians to means across all APCs in order to capture the complete range of costs associated with all services, and to ensure that the relative payment weights of the various APCs are properly aligned. If some OPPS payments calculated using relative payment weights are based on means while others are based on medians, the ratio of the two payments will not accurately reflect the ratio of the relative costs reported by the hospitals. This is of particular significance in the process of establishing the budget neutral weight scaler, discussed in section II.A.4. of the proposed rule.

We noted that the few exceptions to the applications of the geometric mean-based relative payment weights would be the same exceptions that exist when median-based weights are applied, including codes paid under different payment systems or not paid under the OPPS, items and services not paid by Medicare, items or services paid at reasonable cost or charges reduced to cost, among others. For more information about the various proposed payment status indicators for CY 2013, we referred readers to Addendum D1 to the proposed rule (which was available via the Internet on the CMS Web site).

We proposed for CY 2013 that payment for nonpass-through separately payable drugs and biologicals will continue to be developed through its own separate process. Payments for drugs and biologicals are included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act, but the budget neutral weight scaler is not applied to their payments because they are developed through a separate methodology, outside the relative payment weight based process. We noted that, for CY 2013, we proposed to pay for nonpass-through separately payable drugs and biologicals under the OPPS at ASP+6 percent, based upon the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. Also, as is our standard methodology, for CY 2013, we proposed to use payment rates based on the ASP data from the fourth quarter of CY 2011 for budget neutrality estimates, packaging determinations, and the impact analyses. For items that did not have an ASP-based payment rate, such as some therapeutic radiopharmaceuticals, we proposed to use their mean unit cost derived from the CY 2011 hospital claims data to determine their per day cost. The nonpass-through separately payable drug and biological payment policy for CY 2013 is described in greater detail in section V.B. of the proposed rule and this final rule with comment period.

Comment: Many commenters expressed cautious support for the proposal to calculate the relative payment weights based on geometric mean costs. The commenters believed that the inclusion of additional cost data in developing the APC relative payment weights would represent an improvement to the ratesetting process, while the generally limited provider impacts and enhanced sensitivity to cost changes in calibrating the 2 times rule would be appropriate. While the commenters supported improvements in the accuracy of the OPPS relative payment weights and the goals of the proposed policy, they requested that CMS proceed with caution and transparency in this process to avoid unintended consequences on beneficiaries and hospitals. The commenters also suggested that CMS monitor changes in frequency and cost distributions for services for several years to ensure that no access to care issues develop as a result of the geometric means-based payment policy. Several commenters requested a transitional approach to relative payment weights based on geometric mean costs to mitigate any potentially negative payment effects.

Response: We appreciate the commenters' support. As discussed in the CY 2013 OPPS/ASC proposed rule, we believe that using geometric mean costs to calculate the APC relative payment weights will make them more reflective of the range of service costs, introduce greater sensitivity to the 2 times rule, as well as potentially allow for cross-system payment comparisons (77 FR 45094). We believe that the numerous changes we have made to the data process to obtain additional information from the available cost report and claims data and ensure the accuracy of the cost estimation, in addition to hospital experience with the OPPS, have prepared us to make this incremental change. We agree that the change to base the relative payment weights on geometric mean costs is appropriate.

We recognize the concerns that commenters have regarding a transitional process towards geometric mean-based APC payment and the possibility that payment fluctuations based on both the naturally occurring variation from year to year and those variations associated with basing the relative payment weights on geometric mean costs may occur. However, we do not believe that an approach to geometric mean-based OPPS relative payment weights beyond the changes we have proposed for the CY 2013 OPPS is necessary or appropriate. Prior to proposing this change, we evaluated the last 4 years of OPPS claims data to model the fluctuations that would have resulted from geometric or arithmetic means in comparison to our traditional medians. We determined that there was no significant difference in the degree of fluctuation with geometric means or with medians, and we also believe that the one-time differences created by the switch are typically small; therefore, we do not believe that a transition period is necessary. In the CY 2013 OPPS/ASC proposed rule, we noted that we made limited changes in APC assignments except where necessary as a result of the proposal to base the relative payment weights on geometric mean costs and stated our intention to further examine appropriate OPPS reconfigurations in the future to resolve potential clinical or resource homogeneity inconsistencies in the future to promote stability (77 FR 45097). Geometric mean costs more fully encompass the range of costs, including packaged costs, associated with providing a service and, therefore, may result in payments that are more reflective of actual cost. Transitioning into a geometric mean-based system would not be practical, as one of the overarching goals of using geometric mean costs is better relativity across the OPPS. Applying a phased-in approach would potentially distort the relativity of the OPPS payment weights. As we discuss in section II.A.2 of this final rule with comment period, there are various reasons that contribute to cost fluctuation from year to year. We believe that artificially introducing stability into the payment system could potentially distort the relativity of the payment system, especially when doing so could potentially dampen both decreases and increases.

We agree that continued monitoring of changes in cost distributions and the frequency of services is important in understanding the impact of basing the APC relative payment weights on geometric mean costs. However, we note that the frequency of services may change from year to year based on a variety of factors, issues unrelated to OPPS payment, and situations where APC overpayment may have potentially led to inappropriate incentives to provide care. Despite the consideration of the many reasons that may cause service frequency and cost structures to change over time, we will continue to monitor these data, as well as make that information available online through the cost statistics files associated with each rulemaking cycle.

Comment: A number of commenters disagreed with the proposal to base the CY 2013 OPPS/ASC relative payment weights on geometric mean costs. Many of these commenters preferred continued use of median costs in the ratesetting process. Several commenters believed that the geometric mean costs were inappropriate for OPPS ratesetting for statistical reasons, including their heightened sensitivity to lower cost inliers and lowered sensitivity for high-cost outliers relative to arithmetic means. Other commenters were concerned about the range between minimum and maximum cost values for each APC, and believed them to be implausible. A few commenters stated that while there have been advances in coding practice over the past decade, the same problems of upcoding and outliers will continue to exist, and that the original selection of median costs would continue to be appropriate. One commenter suggested that, beyond the initial years of the OPPS, there have been no cost reporting and coding practice improvements over the years.

Response: We noted in the CY 2013 OPPS/ASC proposed rule that median costs have historically served and may continue to serve as an appropriate measure on which to base the relative payment weights (77 FR 45096). However, we believe that a policy of developing the relative payment weights based on geometric mean costs would represent an improvement beyond our current use of the cost information available to us.

In our discussion in the CY 2013 OPPS/ASC proposed rule relating to basing the relative payment weights on geometric mean costs, we stated that there are a variety of reasons that one metric might be more appropriate than the other. However, the reasoning for selecting one metric relative to any others must be considered in the context of the issues at that time. In our discussion of our proposal to develop the relative payment weights based on geometric mean costs, we described the issues at the initial development of the OPPS and our original reasons for selecting median costs as the preferred metric. We also described in the proposed rule the many data process changes that we made over the history of the OPPS, including various trimming methodologies, processes to generate more information from the claims and cost report data available to us, steps to address charge compression, modeling and payment edits, modeling configurations to make payment more reflective of the service or services provided, and others (77 FR 45095 through 45096). In addition, we discussed our belief that CMS and hospital experience with the OPPS as well as the coding methodologies for

payment would have improved over the past decade. Finally, we discussed various aspects of the geometric means proposal that would affect other policy areas, such as ASC payment, application of the 2 times rule, and other payment methodologies under the OPPS. For these reasons, we established the CY 2013 OPPS/ASC proposal to base the relative payment weights using geometric mean costs (77 FR 45094 through 45098).

We recognize that there are different aspects of each statistical metric that may make any of them preferable to the others. Means-based methodologies, whether arithmetic means or geometric means, incorporate a broader range of estimated cost values into the relative payment weights, whereas medians are less sensitive to that range of costs as well as any changes in them. Depending on whether sensitivity towards changes in service costs is viewed as a relevant objective or not may guide whether selecting means or medians is a preferable alternative. As described above, several commenters have suggested that the lack of sensitivity towards cost changes is precisely why medians remain the preferable option. However, in the CY 2013 OPPS/ASC proposed rule, we noted comments in the past expressing concern regarding the degree to which payment rates failed to reflect the costs associated with providing a service (77 FR 45096). In light of those concerns, we believe that geometric means and their ability to better reflect packaging patterns and ranges in cost represent an improvement in our cost estimation process.

With regards to the varying level of sensitivity towards cost outliers that geometric means represent, as described above, there are various benefits and drawbacks to each selected metric. Accordingly, the relative payment weights associated with any service may rise or fall, depending on the specific distribution of reported costs, and where the geometric mean appears not only relative to the median but also that of APC 606 (Level 3 Hospital Clinic Visits). While commenters have suggested that there is a systemic risk for ''implausible'' values, we believe that many of the outlier values present in the data represent actual cost outliers rather than errors, with different accounting assumptions creating different populations of values. At the low-cost and high-cost ends of the cost spectrum for each APC, there is thus the potential for both ''spurious'' (atypical and/or incorrect) data as well as accurate data to appear. Furthermore, while the minimum and maximum values identify the most extreme outlier values, they do not necessarily reflect the distribution of costs within the model; the minimum and maximum values may not accurately represent the range of costs describing the codes with greatest representation within an APC.

While commenters suggested that there has not been much of an improvement we believe the possibility exists that conditions and circumstances have stabilized to a certain degree over the past decade. Part of the argument for medians at the inception of the OPPS was that the coding system was still new, as was our use of claims data to calculate prospective payments. Given the many improvements we have made to our internal process of modeling and using data, we would expect that coding and cost reporting practices have improved over that time period as both CMS and hospitals have had the opportunity to develop more experience with the system.

Comment: Some commenters believed that aligning the OPPS relative payment weights on geometric mean costs would hamper hospitals' ability to plan budgets for each year, given the degree to which payments might fluctuate. The commenters also believed that geometric mean costs would lead to greater instability of OPPS payment. Some commenters were concerned about the negative impacts of APC payments declining due to use of geometric mean costs, believing that those changes hindered hospitals' ability to provide high quality health care.

Response: We do not believe that the policy of calculating relative payment weights based on geometric mean costs will inevitably lead to greater payment instability. There are a variety of factors that may contribute to payment volatility from year to year, as we have previously described in section II.A.2. of this final rule with comment period. While there may be some interim fluctuation in the short term as we realign the OPPS to be based on geometric mean costs, we expect many of those issues to stabilize over time. When discussing payment stability, the natural inclination is to view stability as a fixed numerical value that stays the same over time. We evaluated this numerical definition of stability and determined that it was not significantly greater when geometric means were used. However, another view of payment stability is through the relationship between costs and the degree to which they are reflected in payments. We believe that a policy of using geometric mean costs to develop the APC relative payment weights will make them more reflective of the costs associated with providing services. Further, using geometric mean costs helps ensure that the relative payment weights accurately reflect the distribution of costs associated with providing services, and mitigates the possibility that any fluctuation occurs due to gaps in the distribution of the model, rather than any material changes to the service costs.

We also disagree with the commenter's belief that use of geometric mean costs in calculating the relative payment weights will lead to hospitals being unable to provide access to high-quality health care. Geometric mean costs encompass a broader range of costs, and will result in payments that more fully reflect the range of costs both on the low and high ends, than median-based costs. We believe that this will ultimately be an improvement in the data process as well as OPPS payment policy. Although, as commenters have noted, there are many APC payment rates that decline as a result of the alignment of relative payments weights based on geometric mean costs, we note that a number of APC payment rates also increase as a result of this policy. We believe that, for most provider classes that furnish a mixed array of services to meet the various needs of their patients, the financial impacts from the changes in APC payment rates will be relatively limited. In consideration of all of those factors, we believe that the use of geometric mean costs will result in APC payments that are more reflective of the range of service costs.

Comment: One commenter believed that median costs and the fact that they do not reflect subtle changes in cost distributions was appropriate to use to determine the OPPS payment rates, given aberrant coding, billing, and charging practices by hospitals. The commenter also believed that OPPS outlier payments would address issues where high-cost services did not have those costs reflected in their APC payments. Several commenters suggested that lack of sensitivity towards packaging patterns when using median cost was why median costs would be a more appropriate metric. Other commenters believed that the hospital claims do not provide reliable data and that the Medicare cost report data at the departmental level are not accurate because there is no financial incentive to report accurate data. Commenters also stated that RTI identified flawed cost data and pointed out that charges on hospital claims do not match those on the cost reports. One commenter requested that CMS delay the proposal to use geometric mean

costs in ratesetting until it can verify that the data are not flawed.

Response: We appreciate the need for accurate and reliable cost information for use in the OPPS ratesetting process. Many of the changes we have made to our data process over the past decade have arisen with consideration of the need for accurate and reliable cost information. To a certain extent, we can mitigate the issues raised by those concerns through data process changes like trimming methodologies, such as those for the line items as well as cost and unit outliers, and modeling changes, such as those for composite and device-dependent methodologies, to more accurately estimate cost. However, more broadly, we rely on OPPS providers to submit accurate cost and charge information to establish the relativity in the OPPS on which APC payments are based.

We value the comments that stakeholders provide with regards to potential data improvements as well as methods by which we can obtain more accurate data. In situations such as the proton beam APCs for the CY 2013 OPPS/ASC proposed rule and subsequent information about cost report revisions and inaccurate coding, we must balance our reliance on information from OPPS providers with the complementing goal of obtaining accurate cost information. As we described in the CY 2013 OPPS/ASC proposed rule, we have taken steps to address issues such as charge compression in areas such as the former ''Medical Supplies Charged to Patients'' cost center by establishing a new standard cost center for ''Implantable Medical Devices Charged to Patients.''

In the case of calculating relative payment weights based on geometric mean costs, we believe that such a change, while affecting the OPPS very broadly, would not involve much manipulation of the data. Although several commenters have suggested that the lack of sensitivity towards cost outliers is appropriate, we also have received comments and HOP Panel presentations in the past regarding the degree to which APC relative payments fail to reflect high-cost packaged services. Calculating relative payment weights based on geometric mean cost is one way of being responsive to those concerns regarding the degree to which correctly reported claims with unusually high costs are incorporated into the relative payment weights. While we agree that OPPS outliers do help mitigate the financial risk associated with performing certain services that require additional complexity or resources, we also believe that developing the relative payment weights based on geometric mean-based costs will help ensure that payments are more reflective of the range of service cost.

In the CY 2013 OPPS/ASC proposed rule, in our proposal to base the CY 2013 relative payments weights on geometric mean costs, we described the many changes we have made since the inception of the OPPS to improve upon our data process. These improvements have helped us obtain more information from the claims and cost report data we have available to us, in addition to ensuring the accuracy of the resource cost estimates we use to model the APC relative payment weights. While we continue to look for ways in which we can improve the OPPS and our modeling of the estimated costs used to develop the relative payment weights, we do not believe that the cost information and methods through which we establish the relative payment weights are inherently flawed. Aligning the relative payment weights based on geometric mean costs may be a significant change in how the relative payment weights are calculated; however, the change can be viewed as incremental based on the other data improvements throughout the history of the OPPS, as described earlier in this section.

We believe that incentives exist for accurate cost reporting beyond direct financial incentives. We believe that external perceptions of incorrect reporting are based primarily on the failure to consider limitations of the data collection methodology when making assumptions and conclusions. The Medicare cost report form allows hospitals to report in a manner that is consistent with their own financial accounting systems and, therefore, should be accurate for each individual hospital.

The regulations at 42 CFR 413.24(f)(4)(iv) specify the certification statement on the first page of the Medicare cost report (Hospital and Hospital Heath Care Complex Cost Report, Form CMS–2552–10) that must be signed by the hospital's administrator or chief financial officer certifying that the data contained in the cost report are true and accurate. Also included on the certification page is a ''penalty statement'' which conveys to the hospital official signing the cost report that misrepresentation or falsification of any information contained in the cost report is punishable by criminal, civil, and administrative action, fine, and/or imprisonment under Federal law. Further, the ''penalty statement'' also states that if services identified in the cost report were provided or procured through the payment directly or indirectly of a kickback or were otherwise illegal, then criminal, civil, and administrative action, fine, and/or imprisonment may result. We believe that the possibility of mandatory cost report adjustments by fiscal intermediaries or MACs where erroneous amounts are found to exist and the possibility of Federal prosecution where potentially false claims and/or fraudulent conduct are found to exist act as reasonable incentives to complete the cost report accurately. Further, the cost report data and their use in the OPPS cost estimation and payment rate development process, combined with potential penalties for inaccurate reporting, provide financial incentive for reporting costs accurately.

We recognize that hospitals are complex entities, each having their own accounting systems and reporting methodology. As such, the cost and charge data that they provide through the Medicare cost report forms are structured in a way that reflects their own internal accounting systems. Although we would obtain the most accurate information by using a highly structured reporting format across hospitals, in using these data for OPPS ratesetting, we must balance between our use of these data for the cost estimation process and the burden associated with forcing hospitals to convert to a government-mandated standardized financial management system. The current mechanism allows us to collect information that is accurate in the aggregate and that further, at a granular level, reflects the relative allocation of costs to departments and services by the industry as a whole without creating additional burden.

We note that while the RTI investigation into charge compression and the calculation of the relative payment weights yielded areas where the cost estimation process could be improved, there was no suggestion that the process or data itself were fundamentally flawed. We also note that we have tried to be responsive to the concerns raised in the RTI report regarding charge compression and the accuracy of the relative payment weights, for example, through the creation of the new ''Implantable Medical Devices Charged to Patients'' standard cost center or through the packaged cost redistribution to account for pharmacy overhead in the past several years. Regarding the concern about the matching process between the data used to calculate the CCRs on the Medicare cost report and the claims-

based charges, we note that we use the most updated accurate information made available to us and match them to the degree possible to accurately calculate estimated costs. In the revenue code-to-cost center modeling crosswalk that we use to estimate cost, the hierarchy of cost center CCRs is based on our best assumption of where those revenue code charges would be placed even though it may not necessarily reflect every hospitals' individual cost report structure.

As discussed earlier in this section, we have made many improvements to the OPPS data process over the course of the past decade. Many of those changes were intended to either derive more information from the claims and cost report data we have available to us, while others were intended to estimate cost in a way that more accurately represented the provision of the service and associated resources. We believe that basing the relative payment weights on geometric mean costs will improve the degree to which our APC payments reflect the range of resource costs associated with providing services, and represents an incremental data improvement. Therefore, we do not believe it is appropriate to postpone the use of geometric mean costs in establishing the CY 2013 OPPS/ASC relative payment weights.

Comment: Several commenters requested clarification regarding why CMS selected geometric mean costs as the metric for our proposed policy for calculating the CY 2013 OPPS/ASC relative payment weights rather than arithmetic mean costs. Other commenters noted that using arithmetic means would bring the OPPS even further in line with the IPPS ratesetting methodology.

Response: While developing the proposal to establish the CY 2013 OPPS/ASC relative payment weights using geometric mean costs, we also reviewed the volatility associated and impact of an OPPS based on arithmetic mean costs. We also considered many of the same issues that commenters described with respect to the use of arithmetic means, including whether their ability to more sensitively consider the variety of cost patterns, provide a better reflection of total costs, and to synchronize the OPPS system with the IPPS methodology, would be a preferable option among the three metrics.

We noted that because only natural and ''pseudo'' single major claims would be used to model the relativity of the OPPS, arithmetic means would not truly reflect total cost in the system. Although arithmetic mean costs would be more sensitive towards outlier values than both geometric mean costs and median costs, there would also be greater volatility associated with the use of them due to their sensitivity towards outlier values. Similarly, the short-term transition from medians to arithmetic means would also include a greater range of both positive and negative provider payment impacts and would result in the need for more reconfiguration of the APCs to resolve 2 times rule violations than geometric mean costs. While we have discussed our intention to perform a thorough review of the OPPS in the future that may involve more significant reconfiguration, that review would be performed with the goal of developing more accurate and stable payment rates, to the extent that they reflect the range of service costs. Although we stated the possibility of using these geometric mean based payments for exploring cross-system payment comparisons, we recognize that there may be aspects of each payment system data methodology that may be unique. While using arithmetic mean costs would potentially capture the full range of costs better than both geometric means and medians, that benefit has limited value in a relative system such as the OPPS, where all total costs are reduced to relative rates. Conversely, it also would potentially allow an inappropriate impact due to aberrant values because there would be no mitigation of the influence of outlier costs, which could be accurate or aberrant values. Therefore, we viewed the use of geometric mean costs as a balanced approach between both the strengths and weaknesses of using medians and arithmetic means.

Comment: Several commenters expressed concern with regard to the decline in APC payment to CMHCs due to use of the geometric mean cost for calculating the OPPS relative payment weights, and recommended that CMS continue to monitor the impact of its payment policies on CMHCs.

Response: Over the past several years, we have made changes to the calculation of PHP relative payment weights to more accurately align their PHP APC payments to their specific costs. These changes to PHP relative payment weights have included establishing a separate cost estimation process based on provider type as well as a two-tiered APC payment system under which we pay one amount for days with 3 services and a higher amount for days with 4 or more services for both CMHC and hospital-based PHPs. As discussed in the CY 2013 OPPS/ASC proposed rule, we believe that the use of geometric mean costs rather than median costs in the ratesetting process is one such improvement because it allows the payment metric to consider a broader range of service costs (77 FR 45097). We will continue to monitor the impact of our payment policies on OPPS providers, including CMHCs.

Comment: One commenter was concerned with the minimum and maximum values associated with APCs 0690 (Level I Electronic Analysis of Devices) and 0105 (Repair/Revision/Removal of Pacemakers, AICDs, or Vascular Devices). In the case of APC 0690, the commenter suggested that the APC payment rate be set to the median cost and not allowed to drop below the payment that CMS would have calculated using medians. For CPT 0307T (Removal of intracardiac ischemia monitoring device), the commenter also believed that its placement in APC 0105 was appropriate. However, the commenter requested that CMS perform an analysis to determine whether some of the procedures might be more appropriately placed in a different APC.

Response: In the case of both of these APCs, the presence of high-cost, low-volume services in the claims used to model each APC creates outliers that foster the perception that the services spread more evenly across the range between the minimum and maximum values than actually is the case. Those minimum and maximum values represent individual points at the most extreme ends of the model, and include service cost estimations that do not contribute significantly enough to the APC weight to be considered in the application of the 2 times rule. In that sense, those values can be misleading because the minimum and maximum should be considered as the most extreme outlier cases; we evaluate the range through the application of the 2 times rule, which only considers services that have sufficient volume to demonstrate stability and reliability and which significantly contribute to the relative payment weight of the APC. Both medians and means are measures of central tendency and have strengths and weaknesses when considering the degree to which they accurately represent the dataset. Similarly, the minimum and maximum values are informative in identifying the most extreme outliers of a dataset but do not necessarily reflect the bulk of the distribution.

For CPT codes 0305T and 0306T which are assigned to APC 0690, we note that the geometric mean cost ($34.78) was slightly higher than the

median cost ($33.71) for the APC in the data used for the CY 2013 OPPS/ASC proposed rule. In addition, after calculation of budget neutrality and other adjustments, the national unadjusted payment rate for a geometric mean cost-based APC payment was proposed to be higher than a median cost-based one for CY 2013. Finally, for prospective APC payment rates which are calculated through the standard process, we would not pay using the cost as a rate but we would use the estimated costs to establish the relative payment weights on which OPPS payments are based. Therefore, we are not setting the payment rate for APC 0690 at the median cost.

We appreciate the commenters' support regarding the placement of CPT code 0307T in APC 0105. We do not agree that having a wide distribution of costs in an APC necessarily implies that a problem in the construction of the APC exists, particularly in cases where we believe the clinical placement and resource use is appropriate. As described above, the minimum and maximum values identified within each CPT or APC are the most extreme outliers, and may not necessarily reflect where the majority of the cost estimates are within each code. For application of the 2 times rule discussed in section III.B. of this final rule with comment period, we only consider codes that are ''significant'' in their contribution towards the cost estimates in the APC as being useful in the identification of how similar the services within an APC are to each other, from a cost perspective. However, this does not eliminate the need to consider clinical factors when constructing the APC assignments. We do not believe that differences in the distribution of costs for a service automatically creates the need for further study, especially because the purpose of geometric mean costs is to more fully include those cost observations. Similarly, the APC configurations are intended to group together services with clinical and resource homogeneity. However, in the CY 2013 OPPS/ASC proposed rule, we stated our intention of using the information we have available to us to reexamine the APC structure and assignments to consider further ways of increasing the stability of payments over time, and will consider these issues as we do so in the future.

Comment: Commenters expressed concern with regard to the impact of the use of geometric mean-based costs for other specific APCs as well as certain clinical areas. APCs that commenters requested specific detail about included APCs 0690 (Level I Electronic Analysis of Devices); 0105 (Repair/Revision/Removal of Pacemakers, AICDs, or Vascular Devices); 0331 (Combined Abdomen and Pelvis CT without Contrast); 0334 (Combined Abdomen and Pelvis CT with Contrast); 0383 (Cardiac Computed Tomographic Imaging); 0336 (Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast); 0337 (Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast followed by Contrast); 0308 (Positron Emission Tomography (PET) imaging); 0402 (Level II Nervous System Imaging); 0408 (Level III Tumor/Infection Imaging); 0169 (Lithotripsy); 0385 (Level I Prosthetic Urological Procedures); 0386 (Level II Prosthetic Urological Procedures); and 0674 (Prostate Cryoablation). Other clinical areas that commenters expressed concern about included otolaryngological and orthopaedic procedures. One commenter requested that CMS ensure that there was no disproportionate impact to any given medical specialty.

Response: In the case of these APCs, generally the issue is that the geometric mean costs reflect lower cost values than otherwise indicated by the median value. We have identified numerous other data issues or policies beyond the use of geometric mean costs that may attribute to potential declines in the relative payment weight.

For APCs 0331 and 0334, this is the first year where actual data are available for ratesetting based on the new CY 2011 computed tomography of abdomen/pelvis codes: CPT codes 74176 (Computed tomography, abdomen and pelvis; without contrast material); 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 more discussion on the Computed Tomography of Abdomen/Pelvis APCs, we refer readers to section II.A.7.c. of this final rule with comment period.

Another influencing factor may be the use of the new standard cost center for ''Implantable Devices Charged to Patient''. For device-dependent APCs 0385, 0386, and 0674, there may be effects based on use of the new standard cost center CCR being mapped to revenues codes where appropriate. For a discussion of the cost report CCRs used to estimate service cost, we refer readers to section II.A.1.c. of this final rule with comment period.

For APC 0169, the estimated costs of the APC may have changed based on corrections to the revenue code-to-cost center crosswalk described in the second correction notice to the CY 2012 OPPS/ASC final rule with comment period (77 FR 24409). Further, because CPT code 50590 (Lithotripsy, extracorporeal shock wave) is the only code used to model the APC, any variation with the estimated costs for the CPT code will directly affect the APC relative payment weight.

For all the APCs referenced by commenters, the relative payment weights based on using geometric mean costs now include a greater range of resource costs associated with furnishing the services. Declines in their APC relative payment weights can partially be attributable to these changes in the degree to which the relative payment are reflective of costs. As we have noted, there also may be additional influencing factors that have led to those changes, including use of actual rather than simulated claims data, the use of the new ''Implantable Medical Devices Charged to Patients'' standard cost center, the corrections we made to our revenue code-to-cost center modeling crosswalk in our data process, and others. We also note that, because of budget neutrality, for each APC that commenters identified as having decreased payments, there are other APCs that have increased payments. As a general matter, we believe that, in their totality, the newly based APC payment rates better reflect the underlying costs in both cases.

We have typically analyzed the impacts of any proposals at the CPT code, APC, and provider levels of granularity, as most hospitals furnish a variety of services to Medicare beneficiaries. We do not believe that observed declines or increases in the payments for codes are typically associated with any individual specialty because, as we have noted, there are both increases and decreases in relative payment weight associated with this proposal. Additionally, changes generally are due to the degree to which medians were insensitive to the range of service costs.

Comment: One commenter expressed concern regarding the impact of geometric means-based payment on blood products because many of the blood product APCs would experience declines in payment. The commenter recommended that blood products continue to be separately paid based on simulated median costs or that a CY 2013 payment floor be set at the CY 2012 APC payment rates.

Response: While we appreciate the concerns expressed by the commenter, we do not believe that it is appropriate to establish the relative payment weights using different cost metrics for various APC categories. Doing so would potentially distort the cost relativity and APC payments of services paid through the OPPS. We note that, to ensure that the cost estimation process for blood products is as accurate as possible, we have continued to use simulated CCRs where appropriate, as discussed under section II.A.d.2. of this final rule with comment period. Similarly, we do not believe that setting a payment floor for a specific set of services is appropriate. The estimated resource costs associated with providing a service change from year to year and establishing arbitrary payment floors would decrease the degree to which APC payments reflect the range of costs associated with providing a service.

Comment: Commenters also expressed concern regarding the use of geometric mean costs as the basis for APC relative payment weights for brachytherapy sources and recommended that they not be used in establishing the relative payment weights. The commenters believed that geometric mean costs would be inappropriate for use in ratesetting, in particular for the case of brachytherapy sources.

One commenter stated that the geometric mean is inappropriate for use in determining payment levels under the OPPS because it will overemphasize the weight of low and potentially spurious values in the data. The commenter had other statistical concerns regarding the extent to which there were high-cost and low-cost outliers that they believed were not plausible values as well as variation in estimated costs for brachytherapy relative to other OPPS services. The commenter attributed that variation as being due to hospital reporting practices, and contrasted that variation in the OPPS to the IPPS, where the commenter believed the main concern was high-cost outliers and high-cost values. Under the commenter's belief that geometric means would pay inadequately for brachytherapy, the commenter also believed it would create a disincentive to use brachytherapy in the treatment of cancer and create access to care issues. The commenter stated that CMS would be acting contrary to the intent of the cost-based payment extensions for brachytherapy payment from CY 2004 through CY 2009. Further, the commenter stated that CMS did not provide sufficient warning to other policymakers in CYs 2010 and 2011 regarding the likelihood that it might potentially change the cost metric used to establish relative payment weights. The commenter believed that geometric mean costs should not be used to develop the relative payment weights of brachytherapy sources.

Response: As with all other OPPS services that would be affected by the proposed policy, we do not believe that the use of geometric mean costs in establishing the APC relative payment weights for brachytherapy sources is inappropriate. While the use of geometric mean costs will include the weight of low values in the data, we note that it also better incorporates cost observations from the higher values in the data. This can be seen in the increases in the relative payment weight for certain brachytherapy sources based on using geometric mean costs. As discussed earlier in this section, the values now being included could potentially include spurious values on both ends of the dataset, as well as legitimate and accurate data. We believe that encompassing a broader range of service costs in establishing the relative payment weights is a technical improvement and may increase the degree to which payments reflect the range of costs associated with providing a service.

Both the IPPS and OPPS contain reporting variations due to the different charging practices among hospitals. While we agree that some of the variations in cost outlier values may be due to the fact that brachytherapy sources rely on charges and costs associated with a CCR, that does not imply that they are necessarily inappropriate, as all OPPS payments rely on charges and CCRs. As we have noted earlier in this section, as long as providers are using generally acceptable accounting practices (GAAP), and the cost report structure reflects their charging practices, we believe that this results in accurate calculations. While the commenter has suggested that the variation in the costs of brachytherapy sources is inappropriate, this can be attributed to both accounting and real cost differences among the various providers that furnish the service in addition to low frequency of line items which may be used to model cost. Although medians may be less sensitive to cost outliers, or even the range of costs, we believe that is both a strength and a weakness of that metric, but is not a reflection of greater or lesser accuracy. While commenters have provided examples with a sample size of three values to illustrate their point regarding sensitivity to low cost values, we note that cases with this order of extreme observations used to model the relative payment weights would be exceptionally rare. For example, the commenter posited a reported charge of $0.01 which is not only extremely unlikely but also is not supported by institutional claims processing. In situations where there are few claims available to model the service costs, the basic issue is the claims volume and their use in establishing the relative payment weights, and not necessarily the fact that medians or geometric means are used. We can address small claim volumes in some cases through assigning similar services based on resource costs or clinical similarity to the same APCs. However, this method of addressing variability based on low claims volume is unavailable as a tool for line item cost-based APCs.

We do not believe that changes in payment based on the use of geometric mean costs will create a disincentive towards using brachytherapy as a viable option in the treatment of cancer. As we noted earlier in this section, there is variation even among the brachytherapy APCs, which suggests that some of those APC payment rates may now better reflect the range of costs associated with them. There also is extreme variation in the costs reported by individual hospitals for each service within the APC. In considering whether a median cost-based system or a geometric mean-based system is more appropriate at this juncture, the inclination is to view declines in payments as aberrant, without consideration of increases in payment. However, it is equally possible that medians and their lack of sensitivity towards outliers may have led to more payments based on overstated costs than would have been appropriate when considering the broader range of service costs. As discussed in an earlier response, we will continue to monitor the impact of this proposal to base the relative payment weights on geometric mean costs.

With respect to the comments regarding the process through which we establish payment policy for each prospective payment year, we note that the OPPS rulemaking process occurs annually, and is intended to give providers notice as well as the opportunity to inform rulemaking and express their stances regarding various policy proposals. While being able to prepare for each rulemaking cycle so that each prospective payment policy proposal is known years in advance may be preferred by commenters, it is not operationally feasible. As we have discussed in this section, as well as in the CY 2013 OPPS/ASC proposed rule,

the situations that were pressing during the inception of the initial OPPS, and the changes we have made since then, have allowed us to consider different issues as well as areas for improvement. We believe that basing the relative payment weights on geometric mean costs is one such improvement. Although Congress did extend the prior cost-based methodology for brachytherapy sources from CYs 2004 through 2009, we note that no such additional extension has been enacted. Further, the discretion to use a median-based or mean-based system in establishing the OPPS relative payment weights predates those extensions, as authorized by section 201(f) of the BBRA of 1999.

While we recognize the concerns regarding the payments for brachytherapy sources based on geometric mean costs, we continue to believe that this change will result in more accuracy in the cost estimation. We do not believe that paying for some services based on median costs while using geometric mean costs for other services is appropriate, equitable, or consistent with statute. Further, using different cost metrics for different services could distort the relativity of services within the system and increase the inaccuracy and instability of service payment.

Comment: Several commenters noted that they had difficulty modeling the budget neutrality and impact calculations, and suggested that CMS provide a more thorough explanation before proceeding with the proposal to establish OPPS relative payment weights based on geometric mean costs. The commenters stated that lack of a study, in particular one that studies the effect of using geometric mean costs as the basis for the relative payment weights over time, made it difficult for them to make an informed decision. The commenters also stated that an explanation regarding the impacts was necessary before proceeding, with several commenters noting that the effect of basing the relative payment weights on geometric mean costs was not evenly distributed by provider types. One commenter disagreed that there would generally be limited financial impact to hospitals, due to the fluctuations in certain APCs. Some commenters claimed that the proposal to base the relative payment weights on geometric mean costs disproportionately affected teaching hospitals. Other commenters asked CMS to provide a list of APCs whose costs fluctuated above a certain threshold each year, so that those APCs could be identified through rulemaking for public comment and to allow for presentations before the HOP Panel. A few commenters expressed concern in using geometric mean costs for small sample sizes, as was the case with those associated with proton beam therapy.

Response: For the past several years, each OPPS/ASC rule has included a discussion summarizing both our data process, as well as the calculations associated with budget neutrality and hospital impacts. However, we also make available online a claims accounting document that summarizes in great detail the claims manipulation that goes into modeling the costs used to develop the relative payment weights, as well as the calculations and data processes used to model budget neutrality and the hospital impacts each cycle. The budget neutrality and hospital impacts portions of this document were developed beginning with the CY 2007 OPPS proposed rule, and have been available for every OPPS rulemaking cycle thereafter.

While we appreciate the concerns that commenters have with regard to studying the effects over time, we believe that any increased fluctuations due to geometric mean-based payments are generally not significant enough to create cause for concern. This data process change applied to the cost metric used to develop the relative payment weights more fully captures the range of costs associated with providing a service. However, service costs and APC payments fluctuate over time for a variety of reasons, as we have previously discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74139). As we have discussed earlier in this section, we will continue to monitor the impact of using geometric mean costs to establish the APC relative payment weights and any changes in service frequency or beneficiary access. Our investigation into the impact of using geometric mean costs to establish the relative payment weights also suggest that there should be limited volatility in the payment rates after this initial change. We note that some services do have payment decreases associated with using geometric mean-based relative weights. However, many services also experience payment increases as a result of the geometric mean-based calculation, presumably because the relative payment weights more accurately reflect higher costs associated with provisions of those services. Finally, we note that the one-time effect of converting from medians to means this year is not to be confused with the much less significant effect of year-to-year variation associated with means.

We agree with the commenters' concern regarding the issue of APCs with small sample sizes. However, our concern has less to do with the use of geometric mean costs being used to model the relative payment weights where they are appropriate, but more with the degree to which a substantive cost baseline can be established. In general, APCs with relatively low service costs or those where there is low claims volume tend to be more vulnerable to cost and payment volatility. We continue to examine methods and APC configurations, such as larger bundles, to mitigate any concerns related to those issues. As the commenter discussed regarding the case of proton beam therapy, there are situations where the costs of the service reflect only provision from a small number of providers and, therefore, may not establish a broad baseline as is the case for most APCs. However, in the case of the proton beam APCs, a sufficiently large volume of claims had been provided and the geometric means helped carry out our intention of capturing the full range of costs. As discussed in the APC-specific policy section of this final rule with comment period, section II.D., the issues relayed by the commenter primarily were due to presumed idiosyncrasies and errors in the submission of the cost reports, which, in turn, affected the estimation of costs, and was further impacted by the coding practices at an individual provider. We note that the potential of these issues to affect the relative payment weights would occur both under a median-based system, provided there was enough significant volume, as well as under geometric mean costs.

In both the CY 2013 OPPS/ASC proposed rule and in this CY 2013 OPPS/ASC final rule with comment period, we have included a column in the impact tables that separately shows the effects of the use of geometric mean costs on the APC relative payment weights. At a very basic level, provider categories that experienced more significant negative or positive payment impacts did so because of the mix of services furnished by those providers based on our claims data. We note that the OPPS provider payment impacts identified in section XXIII. of this CY 2013 OPPS/ASC final rule are relatively limited. Some commenters have stated that the policy of developing relative payment weights using geometric mean costs disproportionately affects teaching hospitals; other commenters have noted that the impacts are not identical based on the provider categories. That differential in the impacts is to be

expected based on this policy, just as any estimated payment impact based on the mix of services that a hospital provides will vary from year to year. Because this policy affects the calculation of the relative payment weights and does not affect the relative payment weights uniformly, it is natural for the changes in those weights to have corresponding variation reflected in the provider impacts based on the mix of services furnished by providers. In the provider impact table in this CY 2013 OPPS/ASC final rule with comment period, we note that, even among major and minor teaching hospitals, there are different estimated impacts based on this policy. We further note that, while the payment category may reflect an increase or decrease in total estimated payment, even among the hospitals in that category, there may be differential impacts that may not necessarily be in the same direction. As discussed earlier in this section, we will continue to monitor any changes that may be associated with the policy of calculating the relative payment weights using geometric mean costs.

We make available with each proposed rule and final rule cost statistics files that include information about costs by CPT code and APC, as well as modeling and total frequency information for each code. Addenda A and B which show the payment rates associated with each rule, also are made available on the CMS Web site. Therefore, the information to continue monitoring changes in APC payment, code frequency, and cost are made available to the public.

Comment: One commenter supported the goal of making cross-system payment comparison of payment parity. Two commenters cautioned against using OPPS payments based on geometric mean costs as a basis for examining payment parity across the prospective payment systems. They noted that other factors may be involved that would cause those comparisons to potentially be inappropriate, including the acuity of the patients, case-mix, ratesetting methodologies, and resource use in different care settings, as well as different payment adjustments in each system.

Response: While we believe that each of the payment systems has an internally consistent methodology, we recognize the value of including useful information in making potential payment comparisons. We note that we already implement cross-system payment and utilization comparisons in cases such as the MPFS DRA imaging cap, the ASC cap on separately payable radiology services, the cap on ASC office-based covered surgical procedures, and the comparison of service provision across settings for purposes of the inpatient list. The goal in making any potential payment comparisons is to analyze the differences and similarities in as appropriate a manner as possible.

As we discussed in the CY 2012 OPPS/ASC final rule with comment period, in the context of the proposed Cardiac Resynchronization Therapy composite APC, there are various goals associated with making cross-system payment comparisons, including ensuring that we do not create an inappropriate payment incentive to provide services in one setting of care as opposed to another, using more accurate information where it is available, and constructing the payment groups to be more clinically and resource similar to each other where appropriate, among others (76 FR 74179 through 74182). We specifically noted that there could be many payment approaches that could be chosen for comparison purposes for any given item or service (76 FR 74181).

After consideration of the public comments we received, we are finalizing our proposal to develop the APC relative payment weights using geometric mean costs in the manner described above.

As we also discussed in the CY 2013 OPPS/ASC proposed rule (77 FR 45097), under the revised ASC payment system that was effective January 1, 2008, we established a standard ASC ratesetting methodology that bases payment for most ASC covered surgical procedures and some covered ancillary services on the OPPS relative payment weights (72 FR 42491 through 42493). Therefore, because we proposed to calculate CY 2013 OPPS relative payment weights using geometric mean costs, we also proposed that CY 2013 ASC payment rates under the standard ASC ratesetting methodology would be calculated using the OPPS relative payment weights that are based on geometric mean costs. We noted that basing the relative payment weights on geometric mean costs rather than median costs affects the proposed CY 2013 payment rates. We stated that differences in the proposed payment rates, as with any changes from year to year, affect other parts of the OPPS, including the copayments described in section II.I. of the proposed rule as well as the fixed-dollar outlier threshold described in section II.G. of the proposed rule.

We did not receive any public comments on the adoption of OPPS relative payment weights based on geometric means in the ASC system. For a more detailed discussion of the ASC ratesetting methodology, we refer readers to section XIV. of this final rule with comment period.

Under the CY 2013 proposed policy to base the relative payment weights on geometric mean costs, we also proposed to revise the related regulations that currently reflect a median cost-based OPPS to instead reflect a geometric mean cost-based OPPS. Specifically, we proposed to revise 42 CFR 419.31, which describes the 2 times rule discussed in section III.B. of the proposed rule and this final rule with comment period and the development of relative payment weights based on the cost metrics discussed in section II.A.4 of the proposed rule and this final rule with comment period.

Comment: One commenter stated that CMS did not address why it did not apply the 2 times rule based on geometric means while continuing to use medians for calculating the relative weights because the commenter believed that it would improve the detection of changes in service cost while basing relative payment weights on the less volatile median.

Response: In the CY 2013 OPPS/ASC proposed rule, we discussed the impact of evaluating the 2 times rule based on geometric mean costs rather than median costs, noting that while doing so did not significantly affect the application of the rule, it created several additional 2 times rule violations in the rebasing process (77 FR 45097). Similar to the IPPS and since the inception of the OPPS, we have used a statistical outlier trim of three standard deviations beyond the geometric mean cost, even though we have historically used median costs as the metric on which to base the relative payment weights. The application of the 2 times rule is inherently tied to the configuration of the APCs and, therefore, how individual codes are paid. To apply the 2 times rule based on geometric mean cost and reconfigure the APCs based on that metric, while calculating relative payment weights based on medians, would be an inconsistency in the data process in the same way that using geometric mean costs for some services and median costs for others would be. Further, section 1833(t)(2) of the Act states that the application of the 2 times rule should be based on the metric selected in section 1833(t)(2)(C) of the Act.

After consideration of the public comments we received, we are finalizing our proposal to apply the 2 times rule based on geometric mean costs and the corresponding changes in 42 CFR 419.31.

In section XXII. of this final rule with comment period, which discusses the regulatory impact analysis, we are providing an additional column in the impact tables for the OPPS that identifies the estimated impact due to APC recalibration of a geometric means-based OPPS as well as a column that estimates the impact of recalibration based on CY 2011 claims and historical cost report data. As depicted in the impact tables, many provider categories will experience limited impacts under the final policy to base the OPPS relative payment weights on geometric means. We note that the impact tables only estimate the OPPS payment impact based on the most current available claims and cost report data, and that providers' actual payments may vary, depending on the mix of services provided in the actual claims year. Also, the budget neutral payment adjustments ensure that, under a geometric mean-based system or a median cost-based system, aggregate OPPS payments will remain the same.

Section XXII. of this final rule with comment period contains an OPPS provider impact table that estimates the effect of policy changes and budget neutrality adjustments on provider payment under the CY 2013 OPPS. Column 3 of the impact table shows the estimated impact by provider category of calculating the CY 2013 OPPS payments based on geometric mean costs rather than median costs. While the policy to shift the basis for relative payment weights to geometric mean costs may involve some changes to the relative weights on which OPPS payments are based, providers will generally experience limited impacts to payment as a result of the CY 2013 final policy. Those provider categories that are estimated to experience increased payments as a result of the policy to base the CY 2013 relative payment weights on geometric mean costs generally included non-IPPS hospitals that provided psychiatric, hospital-based PHPs, and other services whose relative payment weights increased based on geometric mean costs. As noted above, we recognize that there may be fluctuations in the relative payment weights based on this CY 2013 final policy, but we believe that this policy represents an improvement that more accurately estimates the costs associated with providing services.

In our experience developing the OPPS, we have implemented many changes to obtain more cost information from the claims and cost report data available to us, in an effort to arrive at more accurate estimates of service cost. Many of those changes are described above and in prior OPPS final rules. Despite the challenges created by the complexity of the data and the diversity of facility accounting systems, we continue to examine possible process and data changes that may further improve precision, validity, and utility. Commenters have historically expressed concerns about the degree to which OPPS relative payment weights are reflective of the service costs associated with providing them, APC payment rate volatility from year to year, and other cost modeling related issues. We recognize that some of those issues will remain because they are related to naturally occurring changes in the economic environment, clinical practice, and the nature of payment systems, among other reasons. However, we believe that basing the OPPS relative payment weights on geometric means better captures the range of costs associated with providing services, improves payment accuracy while limiting year-to-year volatility, and allows reconfigurations in the APC environment using a metric that provides greater computational depth. For these reasons, and those discussed above, we are basing the CY 2013 OPPS/ASC final relative payment weights on geometric mean costs.

3. Changes to Packaged Services

a. Background

Like other prospective payment systems, the OPPS relies on the concept of averaging, where the payment may be more or less than the estimated cost of providing a specific service or bundle of specific services for a particular patient. However, with the exception of outlier cases, overall payment is adequate to ensure access to appropriate care. The OPPS packages payment for multiple interrelated services into a single payment to create 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 which are more expensive than others, packaging encourages hospitals to use the most cost-efficient item that meets the patient's needs, rather than to routinely use a more expensive item, which could result if separate payment is provided for the items. Packaging also encourages hospitals to negotiate 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 scrutinizing the services ordered by practitioners to maximize the efficient use of hospital resources. Packaging payments into larger payment bundles promotes the predictability and accuracy of payment for services over time. Finally, packaging may reduce the importance of refining service-specific payment because packaged payments include costs associated with higher cost cases requiring many ancillary services and lower cost cases requiring fewer ancillary services. For these reasons, packaging payment for items and 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 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.''

We assign status indicator ''N'' to those HCPCS codes of dependent services 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 to 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 with one or more separately paid primary services with the status indicator of ''S,'' ''T,'' ''V,'' or ''X'' furnished in the hospital outpatient encounter. A T-packaged code describes a code whose payment is only packaged with 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 XII.A.1. of this final rule with comment period and Addendum D1, which is available via the Internet on the CMS Web site with other Addenda, for a complete listing of status indicators and the meaning of each status indicator.

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 to establish prospective payment rates. We encourage hospitals to report all HCPCS codes that describe packaged services provided, unless the CPT Editorial Panel or CMS provides 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 Medicare beneficiaries.

In addition to the packaged items and services listed in 42 CFR 419.2(b), 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 with 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. Packaging under the OPPS also includes composite APCs, which are described 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 2013 OPPS/ASC proposed rule (77 FR 45098 through 45101), we invited public comments regarding our packaging proposal for the CY 2013 OPPS.

b. Clarification of the Regulations at 42 CFR 419.2(b)

In the CY 2013 OPPS/ASC proposed rule (77 FR 45099), we proposed to clarify the regulatory language at 42 CFR 419.2(b) to make explicit that the OPPS payments for the included costs of the nonexclusive list of items and services covered under the OPPS referred to in this paragraph are packaged into the payments for the related procedures or services with which such items and services are provided. We stated that this proposed clarification is consistent with our interpretation and application of 42 CFR 419.2(b) since the inception of the OPPS. We invited public comments on this clarification.

Comment: One commenter objected to the proposed clarification of the regulatory language at 42 CFR 419.2(b). The commenter expressed concern that the proposed changes to the regulatory language are ambiguous and may result in confusion for hospitals and contractors. The commenter believed that Medicare audit contractors will try to assert that all services furnished during a particular encounter, such as E/M visits, drug administration, X-rays, or other ancillary tests, are all related to the main procedure or service received. The commenter further stated that this may lead to payment denials or monies taken during audits and/or post-payment reviews based on the proposed clarification. Therefore, the commenter recommended that CMS abandon this proposal because the current regulatory language is clear and instructs all entities about CMS' packaging principles.

Another commenter did not object to the proposed wording change from ''included costs'' to ''packaged costs'' because, the commenter stated, CMS did not propose to add or alter any of the examples of packaged items and services, and the language used already notes that the list provided is not an inclusive one. However, the commenter was concerned that the proposed addition of the phrase ''the payments for which are packaged into the payment for the related procedures or services'' introduces a new concept that may lead to a broad interpretation of the regulatory text. The commenter expressed concern that when audits of OPPS accounts occur, the proposed regulatory text may be used to broaden the packaging concept beyond accurate CPT coding by using a subjective interpretation of the term ''related''. Therefore, the commenter requested that CMS not add the phrase ''the payments for which are packaged into the payment for the related procedures or services''.

Response: We disagree with the commenters' assertion that the proposed clarification of the regulatory text at 42 CFR 419.2(b) is ambiguous or confusing. We note our proposal simply clarifies our longstanding policy of packaging, which is a fundamental concept of the OPPS. Specifying that included costs are packaged under the OPPS and that the payment for these packaged costs is packaged into the payment of the related procedures or services is consistent with our longstanding policies related to packaging. In addition, we disagree with the commenter's statement that the proposed addition to 42 CFR 419.2(b) of the phrase ''the payment for which are packaged into the payment for the related procedures or services'' introduces a new concept into the current regulation text.

As we have repeatedly stated, since the inception of the OPPS, packaging payment for items and services that are typically ancillary and supportive to a primary service has been a fundamental part of the OPPS. The concept of packaging entails that the costs for packaged services that are billed with a status indicator of ''N'' are packaged into the costs of the separately paid primary service with which they are billed. This then means that no separate APC payment is made for the packaged service alone but payment is instead included in the payment for the service or procedure with which the packaged service has been billed.

We believe that our clarification of the regulations at 42 CFR 419.2(b) is consistent with the concept of packaging under the OPPS and does not deviate in any way from our current and longstanding policies regarding packaging under the OPPS.

After consideration of the public comments we received, we are finalizing our proposed policy, without modification, to clarify 42 CFR 419.2(b) to make explicit that the OPPS payments for the included costs of the nonexclusive list of items and services covered under the OPPS referred to in this paragraph are packaged into the payments for the related procedures or services with which such items and services are provided.

c. Packaging Recommendations of the HOP Panel (''The Panel'') at Its February 2012 Meeting

During its February 2012 meeting, the Panel made five recommendations related to packaging and to the function of the subcommittee. One additional recommendation that originated from

the APC Groups and Status Indicator (SI) Assignment Subcommittee about observation services is discussed in section II.A.2.e. of this final rule with comment period. The report of the February 2012 meeting of the Panel may be found on the CMS Web site at: *http://www.cms.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp*.

Below we present each of the Panel's five packaging recommendations and our responses to those recommendations.

Panel Recommendation: CMS should delete HCPCS code G0259 (Injection procedure for sacroiliac joint; arthrography) and HCPCS code G0260 (Injection procedure for sacroiliac joint; provision of anesthetic, steroid and/or other therapeutic agent, with or without arthrography), and instead use CPT code 27096 (Injection procedure for sacroiliac joint, anesthetic/steroid, with image guidance (fluoroscopy or CT) including arthrography, when performed) with a status indicator of ''T,'' and assign CPT code 27096 to APC 0207 (Level III Nerve Injections).

Response: In the CY 2013 OPPS/ASC proposed rule, we did not accept the Panel's recommendation to delete HCPCS code G0259 and G0260 and instead use CPT code 27096 with a status indicator of ''T'' and assign CPT code 27096 to APC 0207. For CY 2012, we assigned CPT code 27096 to status indicator ''B,'' meaning that this code is not payable under the OPPS. In order to receive payment for procedures performed on the sacroiliac joint with or without arthrography or with image guidance under the OPPS, hospitals must use either HCPCS code G0259, which is assigned to status indicator ''N'' for CY 2012, or HCPCS code G0260, which is assigned to status indicator ''T'' for CY 2012, as appropriate. CMS created HCPCS codes G0259 and G0260 to separate and distinguish the image guidance procedure from the therapeutic injection procedure for the sacroiliac joint. As stated above, guidance procedures are packaged under the OPPS because we believe that they are typically ancillary and supportive to a primary diagnostic or therapeutic modality and are an integral part of the primary service they support.

We believe that the existence of HCPCS codes G0259 and G0260 is necessary to assign appropriate packaged payment for the image guidance procedure, according to our established packaging policy, and separate payment for the therapeutic injection procedure. Therefore, we did not accept the Panel's recommendation and followed the previously established policy to continue to assign HCPCS code G0259 to status indicator ''N,'' HCPCS code G0260 to status indicator ''T,'' and CPT code 27096 to status indicator ''B'' for CY 2013.

Comment: Several commenters disagreed with CMS' proposal to not accept the Panel's recommendation on HCPCS codes G0259 and G0260 and to continue to assign a status indicator of ''B'' for CPT code 27096. One commenter expressed concern that the continued use of HCPCS codes G0259 and G0260 instead of the CPT code 27096 is administratively burdensome to hospitals because it does not allow standardized code reporting among all payers.

Another commenter stated that there is no CPT code that would describe the radiological portion of the procedure to be reported in addition to HCPCS code G0259 because the AMA deleted CPT code 73054. As of January 1, 2012, the commenter stated that CPT code 27096 is always a complete procedure that includes the injection of a diagnostic or therapeutic agent and the associated imaging. The commenter recommended that CMS recognize CPT code 27096 and assign the appropriate APC code to this CPT code based on the CY 2011 claims data for HCPCS code G0259 with CPT code 73542 and HCPCS code G0260 or modify the descriptor of HCPCS code G0259 to include the radiological portion of the procedure and assign the appropriate status indicator and APC for the complete procedure.

One commenter stated that CPT codes 77003 (Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural or subarachnoid)) and 77012 (Computed tomography guidance for needle placement (eg, biopsy, aspiration, injection, localization device), radiological supervision and interpretation) that are billed with HCPCS code G0260 have a NCCI edit with an indicator of ''1.'' Therefore, the commenter stated that CPT codes 77003 and 77012 cannot be reported with modifier ''59'' because the imaging guidance is not separate and distinct and it is instead part of the procedure. The commenter stated that providers cannot accurately report the cost of the imaging guidance (either fluoroscopy or CT) due to the CCI edits and the fact that the HCPCS code G0260 descriptor does not indicate if either fluoroscopy or CT imaging is bundled into the procedure code. Therefore, the commenter asked that CMS establish a new HCPCS code to describe the sacroiliac injection procedure performed with imaging (fluoroscopy or CT) or allow the reporting of CPT code 27096 and revise the status indicator from ''B'' to ''T.''

Response: We continue to believe that assigning HCPCS codes G0259 to status indicator ''N'' is necessary in order to designate appropriate packaged payment for the image guidance procedure, according to our established packaging policy, and separate payment for the therapeutic injection procedure. However, we will reevaluate the descriptors for HCPCS code G0259 and G0260 for CY 2014 in light of the commenter's concerns on the AMA's modification of the descriptor for CPT code 27096 in CY 2012 to include the arthrography services described by CPT code 73542.

After consideration of the public comments we received, for CY 2013, we are continuing to assign a status indicator of ''N'' to HCPCS code G0259, a status indicator of ''T'' to HCPCS code G0260, which is assigned to APC 0207 with a final CY 2013 geometric mean cost of approximately $582, and a status indicator of ''B'' to CPT code 27096.

Panel Recommendation: CMS provide data to the APC Groups and SI Subcommittee on the following arthrography services, so that the Subcommittee can consider whether the SI for these services should be changed from ''N'' to ''S'':

- HCPCS code 21116 (Injection procedure for temporomandibular joint arthrography);
- HCPCS code 23350 (Injection procedure for shoulder arthrography or enhanced CT/MRI shoulder arthrography);
- HCPCS code 24220 (Injection procedure for elbow arthrography);
- HCPCS code 25246 (Injection procedure for wrist arthrography);
- HCPCS code 27093 (Injection procedure for hip arthrography; without anesthesia);
- HCPCS code 27095 (Injection procedure for hip arthrography; with anesthesia);
- HCPSC code 27096 (Injection procedure for sacroiliac joint, anesthetic/steroid with image guidance (fluoroscopy or CT) including arthrography when performed);
- HCPCS code 27370 (Injection procedure for knee arthrography); and
- HCPCS code 27648 (Injection procedure for ankle arthrography).

CMS Response: In the CY 2013 OPPS/ASC proposed rule, we accepted the Panel's recommendation that CMS provide data to the APC Groups and SI Assignment Subcommittee on CPT codes 21116, 23350, 24220, 25246, 27093, 27095, 27096, 27370, and 27648 at a future Panel meeting.

We did not receive any public comments on this recommendation.

Panel Recommendation: CMS change the status indicator for HCPCS code 19290 (Preoperative placement of needle localization wire, breast) from ''N'' to ''Q1'' and continue to monitor the frequency of the code when used in isolation.

CMS Response: In the CY 2013 OPPS/ASC proposed rule, we agreed with the Panel that a status indicator of ''Q1'' is appropriate for CPT code 19290. This status indicator will allow for separate payment when this procedure is performed alone or packaged payment when this procedure is performed with an associated surgical procedure. Therefore, as we proposed, we are accepting the Panel's recommendation and assigning CPT code 19290 to APC 0340 (Minor Ancillary Procedures) and status indicator ''Q1'' for the CY 2013 OPPS. APC 0340 has a final geometric mean cost of approximately $51 (as compared to approximately $50 calculated for the proposed rule) for CY 2013.

Comment: Several commenters supported CMS' proposal to reassign HCPCS code 19290 from ''N'' to ''Q1''. However, one commenter recommended that CMS review the APC assignments for HCPCS codes 19290 and 19295 (Image guided placement, metallic localization clip, percutaneous, during breast biopsy/aspiration (list separately in addition to code for primary procedure) during the CY 2014 rulemaking cycle and propose a more appropriate and higher paying APC for these services.

Response: We appreciate the commenters' support. For CY 2013, we are accepting the Panel's recommendation and finalizing our proposal to assign a status indicator of ''Q1'' to HCPCS code 19290, which is assigned to APC 0340 with a CY 2013 final payment rate of approximately $51. 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 assignments for CPT codes 19290 and 19295.

Panel Recommendation: Judith Kelly, R.H.I.T., R.H.I.A., C.C.S., remain the chair of the APC Groups and SI Subcommittee.

CMS Response: In the CY 2013 OPPS/ASC proposed rule, we indicated that we accepted the Panel's recommendation that Judith Kelly, R.H.I.T., R.H.I.A., C.C.S., continue to chair the APC Groups and SI Assignment Subcommittee.

We did not receive any public comments on this recommendation. We appreciate the services of Ms. Kelly as chair of the Subcommittee for CY 2012.

Panel Recommendation: The work of the APC Groups and SI Assignment Subcommittee continue.

CMS Response: In the CY 2013 OPPS/ASC proposed rule, we indicated that we accepted the Panel's recommendation that the work of the APC Groups and SI Assignment Subcommittee continue.

We did not receive any public comments on this recommendation.

d. Packaging Recommendations of the HOP Panel (''The Panel'') at Its August 2012 Meeting

During its August 2012 meeting, the Panel accepted the report of the Subcommittee for APC Groups and Status Indicator (SI) Assignments, heard several public presentations related to packaged services and APC grouping and status indicator assignments, and made two recommendations related to the function of the subcommittee. The subcommittee also made recommendations with regard to APC assignment of specific services that are discussed in section III.D. of this final rule with comment period. The report for the August 2012 meeting of the Panel may be found on the CMS Web site at: *http://www.cms.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp*.

Below we present the two recommendations related to the function of the subcommittee. Recommendations that evolved from the discussions of the Subcommittee on APC Groups and SI Assignments that are specific to the APC assignment of HCPCS codes and the removal of HCPCS codes from the inpatient list are discussed in section III. and IX., respectively, of this final rule with comment period.

Panel Recommendation: The Panel recommends that Jacqueline Phillips be named chair of the APC Groups and SI Assignments Subcommittee.

CMS Response: We accept the Panel's recommendation that Jacqueline Phillips be named chair of the APC Groups and SI Assignments Subcommittee. We thank Ms. Judith Kelly for her service as chair of the APC Groups and SI Assignments Subcommittee, and we welcome Ms. Phillips as chair of the APC Groups and SI Assignments Subcommittee.

Panel Recommendation: The Panel recommends that the work of the APC Groups and SI Assignments Subcommittee continue.

CMS Response: We are accepting the APC Panel's recommendation that the work of the APC Groups and SI Assignments Subcommittee continue.

e. Other Packaging Proposals and Policies for CY 2013

The HCPCS codes that we proposed to be packaged either unconditionally (for which we continue to assign status indicator ''N''), or conditionally (for which we continue to assign status indicator ''Q1'', ''Q2'', or ''Q3''), were displayed in Addendum B of the CY 2013 OPPS/ASC proposed rule. The supporting documents for the CY 2013 OPPS/ASC proposed rule, including but not limited to Addendum B, are available at the CMS Webs site at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. To view the status indicators by HCPCS code in Addendum B, select ''CMS 1589'' and then select the folder labeled ''2013 OPPS Proposed Rule Addenda'' or ''2013 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 payment because the policies are based on several flawed assumptions. The 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 HOPDs as to inpatient services. One commenter stated that, under the IPPS, hospitals have an incentive to provide care in an efficient manner to ensure the lowest cost for the patient's diagnosis. In contrast, in HOPDs, 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: As we stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74186), 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 practitioner 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 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. Whether 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 service 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 hospitals 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: One commenter stated that continued reporting by CMS on utilization of all packaged services and access to care will be essential to ensure that Medicare's payment policies do not restrict beneficiaries' access to necessary care. The commenter asked that CMS make annual reports to the HOP Panel on reporting of services subject to CMS' expanded packaging services.

Response: Each year, we make 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 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, stakeholders 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 cost for every independent service. However, stakeholders 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.

Furthermore, we are not required, nor do we intend, to make annual reports to the Panel regarding services that are subject to CMS' packaging policies. We note that the Panel did not recommend at either the February 2012 meeting or the August 2012 meeting that CMS present annual reports on services subject to CMS' packaging services.

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. The 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 calculations of future payment rates for that Medicare Severity-Diagnosis Related Group (MS–DRG). The commenters further stated that, under the IPPS, hospitals report only the data required to assign a case to the highest paying appropriate MS–DRG, even though other data might affect payment in the long term. The commenters stated that they saw no reason to believe that the current approach would have a different outcome unless CMS gives clear instruction to continue coding for all items and services provided and provides some incentive to do so. The commenters asked that CMS require complete and correct coding for packaged services.

Response: We do not believe that there has been or will be a significant change in what hospitals report and charge for the outpatient service 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 (73 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 that service to Medicare and all other payers. We encourage hospitals to report on their claim for payment all HCPCS codes that describe packaged service 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 certainty whether hospitals are failing to report HCPCS codes and charges for service 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 service they furnish, if the hospital's charge for the independent services also reflects the charge for all ancillary and supportive service it typically provides, the absence of HCPCS codes and separate charges would not result in inappropriately low 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: As we stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74188), 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. 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.

Comment: One commenter expressed concern over a statement made in the proposed rule that indicated that CMS might propose to bundle payment for [services] that [it] now refers to as ''independent [services'']. The commenter stated that CMS did not provide any statutory authority that would allow it to move away from a fundamental OPPS policy, that only ''dependent services'' are potentially considered as part of a bundled reimbursement methodology. The commenter further stated that packaging payment for multiple services that are not interrelated presents no efficiency or resource management incentives, because, by definition, these services are not related, meaning there are no efficiencies to be gained and no overlap in resources expended.

Response: In the CY 2013 OPPS/ASC proposed rule (77 FR 45089), we noted that 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. We also noted that, 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.'' We disagree with the commenter that we do not have the statutory authority to consider larger payment bundles that more broadly reflect services provided in an encounter or episode of care. Our statutory authority is defined in section 1833(t)(2)(B) of the Act, which allows the OPPS to establish groups of covered HOPD services, namely APC groups, and use them as the basic unit of payment.

Furthermore, for CY 2008, we expanded packaging to services that were once considered independent services and items, such as nonpass-through contrast agents and observation services. We now consider these services to be ancillary and supportive to a primary diagnostic or therapeutic modality and have assigned these services an unconditionally packaged status indicator of ''N.'' It follows then that items or services that are currently considered to be ''independent'' services within this final rule with comment period may be packaged where appropriate in future years, after taking into consideration the clinical nature of the item or service and then determining whether or not that item or service is considered ancillary and supportive to a primary diagnostic or therapeutic modality.

We note that we did not make any new proposals to develop additional payment bundles for CY 2013, but that we will likely do so in future rulemaking. For CY 2013, we proposed to continue to package the payment for items and services in seven categories with the primary diagnostic or therapeutic modality to which we believe that these items and services are typically ancillary and supportive. Because the commenter does not question the appropriateness of these seven categories of packaged payment given in the proposed rule nor does the commenter question the appropriateness of a specific APC assignment for a packaged HCPCS or CPT code, we cannot fully address the commenter's concerns about bundling multiple services that are not interrelated and that may or may not present efficiency or resource management incentives. We continue to believe that the seven categories of packaged services and items are appropriate to encourage hospital efficiency, flexibility, and ultimately cost containment.

Comment: One commenter requested that CMS change the status indicator for HCPCS code L8604 (Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, urinary tract, 1 ml, includes shipping and necessary

supplies) from ''N'' to ''A.'' The commenter argued that this would allow HCPCS code L8604 to be paid under a different fee schedule and would allow for access to the product SOLESTA® in the HOPD. The commenter also asked that CMS cover and pay for SOLESTA® in the same manner as other hyaluronic acid products and assign SOLESTA® a separate and unique HCPCS code.

Response: HCPCS code L8604 describes several products that are implantable prosthetic devices. According to 42 CFR 419.2(b)(11), implantable prosthetic devices are packaged under the OPPS. Therefore, status indicator ''N'' is the correct status indicator for HCPCS code L8604. We also note that any coverage, reclassification, or HCPCS code change requests for SOLESTA® are outside the scope of this final rule with comment period. Such issues are addressed by processes outside the OPPS/ASC rule by either CMS' HCPCS Workgroup or CMS' Coverage and Analysis Group.

Comment: One commenter requested that CMS assign HCPCS code J7665 (Mannitol, administered through an inhaler, 5 mg) to a status indicator of ''K'' for CY 2013. The commenter stated that the product that is described by HCPCS code J7665 is a drug indicated for the assessment of bronchial hyperresponsiveness in individuals at least six years of age without clinically apparent asthma and that, consistent with its FDA labeling, the product that is described by HCPCS code J7665 can only be used in an institutional setting or a physician's office. The commenter argued that HCPCS code J7665 was incorrectly assigned a status indicator of ''N'' because this product is approved as a drug through the NDA process and should be paid under the OPPS as a separately paid drug as opposed to a supply under the OPPS.

Response: We agree with the commenter that HCPCS code J7665 can be administered in the HOPD. However, we do not believe that the product described by HCPCS code J7665 is a separately payable drug as we have described here within this final rule with comment period, and is instead a supply with costs included in the payment under the OPPS as described in 42 CFR 419.2(b). Mannitol (HCPCS code J7665), when administered through an inhaler, is always used as a supply in bronchial challenge testing. Therefore, for CY 2013, we are assigning a status indicator of ''N'' to HCPCS code J7665.

After consideration of the public comments we received, for CY 2013, we are finalizing our proposed policy to continue 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.

f. Packaging of Drugs, Biologicals, and Radiopharmaceuticals

(1) Existing Packaging Policies

In the OPPS, we currently package five categories of drugs, biologicals, and radiopharmaceuticals (unless temporary pass-through status applies): (1) Those with per day costs at or below the packaging threshold; (2) diagnostic radiopharmaceuticals; (3) contrast agents; (4) anesthesia drugs; and (5) drugs treated as surgical supplies. Anesthesia drugs are discussed further in section II.A.3.c.(2) of this final rule with comment period. For detailed discussions of the established packaging policies for diagnostic radiopharmaceuticals and contrast agents, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765 through 66768). For further details on drugs treated as surgical supplies, we refer readers to the CY 2003 OPPS final rule (67 FR 66767) and Chapter 15, Section 50.2 of the Medicare Benefit Policy Manual.

(2) Clarification of Packaging Policy for Anesthesia Drugs

It has been longstanding OPPS policy to package ''anesthesia'' and ''supplies and equipment for administering and monitoring anesthesia or sedation,'' as described in 42 CFR 419.2(b)(4) and (b)(5). As described above, items and services paid under the OPPS that are typically ancillary and supportive to a primary diagnostic or therapeutic modality and, in those cases, are considered dependent items and services are packaged into the payment of their accompanying independent primary service. In accordance with our current policy on packaging items and services, drugs that are used to produce anesthesia in all forms are ancillary and supportive to a primary diagnostic or therapeutic modality, and are included in our definition of ''anesthesia'' as described in § 419.2(b)(4) and (b)(5). However, we recognize that some anesthesia drugs may qualify for transitional pass-through status under section 1833(t)(6) of the Act. Therefore, in the CY 2013 OPPS/ASC proposed rule (77 FR45100), we proposed to clarify that our general policy is to package drugs used to produce anesthesia, and that those anesthesia drugs with pass-through status will be packaged upon the expiration of pass-through status. We invited public comment on our clarification of the existing packaging policies for anesthesia drugs under § 419.2(b)(4) and (b)(5).

Comment: Commenters objected to the proposed clarification of the OPPS policy on anesthesia and all future policies that expand the packaging of drugs, through the increase of the drug packaging threshold or otherwise. The commenters expressed their concern over the increase in packaging for drugs in general and urged CMS not to finalize this policy. The commenters also stated their concern that the CMS drug packaging polices used in the HOPD could encourage hospitals to under utilize critically important drugs and ultimately compromise beneficiary's access to care and undercut CMS' work to improve the quality of care. The commenters urged CMS not to finalize this proposal, to conduct a careful review to assess the effect of packaging on quality of care, and to forego any new packaging policies as a whole.

One commenter expressed support for the clarification of this policy. The commenter further encouraged CMS to continue to monitor packaged drugs and biologicals to ensure they are appropriately paid.

Response: For the CY 2013 OPPS/ASC proposed rule (77 FR 45100), we proposed to clarify the existing policies related to nonpass-through and pass-through anesthesia drugs. It has been our longstanding policy to package anesthesia drugs, which are drugs that are used to produce anesthesia in all forms and are ancillary and supportive to a primary diagnostic or therapeutic modality, that are not on pass-through status as included costs under the OPPS, as described in 42 CFR 419.2(b)(4) and (b)(5). However, we also clarified in the proposed rule that anesthesia drugs are eligible for transitional pass-through status as a drug, as provided in section 1833(t)(6) of the Act. Therefore, we noted that we were not finalizing a new policy to package nonpass-through anesthesia drugs but were clarifying in our preamble language our currently existing policies.

In addition, as we stated above, we continue to believe that 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. We address additional comments on packaging for drugs, biologicals, diagnostic radiopharmaceuticals, and contrast agents below in section II.A.3.f. and section V.A. of this final rule with comment period.

After consideration of the public comments we received, we are finalizing this proposed clarification for CY 2013. Anesthesia drugs that are used to produce anesthesia in all forms are ancillary and supportive to a primary diagnostic or therapeutic modality under 42 CFR 419.2(b)(4) and (b)(5). Therefore, nonpass-through anesthesia drugs are packaged under the OPPS. New anesthesia drugs 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 payment for the procedures or services associated with the new anesthesia drug are eligible for transitional pass-through status as a drug or biological, as described in section 1833(t)(6) of the Act. We discuss OPPS transitional pass-through payment for additional costs of drugs, biologicals, and radiopharmaceuticals in section V.A. of this final rule with comment period.

g. 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 the 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, regardless of their per day cost (73 FR 68633 through 68636). We refer to diagnostic radiopharmaceuticals and contrast agents collectively as ''policy-packaged'' drugs. We refer to implantable biologicals as ''devices'' because, in CY 2010, we finalized a policy to treat implantable biologicals as devices for OPPS payment purposes (74 FR 60471 through 60477).

As set forth at § 419.2(b), as a prospective payment system, the OPPS establishes a national payment rate, standardized for geographical wage differences, 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, and in general, these costs include, but are 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 efficiency 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 had expired; (2) diagnostic radiopharmaceuticals and contrast agents function effectively as supplies that enable the provision of an independent service, rather than serving themselves as a therapeutic modality; and (3) section 1833(t)(14)(A)(iii) of the Act required that payment for specified covered outpatient drugs (SCODs) be set prospectively based on a measure of average hospital acquisition cost (76 FR 74307).

Therefore, in the CY 2013 OPPS/ASC proposed rule (77 FR 45100), we stated that we believe it is appropriate to continue to treat diagnostic radiopharmaceuticals and contrast agents differently from specified covered outpatient drugs (SCODs) for CY 2013. Therefore, 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 2013. 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 for 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: Commenters objected to CMS' proposal to package payment of all nonpass-through diagnostic radiopharmaceuticals and contrast agents in CY 2013. 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 commenters 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.

One commenter supported CMS' continued packaging policy for diagnostic radiopharmaceuticals and contrast agents that do not have pass-through status. The commenter noted that diagnostic radiopharmaceuticals are supplies that are necessary to the provision of the service in which they are used and, like other supplies, payment for them should be part of the payment for the service.

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), the CY 2011 OPPS/ASC final rule with comment period (75 FR 71949), and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74307), 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, as described in section 1833(t)(16)(B) of the Act, 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, 2011, and 2012 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 the efficient use of hospital resources. While we recognize this variability from case to case, on average under a prospective payment system, we expect payment to cover the costs 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 anti-emetics 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 this 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 an independent service, similar to implantable non-biological devices that are always packaged. Therefore, we currently package payment of 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 2013 OPPS/ASC proposed (77 FR 45101), we continue to believe that payment should be packaged for nonpass-through implantable biologicals for CY 2013.

We are continuing our CY 2009 policy for CY 2013 as discussed below, which packages payment for all nonpass-through diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals into the payment for their associated procedures. We also continue to believe that the line-item estimated cost for nonpass-through diagnostic radiopharmaceuticals, contrast agents, or implantable biologicals in our claims data is a reasonable approximation of average acquisition and preparation and handling costs for nonpass-through diagnostic radiopharmaceuticals, contrast agents, and 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 nonpass-through diagnostic radiopharmaceuticals and responded to our instructions to include charges for diagnostic radiopharmaceutical handling in their charges for the diagnostic radiopharmaceutical products. Further, because the standard OPPS packaging methodology packages the total estimated cost of each nonpass-through diagnostic 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 nonpass-through diagnostic radiopharmaceuticals, contrast agents, or implantable biologicals, rather than the cost. In addition, as we noted in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68646), these drugs, biologicals, or diagnostic 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 not considered to be SCODs. Similarly, drugs and biologicals with per day costs of less than the drug packaging threshold for CY 2013, which is discussed in section V.B. of this final rule with comment period, that are packaged and for which a separate APC has not been established also are not SCODs. This reading is consistent with our final packaging payment policy, as discussed in this section, whereby we package payment for nonpass-through diagnostic radiopharmaceuticals, contrast agents, and 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. Some commenters noted that CMS' identification of HCPCS code A0544 (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. Furthermore, many commenters urged CMS to classify dosimetric doses used in radiopharmaceutical procedures as therapeutic in nature, and allow for separate payment for that dosimetric dose.

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), the CY 2011 OPPS/ASC final rule with comment period (75 FR 71949), and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74308), 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 continued 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 HCPSC code A9544 is a diagnostic radiopharmaceutical. While it is not used to necessarily diagnose a general disease state, we understand that 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 not different than the use of a laboratory 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, on which its intent is 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: Commenters recommended using the ASP methodology and the proposed statutory default rate of ASP+6 percent to make payment for nonpass-through diagnostic radiopharmaceuticals and contrast agents. The commenters noted that it would be inconsistent for CMS to treat diagnostic radiopharmaceuticals and contrast agents as ''drugs'' for pass-through payment purposes and provide payment for diagnostic radiopharmaceuticals and contrast agents that have pass-through status based on the ASP methodology, and, then, after the diagnostic radiopharmaceutical's or contrast agent'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 manufacturer to voluntarily submit ASP data, and then default to the mean unit cost when ASP data are unavailable. Some commenters recommended that CMS use ASP data as a benchmark for determining costs for diagnostic radiopharmaceuticals that are packaged.

One commenter stated that payment for diagnostic radiopharmaceuticals should not be paid at ASP+6 percent for the reasons commenters provided when CMS proposed to make payment at ASP+6 percent in prior years. Specifically, the commenter noted that the ASP statute excludes reporting of the ASP for diagnostic radiopharmaceuticals and, therefore, such reporting would need to be voluntary. However, in terms of voluntary reporting of diagnostic radiopharmaceuticals, the commenter further noted that CMS could never be confident that it would receive reports from all manufacturers of any particular diagnostic radiopharmaceutical. Moreover, the commenter stated, high volume diagnostic radiopharmaceuticals are furnished using generators that hospitals use for up to 28 days to provide doses of diagnostic radiopharmaceuticals as needed and therefore the manufacturer, who would report the ASP under penalty of perjury, would never be able to certify the actual number of doses furnished with confidence. The commenter finally noted that packaging is consistent with the general principles of a prospective payment system, one goal of which is to encourage hospital cost containment.

Response: As we stated above, the statutorily required OPPS drug packaging threshold has expired, and we continue to believe that nonpass-through 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 and contrast agents should be paid under the ASP methodology, that nonpass-through diagnostic radiopharmaceuticals and contrast agents 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, contrast agents, and implantable biologicals 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 (73 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 not to be SCODs. We continue to believe that the line-item estimated cost for nonpass-through diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals in our claims data is a reasonable approximation of average acquisition and preparation and handling costs for diagnostic radiopharmaceuticals, contrast agents, and 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 nonpass-through 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 nonpass-through diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals, when each of these items is ancillary or supportive to an independent service, is contrary to this principle of a prospective payment system.

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 CY 2006 OPPS final rule with comment period (70 FR 68653 through 68657), numerous commenters advised CMS that diagnostic radiopharmaceuticals are formulated, distributed, compounded, and administered in unique distribution channels that preclude the determination of ASP relevant to a diagnostic radiopharmaceutical HCPCS codes. 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 its 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 with comment period, 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 (or contrast agents or implantable biologicals) should be paid separately under the OPPS such that manufactures 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 services.

Comment: Commenters recommended that CMS modify the way that it applies the ''2 times'' rule for nuclear medicine APCs by including the cost of the packaged diagnostic radiopharmaceutical drugs in its analysis and not just the cost of services. The commenters argued that this is mandated by the statute, which provides that an APC group cannot be considered comparable with respect to the use of resources if the highest cost for an item or service in the APC group is more than two times greater than the lowest cost for an item or service within the same APC group. Therefore, the commenters believed that it is logical that as long as CMS views the packaged nuclear medicine service and the radiopharmaceutical as one unit for APC payment purposes, it should consider both components together in applying the 2 times rule and analysis to APC payment.

Response: While the language in section 1833(t)(2) of the Act regarding the 2 times rule describes consideration of both items and services for purposes of identifying exceptions to the rule, it does so within the context of services that belong to an APC group. Unconditionally packaged items and services, being associated with the particular item or service being modeled for separate payment, would not individually belong to any APC group. However, these unconditionally packaged costs would be incorporated into the system through the separately paid items or services with which they appear on the claim, and would thus be factored into the ultimate consideration of the 2 times rule. Therefore, consideration of items and services within each APC only applies to the separately paid HCPCS and CPT codes assigned to each APC and would thus not include any discrete calculation for packaged costs with regards to the two times rule.

Comment: One commenter recommended that CMS establish a threshold for radiopharmaceutical drugs that would trigger separate payment when the cost of the radiopharmaceutical is greater than the total APC payment or over another threshold value.

Response: Consistent with the CY 2013 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 because 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 this 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 and 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 polices 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 diagnostic radiopharmaceuticals or another relatively high cost element in the patient's course of care.

Comment: One commenter requested that CMS present additional, detailed information regarding how the agency ensures that the full cost of diagnostic radiopharmaceuticals are captured in the associated packaged APC procedural payments, including the validation methods used by the agency.

Response: The data that CMS used to calculate, propose, and finalize APC assignments and rates, including costs associated with diagnostic radiopharmaceuticals, for the CY 2013 OPPS, are available for purchase under a CMS data use agreement through the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatinetPPS/index.html.* This Web site includes information about purchasing the ''OPPS Limited Data Set,'' which now includes the additional variable previously available only in the OPPS Identifiable Data set, including ICD–9–CMS diagnosis codes and revenue code payment amounts.

As we state above, we discuss in detail in section II.A.2. of this final rule with comment period the availability to the public of the use of 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.

We continue to believe that the cost of a diagnostic radiopharmaceutical is captured into the associated packaged APC procedural payment. We see no need at this time to provide further data analyses.

For CY 2013, we proposed to make an additional payment of $10 for diagnostic radiopharmaceuticals that utilize the Tc-99m radioisotope produced by non-HEU methods (77 FR 45121). We proposed to base this payment on the best available estimations of the marginal costs associated with non-HEU radioisotope production, pursuant to our authority described in section 1833(t)(2)(E) of the Act which allows us to establish ''other adjustments as determined to be necessary to ensure equitable payments'' under the OPPS. We described this policy in further detail in section III.C.3. of the proposed rule.

We received numerous comments on this proposal, including comments that suggested that separate payment for diagnostic radiopharmaceuticals is the most effective way to encourage hospital conversion from HEU to non-HEU sources that utilize Tc-99m. We have addressed these comments on the proposed payment for non-HEU sources that recommended separate payment for diagnostic radiopharmaceuticals above and in section III.C.3. of this final rule with comment period.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68634), we 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. We continued to follow this policy in CY 2012 (76 FR 74306 through 74310). Specifically, we continue to 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. In the CY 2013 OPPS/ASC proposed rule (77 FR45101), for CY 2013, we proposed to continue to apply the policies finalized in CY 2012, to package payment for nonpass-through implantable biologicals (''devices'') that are surgically inserted or implanted (through a surgical incision or a natural orifice) into the body.

Comment: One commenter requested that HCPCS code Q4130 (Strattice tm, per square centimeter) be assigned status indicator ''K'' for CY 2013 because, the commenter argued, HCPCS code Q4130 is a skin substitute graft for chronic wounds and a surgical biological implant for breast reconstruction and hernia repair procedures. The commenter stated that assigning HCPCS code Q4130 to a status indicator of ''K'' would signify its use as a biological skin substitute graft for which separate payment is available.

The commenter further noted that Transmittal 2418 of the Medicare Claims Processing Manual lists HCPCS code Q4130 in table 5 of the transmittal, along with other biologicals with ''dual'' use.

Response: HCPCS code Q4130 was assigned a status indicator of ''N'' in the CY 2013 OPPS/ASC proposed rule, signifying that the product that is represented by this code is an implantable biological device. We continue to believe that the product described by HCPCS code Q4130 is an implantable biological device, as evidenced by language within the 510(k) FDA clearance which lists the product described by HCPCS code Q4130 as a surgical mesh intended for the reinforcement of soft tissue repaired by sutures or suture anchors during tendon repair surgery including reinforcement of rotator cuff, patella, Achilles, biceps, quadriceps, or other tendons. Further indications of use include the repair of body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome. As we stated above, the payment for nonpass-through implantable biologicals, or implanted devices, is packaged into the payment for the primary procedure. Therefore, we are continuing to assign a status indicator of ''N'' to HCPCS code Q4130 for CY 2013. Additionally, we are correcting the table within Transmittal 2418 which contains a list of skin substitutes only.

Comment: One commenter who responded to the CY 2012 OPPS/ASC final rule with comment period expressed concern that Medicare contractors had been inadvertently making separate payment for nonpass-through biological implants as they process OPPS claims for breast reconstruction and hernia repair procedures. The commenter stated that these procedure claims included claims for biological implants, including HCPCS codes Q4100 through Q4130. The commenter noted that HCPCS code Q4116 (Alloderm, per square centimeter) in particular was paid separately on several occasions. Therefore, the commenter recommended that CMS take several steps to prevent further billing errors with respect to the OPPS payment policy for implantable biologicals.

Response: For the April 2012 quarterly update, we installed logic changes in the I/OCE to allow for separate payment for separately payable skin substitute HCPCS codes that are coded with skin substitute procedure CPT codes only. We reminded hospitals that HCPCS codes describing skin substitutes should only be separately reported when used with one of the CPT codes describing the application of a skin substitute (CPT codes 15271 through 15278). Therefore, we have previously addressed the commenters' concerns.

Under the OPPS, HCPCS codes that describe skin substitute products, with a separately payable status indicator of ''K'' or ''G'' that are billed with a skin substitute application procedure, will receive separate payment for both the skin substitute product and the procedure. Payment for skin substitute HCPCS codes that are billed with other procedures will be packaged into the payment for the corresponding procedure.

After consideration of the public comments we received, we are finalizing our 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 diagnostic radiopharmaceuticals and contrast agents 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 diagnostic radiopharmaceuticals, contrast agents, 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'' alone 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 radiopharmaceuticals in their long code descriptors. We believe that the current descriptors accurately discriminate between those radiopharmaceuticals that 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 will be packaged in CY 2013.

We refer reader to section III.D.1.f. of this final rule with comment period for a discussion of comments related to echocardiography services furnished with and without contrast. For more information on how we set CY 2013 payment rates for nuclear medicine procedures in which diagnostic radiopharmaceuticals are used an 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).

h. Summary of Proposals

As we proposed, we are finalizing, for this final rule with comment period, the HCPCS codes that we unconditionally packaged (for which we continue to assign status indicator ''N''), or conditionally packaged (for which we continue to assign status indicators ''Q1,'' ''Q2,'' or ''Q3''), and those codes are displayed in Addendum B of this final rule with comment period (which is available via the Internet on the CMS Web site). The supporting documents for this CY 2013 OPPS/ASC final rule with comment period, including, but not limited to, Addendum B, are available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.* To

view the status indicators by HCPCS code in Addendum B, select ''CMS 1589–FC'' and then select the folder labeled ''2013 OPPS Final Rule 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.

4. Calculation of OPPS Scaled Payment Weights

In the CY 2013 OPPS/ASC proposed rule (77 FR 45101), we proposed for CY 2013 to calculate the relative payment weights for each APC for CY 2013 shown in Addenda A and B to the proposed rule (which were available via the Internet on the CMS Web site) using the APC costs discussed in sections II.A.1. and II.A.2. of the proposed rule. 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 for 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). For CY 2013, we proposed to base the relative payment weights on which OPPS payments will be made by using geometric mean costs, as described in section II.A.2.f. of the proposed rule. However, in an effort to maintain consistency in calculating unscaled weights that represent the cost of some of the most frequently provided services, we proposed to continue to use the cost of the mid-level clinic visit APC (APC 0606) in calculating unscaled weights. Following our general methodology for establishing relative payment weights derived from APC costs, but using the proposed CY 2013 geometric mean cost for APC 0606, for CY 2013, we proposed to assign APC 0606 a relative payment weight of 1.00 and to divide the geometric mean cost of each APC by the proposed geometric mean cost for APC 0606 to derive the proposed unscaled relative payment weight for each APC. We stated that the choice of the APC on which to base the proposed relative payment 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 2013 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 2012 scaled relative payment weights to the estimated aggregate weight using the CY 2013 unscaled relative payment weights. For CY 2012, we multiplied the CY 2012 scaled APC relative weight applicable to a service paid under the OPPS by the volume of that service from CY 2011 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 2013, as we proposed, we performed the same process using the CY 2013 unscaled relative payment weights rather than scaled relative payment weights. We then calculated the weight scaler by dividing the CY 2012 estimated aggregate weight by the CY 2013 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/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

As we proposed, in this final rule with comment period, we include estimated payments to CMHCs in our comparison of estimated unscaled weights in CY 2013 to estimated total weights in CY 2012 using CY 2011 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 payment weights for purposes of budget neutrality. The CY 2013 unscaled relative payment weights were adjusted by multiplying them by a weight scaler of 1.3596 to ensure that the CY 2013 relative payment weights are budget neutral.

Section 1833(t)(14) of the Act provides the payment rates for certain SCODs. Section 1833(t)(14)(H) of the Act 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 SCODs (as discussed in section V.B.3. of this final rule) was included in the budget neutrality calculations for the CY 2013 OPPS.

We did not receive any public comments on the proposed methodology for calculating scaled weights based on the geometric mean costs for the CY 2013 OPPS. Therefore, for the reasons set forth in the proposed rule (77 FR 45101), 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 relative payment weights were adjusted by a weight scaler of 1.3596 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 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.

We noted in the proposed rule that we were providing additional information, in association with the proposed rule, so that the public could provide meaningful comment on our proposed policy to base the CY 2013 OPPS relative payment weights on geometric mean costs. The scaled relative payment weights listed in Addenda A and B to this final rule with comment period (which are available via the Internet on the CMS Web site) incorporate the 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 the Secretary to update the conversion factor used to determine the 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 2013 IPPS/LTCH PPS final rule (77 FR 53414), consistent with current law,

based on IHS Global Insight, Inc.'s second quarter 2012 forecast of the FY 2013 market basket increase, the FY 2013 IPPS market basket update is 2.6 percent. However, sections 1833(t)(3)(F) and 1833(t)(3)(G)(ii) of the Act, as added by section 3401(i) of Pub. L. 111–148 and as amended by section 10319(g) of that law and further amended by section 1105(e) of Public Law 111–152, provide adjustments to the OPD fee schedule increase factor for CY 2013.

Specifically, section 1833(t)(3)(F)(i) of the Act requires that, for 2012 and subsequent years, 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. 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''). In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the MFP adjustment. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27975 through 27976), we discussed the calculation of the proposed MFP adjustment for FY 2013, which was 0.8 percentage point.

We proposed that if more recent data became subsequently available after the publication of the proposed rule (for example, a more recent estimate of the market basket increase and the MFP adjustment), we would use such data, if appropriate, to determine the CY 2013 market basket update and the MFP adjustment, components in calculating the OPD fee schedule increase factor under sections 1833(t)(3)(C)(iv) and (F) of the Act, in this CY 2013 OPPS/ASC final rule with comment period. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53414), we discussed the calculation of the final MFP adjustment for FY 2013, which is 0.7 percentage point.

In addition, section 1833(t)(3)(F)(ii) of the Act requires that for each of year 2010 through 2019, the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act be reduced by the adjustment described in section 1833(t)(3)(G) of the Act. For CY 2013, section 1833(t)(3)(G)(ii) of the Act provides a 0.1 percentage point reduction to the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act. Therefore, in accordance with sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(ii) of the Act, in the CY 2013 OPPS/ASC proposed rule (77 FR 45102), we proposed to apply a 0.1 percentage point reduction to the OPD fee schedule increase factor for CY 2013.

We note that section 1833(t)(3)(F) of the Act provides that application of this subparagraph may result in the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act being less than 0.0 for a year, and may result in payment rates under the OPPS for a year being less than such payment rates for the preceding year. As described in further detail below, using the final methodology and more recent data would result in an OPD fee schedule increase factor of 1.8 percent for the CY 2013 OPPS (2.6 percent, which is the final estimate of the hospital inpatient market basket percentage increase, less the final 0.7 percentage point MFP adjustment, less the 0.1 percentage point additional adjustment).

We note that hospitals that fail to meet the Hospital OQR Program reporting requirements are subject to an additional reduction of 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 for their services, as required by section 1833(t)(17) of the Act. As a result, using the final methodology and more recent data, those hospitals failing to meet the Hospital OQR Program reporting requirements will receive an OPD fee schedule increase factor of −0.2 (2.6 percent, which is the final estimate of the hospital inpatient market basket percentage increase, less the final 0.7 percentage point MFP adjustment, less the 0.1 percentage point additional adjustment, less 2.0 percentage points for the Hospital OQR Program reduction). For further discussion of the Hospital OQR Program, we refer readers to section XV.F. of this final rule with comment period.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45103), we proposed to amend 42 CFR 419.32(b)(1)(iv)(B) by adding a new paragraph (4) to reflect the requirement in section 1833(t)(3)(F)(i) of the Act that, for CY 2013, we reduce the OPD fee schedule increase factor by the MFP 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 an additional 0.1 percentage point for CY 2013.

Comment: Several commenters expressed support for the OPD fee schedule increase factor because they believed it would better align payment with hospital costs.

Response: We appreciate the commenters' support.

We did not receive any public comments on the proposed amendment to 42 CFR 419.32(b)(1)(iv)(B) to add a new paragraph (*4*) to reflect the requirements in section 1833(t)(3)(F) of the Act. For the reasons discussed above, we are adjusting the OPD fee schedule increase factor and adopting as final the amendment to 42 CFR 419.32(b)(1)(iv)(B), as proposed.

We did not receive any public comments on our proposed methodology for calculating the CY 2013 conversion factor. Therefore, we are finalizing our proposed methodology for calculating the budget neutrality adjustment factors, as described in the following discussion.

As we proposed, to set the OPPS conversion factor for CY 2013, we are increasing the CY 2012 conversion factor of $70.016 by 1.8 percent. In accordance with section 1833(t)(9)(B) of the Act, we are further adjusting the conversion factor for CY 2013 to ensure that any revisions made to the updates for a revised wage index and rural adjustment are made on a budget neutral basis (77 FR 45103). We are calculating an overall budget neutrality factor of 0.9998 for wage index changes by comparing total estimated payments from our simulation model using the final FY 2013 IPPS wage indices to those payments using the current (FY 2012) IPPS wage indices, as adopted on a calendar year basis for the OPPS.

For CY 2013, we did not propose to make a change to our rural adjustment policy, and as discussed in section II.E. of this final rule with comment period, we are not making any changes to the rural adjustment policy. Therefore, the budget neutrality factor for the rural adjustment is 1.0000.

For CY 2013, we are finalizing our proposal to continue previously established policies for implementing the cancer hospital payment adjustment described in section 1833(t)(18) of the Act, as discussed in section II.F. of this final rule with comment period. We are calculating a CY 2013 budget neutrality adjustment factor for the cancer hospital payment adjustment by comparing the estimated total CY 2013 payments under section 1833(t) of the Act including the CY 2013 cancer hospital payment adjustment to the estimated CY 2013 total payments using the CY 2012 final cancer hospital payment adjustment under sections 1833(t)(18)(B) and 1833(t)(2)(E) of the Act. The difference in the CY 2013 estimated payments as a result of applying the CY 2013 cancer hospital payment adjustment relative to the CY 2012 final cancer hospital

payment adjustment does not have a significant impact on the budget neutrality calculation. Therefore, we are applying a budget neutrality adjustment factor of 1.0000 to the conversion factor to ensure that the cancer hospital payment adjustment is budget neutral.

For this final rule with comment period, we estimate that pass-through spending for both drugs and biologicals and devices for CY 2013 would equal approximately $74 million, which represents 0.15 percent of total projected CY 2013 OPPS spending. Therefore, the conversion factor is also adjusted by the difference between the 0.22 percent estimate of pass-through spending for CY 2012 and the 0.15 percent estimate of CY 2013 pass-through spending, resulting in an adjustment for CY 2013 of −0.07 percent. Finally, estimated payments for outliers remain at 1.0 percent of total OPPS payments for CY 2013.

The OPD fee schedule increase factor of 1.8 percent for CY 2013 (that is, the estimate of the hospital inpatient market basket percentage increase of 2.6 percent less the 0.7 percentage point MFP adjustment and less the 0.1 percentage point required under section 1833(t)(3)(F) of the Act), the required wage index budget neutrality adjustment of approximately 0.9998, the cancer hospital payment adjustment of 1.0000, 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 2013 of $71.313.

As we stated in the proposed rule, hospitals that fail to meet the reporting requirements of the Hospital OQR Program will continue to be subject to a further reduction of 2.0 percentage points to 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 Program requirements and the payment reduction for hospitals that fail to meet those requirements, we refer readers to section XV.F. of this final rule with comment period. To calculate the CY 2013 reduced market basket conversion factor for those hospitals that fail to meet the requirements of the Hospital OQR Program for the full CY 2013 payment update, we are making all other adjustments discussed above, but using a reduced OPD fee schedule update factor of −0.2 percent (that is, the OPD fee schedule increase factor of 1.8 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 results in a reduced conversion factor for CY 2013 of $69.887 for those hospitals that fail to meet the Hospital OQR requirements (a difference of −$1.426 in the conversion factor relative to those hospitals that met the Hospital OQR requirements).

In summary, for CY 2013, we are using a final conversion factor of $71.313 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs. For further discussion regarding our final policy to base the CY 2013 OPPS relative payment weights on geometric mean costs, we refer readers to section II.A.2.f. of this final rule with comment period. We are finalizing our proposed amendment to § 419.32(b)(1)(iv)(B) by adding a new paragraph (*4*) to reflect the reductions to the OPD fee schedule increase factor that are required for CY 2013 in order to satisfy the statutory requirements of sections 1833(t)(3)(F) and (t)(3)(G)(ii) of the Act. We also are using a reduced conversion factor of $69.887 in the calculation of payments for hospitals that fail to comply with the Hospital OQR Program requirements to reflect the reduction to the OPD fee schedule increase factor that is required by section 1833(t)(17) of the Act.

C. Wage Index Changes

Section 1833(t)(2)(D) of the Act requires the Secretary to determine a wage adjustment factor to account for geographic wage differences in a portion of the OPPS payment rate, which includes the copayment standardized amount and is attributable to labor and labor-related costs. 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, as we proposed, we are not revising this policy for the CY 2013 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 APC costs, we standardize 60 percent of estimated claims costs for geographic area wage variation using the same FY 2013 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 (63 FR 47576), 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 contained provisions affecting the wage index. These provisions were discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74191). As discussed in that final rule with comment period, section 10324 of the Affordable Care Act requires a ''frontier State'' wage index floor of 1.00 in certain cases. For the CY 2013 OPPS, as we proposed, we are implementing this provision in the same manner as we did for CY 2012. That is, frontier State hospitals will receive a wage index of 1.00 if the otherwise applicable wage index (including reclassification, rural floor, and rural floor budget neutrality) is less than 1.00. Similar to our current policy for HOPDs that are affiliated with multicampus hospital systems, 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 through 50161 and 76 FR 51586, respectively) and the FY 2013 IPPS/

LTCH PPS final rule (77 FR 53369 through 53370) 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 final FY 2013 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 2013 IPPS/LTCH PPS final rule (77 FR 53365 through 53374) for a detailed discussion of all changes to the FY 2013 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 102 of the Medicare and Medicaid Extender Act extended, through FY 2011, section 508 reclassifications as well as certain special exceptions. The most recent extension of these special wage indices was included in section 302 of the Temporary Payroll Tax Cut Continuation Act of 2011 (Pub. L. 112–78), as amended by section 3001 of the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96). These legislative provisions extended certain section 508 reclassifications and special exception wage indices for a 6-month period during FY 2012, from October 1, 2011 through March 31, 2012. We implemented this extension in a notice (CMS–1442–N) published in the **Federal Register** on April 20, 2012 (77 FR 23722). As we did for CY 2010, we revised wage index values for certain special exception hospitals from January 1, 2012 through June 30, 2012, 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 end date under the OPPS for certain nonsection 508 and nonspecial exception providers to receive special wage indices was June 30, 2012, instead of March 31, 2012, so that these providers also received a full 6 months of payment under the revised wage index comparable to the IPPS. However, section 508 reclassifications and special exceptions have not been reauthorized since their expiration under Pub. L. 112–96 and, therefore, are no longer applicable.

For purposes of the OPPS, as we proposed, we are continuing our policy in CY 2013 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 2013 IPPS/LTCH PPS final rule (available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) identifies counties eligible for the out-migration adjustment and hospitals that will receive the adjustment for FY 2013. 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 2013 IPPS/LTCH PPS final rule (77 FR 53371) 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 from the FY 2013 IPPS/LTCH PPS final rule 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 2013 OPPS. Addendum L is available via the Internet on the CMS Web site.

In response to concerns frequently expressed by providers and other relevant parties that the current wage index system does not effectively reflect the true variation in labor costs for a large cross-section of hospitals, two studies were undertaken by the Department. First, section 3137(b) of the Affordable Care Act required the Secretary to submit to Congress a report that includes a plan to comprehensively reform the Medicare wage index applied under section 1886(d) of the Act. In developing the plan, the Secretary was directed to take into consideration the goals for reforming the wage index that were set forth by the Medicare Payment Advisory Commission (MedPAC) in its June 2007 report entitled ''Report to Congress: Promoting Greater Efficiency in Medicare'' and to ''consult with relevant affected parties.'' Second, the Secretary commissioned the Institute of Medicine (IOM) to ''evaluate hospital and physician geographic payment adjustments, the validity of the adjustment factors, measures and methodologies used in those factors, and sources of data used in those factors.'' Reports on both of these studies for geographic adjustment to hospital payments recently have been released. For summaries of the studies, their findings, and recommendations on reforming the wage index system, we refer readers to section IX.B. of the preamble of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53660 through 53664).

Comment: Several commenters expressed disappointment that CMS did not set forth a proposal in the CY 2013 OPPS/ASC proposed rule to begin reform of the wage index process and simply proposed to continue adopting the IPPS fiscal year wage indexes. Several commenters encouraged CMS to expedite wage index reform to create a more equitable system that adequately pays hospitals for care provided to Medicare beneficiaries. A few commenters supported the continuation of the current wage index system; one commenter suggested that, as more comprehensive reforms continue to be developed, they encompass the goals of minimizing volatility, discouraging manipulation of the system, and limiting adverse effects on high wage area markets.

Response: In the CY 2012 OPPS/ASC proposed rule, we solicited comment on possible alternative wage index systems under the OPPS (76 FR 42212 through 42213). However, in the CY 2012 OPPS/ASC final rule with comment period, we stated our belief that maintaining the current policy of adopting the fiscal year IPPS wage index and adopting it in the OPPS on a calendar year basis would continue to be appropriate, given our longstanding use of the fiscal year IPPS wage index in the OPPS on a calendar year basis (76 FR 74192) and the broader wage index reform currently under development and consideration (76 FR 74193). In the CY 2013 OPPS/ASC proposed rule, we proposed that continuing to use 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 (77 FR 45105). As discussed above, the FY 2013 IPPS/LTCH PPS final rule contains a discussion of a MedPAC report and an IOM study focused on potential models for wage

index reform (77 FR 53660 through 53664).

After consideration of the public comments we received, we are finalizing our policy to adopt the FY 2013 IPPS wage index for the CY 2013 OPPS in its entirety, including the rural floor, geographic reclassifications, and all other wage index adjustments. As stated earlier in this section, we continue to believe 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. Therefore, we are using the final FY 2013 IPPS wage indices for calculating OPPS payments in CY 2013. 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 2013 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/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. At this link, readers will find a link to the final FY 2013 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). 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.

For CY 2013, 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 proposed CY 2013 OPPS relative payment weights. Table 12 published in the proposed rule (77 FR 45106) listed the proposed CY 2013 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 proposed to adjust ratios from submitted cost reports to reflect the 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 proposed to weight 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.

Comment: One commenter expressed concern that Florida has the lowest CCR in the United States for both rural and urban areas. The commenter suggested that the statewide average default CCRs for Florida are ''significantly skewed'' due to cost report information submitted by hospitals in the Miami area and recommended that CMS evaluate the data used to calculate the CCRs in order to validate this assumption.

Response: As detailed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66680 through 66682), we use only valid CCRs to calculate the default ratios. That is, we remove the CCRs for all-inclusive hospitals and CAHs, we identify and remove any obvious error CCRs, and we trim any outliers. The Florida statewide average default CCRs have been very stable over the last several years. Contrary to the commenter's belief that we use statewide average default CCRs to estimate the costs (from charges on claims) that are used to calculate the OPPS relative weights, Medicare contractors use statewide average default CCRs to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments for hospitals with no available cost report.

After consideration of the public comment we received on our CY 2013 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 2013 OPPS relative weights. We used this methodology to calculate the statewide average default CCRs listed in Table 8 below.

For this CY 2013 OPPS/ASC final rule with comment period, approximately 62 percent of the submitted cost reports utilized in the default ratio calculations represented data for cost reporting periods ending in CY 2010, and approximately 38 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 2012 and CY 2013 are modest and the few significant changes are associated with areas that have a small number of hospitals.

Table 8 below lists the finalized statewide average default CCRs for OPPS services furnished on or after January 1, 2013.

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TABLE 8.–CY 2013 STATEWIDE AVERAGE CCRs

State	Urban/Rural	CY 2013 Default CCR	Previous Default CCR (CY 2012 OPPS Final Rule)
ALASKA	RURAL	0.489	0.487
ALASKA	URBAN	0.307	0.305
ALABAMA	RURAL	0.209	0.210
ALABAMA	URBAN	0.193	0.194
ARKANSAS	RURAL	0.219	0.221
ARKANSAS	URBAN	0.234	0.245
ARIZONA	RURAL	0.238	0.237
ARIZONA	URBAN	0.190	0.190
CALIFORNIA	RURAL	0.192	0.193
CALIFORNIA	URBAN	0.202	0.201
COLORADO	RURAL	0.331	0.342
COLORADO	URBAN	0.226	0.226
CONNECTICUT	RURAL	0.364	0.365
CONNECTICUT	URBAN	0.287	0.288
DISTRICT OF COLUMBIA	URBAN	0.302	0.302
DELAWARE	RURAL	0.282	0.280
DELAWARE	URBAN	0.353	0.347
FLORIDA	RURAL	0.182	0.182
FLORIDA	URBAN	0.167	0.164
GEORGIA	RURAL	0.237	0.238
GEORGIA	URBAN	0.214	0.214
HAWAII	RURAL	0.323	0.321
HAWAII	URBAN	0.306	0.306
IOWA	RURAL	0.296	0.296
IOWA	URBAN	0.269	0.269
IDAHO	RURAL	0.417	0.417
IDAHO	URBAN	0.357	0.353
ILLINOIS	RURAL	0.240	0.238
ILLINOIS	URBAN	0.230	0.230
INDIANA	RURAL	0.285	0.292
INDIANA	URBAN	0.256	0.262
KANSAS	RURAL	0.290	0.279
KANSAS	URBAN	0.210	0.208
KENTUCKY	RURAL	0.217	0.217

State	Urban/Rural	CY 2013 Default CCR	Previous Default CCR (CY 2012 OPPS Final Rule)
KENTUCKY	URBAN	0.241	0.239
LOUISIANA	RURAL	0.242	0.247
LOUISIANA	URBAN	0.225	0.224
MARYLAND	RURAL	0.275	0.276
MARYLAND	URBAN	0.246	0.246
MASSACHUSETTS	RURAL	0.427	0.427
MASSACHUSETTS	URBAN	0.323	0.322
MAINE	RURAL	0.445	0.438
MAINE	URBAN	0.449	0.453
MICHIGAN	RURAL	0.303	0.305
MICHIGAN	URBAN	0.303	0.305
MINNESOTA	RURAL	0.469	0.482
MINNESOTA	URBAN	0.321	0.320
MISSOURI	RURAL	0.241	0.243
MISSOURI	URBAN	0.262	0.260
MISSISSIPPI	RURAL	0.226	0.224
MISSISSIPPI	URBAN	0.182	0.189
MONTANA	RURAL	0.431	0.434
MONTANA	URBAN	0.384	0.386
NORTH CAROLINA	RURAL	0.253	0.251
NORTH CAROLINA	URBAN	0.254	0.257
NORTH DAKOTA	RURAL	0.322	0.322
NORTH DAKOTA	URBAN	0.414	0.421
NEBRASKA	RURAL	0.318	0.318
NEBRASKA	URBAN	0.254	0.252
NEW HAMPSHIRE	RURAL	0.317	0.323
NEW HAMPSHIRE	URBAN	0.292	0.291
NEW JERSEY	URBAN	0.207	0.212
NEW MEXICO	RURAL	0.256	0.264
NEW MEXICO	URBAN	0.279	0.288
NEVADA	RURAL	0.234	0.233
NEVADA	URBAN	0.162	0.167
NEW YORK	RURAL	0.420	0.419
NEW YORK	URBAN	0.369	0.356
OHIO	RURAL	0.321	0.320
OHIO	URBAN	0.237	0.234

State	Urban/Rural	CY 2013 Default CCR	Previous Default CCR (CY 2012 OPPS Final Rule)
OKLAHOMA	RURAL	0.239	0.239
OKLAHOMA	URBAN	0.212	0.217
OREGON	RURAL	0.314	0.311
OREGON	URBAN	0.335	0.328
PENNSYLVANIA	RURAL	0.267	0.270
PENNSYLVANIA	URBAN	0.200	0.199
PUERTO RICO	URBAN	0.504	0.492
RHODE ISLAND	URBAN	0.264	0.270
SOUTH CAROLINA	RURAL	0.211	0.211
SOUTH CAROLINA	URBAN	0.214	0.214
SOUTH DAKOTA	RURAL	0.307	0.307
SOUTH DAKOTA	URBAN	0.218	0.252
TENNESSEE	RURAL	0.209	0.211
TENNESSEE	URBAN	0.195	0.199
TEXAS	RURAL	0.235	0.236
TEXAS	URBAN	0.206	0.196
UTAH	RURAL	0.374	0.379
UTAH	URBAN	0.359	0.359
VIRGINIA	RURAL	0.227	0.226
VIRGINIA	URBAN	0.237	0.239
VERMONT	RURAL	0.408	0.407
VERMONT	URBAN	0.384	0.384
WASHINGTON	RURAL	0.366	0.368
WASHINGTON	URBAN	0.301	0.298
WISCONSIN	RURAL	0.345	0.351
WISCONSIN	URBAN	0.307	0.311
WEST VIRGINIA	RURAL	0.277	0.280
WEST VIRGINIA	URBAN	0.338	0.337
WYOMING	RURAL	0.379	0.386
WYOMING	URBAN	0.301	0.302

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E. OPPS Payments to Certain Rural and Other Hospitals

1. Hold Harmless Transitional Payment Changes

The OPPS was implemented in CY 2000 under the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33). The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) made major changes in the hospital OPPS, including adding a new paragraph (7) to section 1833(t) of the Act, effective as if included in the enactment of the BBA. Section 1833(t)(7) of the Act sets forth that 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), and 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 types

of hospitals excepted from the policy described above, cancer hospitals and children's hospitals. Specifically, 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 all hospitals for covered OPD services furnished before January 1, 2004. However, section 411 of Public Law 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 of Public Law 109–171 also reduced the TOPs to rural hospitals from 100 percent of the difference between the provider's OPPS payments and the pre-BBA amount. This provision provided that, in cases in which the OPPS payment was less than the provider's pre-BBA amount, the amount of payment would be 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 Transmittal 877, we did not specifically address whether TOPs applied to essential access community hospitals (EACHs), which are considered to be SCHs under section 1886(d)(5)(D)(iii)(III) of the Act. Accordingly, by law, 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 with 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 (the Medicare Improvements for Patients and Providers Act of 2008) 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 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 the issuance of the CY 2010 OPPS/ASC final rule with comment period, section 3121(a) of the Affordable Care Act (Pub. L. 111–148) 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 or 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 self-implementing 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 to the hospital 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 the removal of 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 to the hospital 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) are no longer eligible for TOPs, in accordance with section 108 of the MMEA. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74199), we revised our

regulations § 419.70(d) to conform the regulation text to the self-implementing provisions of section 108 of the MMEA described above.

Subsequent to the issuance of the CY 2012 OPPS/ASC final rule with comment period, section 308 of the Temporary Payroll Tax Cut Continuation Act of CY 2011 (Pub. L. 112–78), as amended by section 3002 of the Middle Class Tax Relief and Jobs Creation Act (Pub. L. 112–96), extended through December 31, 2012, 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, 2013, 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.

Section 308 of Public Law 112–78 also extended through February 29, 2012, the hold harmless provision for an SCH (as defined in section 1886(d)(5)(D)(iii) of the Act), including an EACH, without the bed size limitation. Therefore, for such hospitals, for services furnished before March 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. However, section 3002 of Public Law 112–96 extended through December 31, 2012, the hold harmless provision for an SCH (as defined in section 1886(d)(5)(D)(iii) of the Act), including an EACH, that has no more than 100 beds. Therefore, for such hospitals, for services furnished before January 1, 2013, 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. Accordingly, as we proposed in the CY 2013 OPPS/ASC proposed rule (77 FR 45108), we are revising § 419.70(d) of the regulations to reflect the TOPs extensions and amendments described in section 308 of Public Law 112–78 and section 3002 of Public Law 112–96.

Effective for services provided on or after March 1, 2012, SCHs (including EACHs) with greater than 100 beds are no longer eligible for TOPs, in accordance with section 308 of Public Law 112–78. Effective for services provided on or after January 1, 2013, a rural hospital with 100 or fewer beds that is not an SCH and an SCH (including an EACH) are no longer eligible for TOPs, in accordance with section 3002 of Public Law 112–96.

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 Public Law 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 outlier payments and copayments. We stated in the CY 2006 OPPS final rule with comment period (70 FR 68560) that 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 2012. 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.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45109), we proposed to continue for CY 2013 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. We indicated in the proposed rule that we intend to reassess the 7.1 percent adjustment in the future by examining differences between urban hospitals' costs and rural hospitals' costs using updated claims data, cost reports, and provider information.

Comment: Several commenters expressed support for the proposed continuation of the 7.1 percent rural SCH adjustment. A few commenters also suggested that the rural SCH adjustment also apply to urban SCHs. One commenter suggested that the 7.1 percent payment adjustment also be applied to MDHs, given that their inpatient classification was set to expire in October 2012.

Response: We agree that it is appropriate to continue the 7.1 percent adjustment for rural SCHs (including EACHs) as we proposed for CY 2013. We note that the rural SCH adjustment was developed under the authority described in section 1833(t)(13) of the Act, which applies specifically to rural hospitals. Although commenters have suggested that the rural SCH adjustment also apply to urban SCHs, the study authorized under section 1833(t)(13)(A) of the Act specifically focuses on APC costs incurred by rural hospitals, as they exceed those costs incurred by hospitals in urban areas. Moreover, the Secretary's authority to make an adjustment based on that study was with respect to a determination that costs incurred by rural hospitals exceed those costs incurred by urban hospitals and to reflect those higher costs. Therefore, the authority to make any such adjustment was limited to reflect the higher costs incurred by such applicable rural hospitals. Although the MDH classification is currently set to expire, we note that the definition of a MDH at 1886(d)(5)(G)(iv)(III) of the Act specifically excludes sole community hospitals, to which the rural adjustment applies. Further, as we discussed in the CY 2006 OPPS final rule, our analysis of urban SCHs as well as rural MDHs did not support the application of a

rural adjustment (70 FR 68560 through 68561).

After consideration of the public comments we received, we are finalizing our CY 2013 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 2013, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs. We continue to believe that the adjustment is appropriate for application in CY 2013.

F. OPPS Payment 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 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.

Section 3138 of the Affordable Care Act amended section 1833(t) of the 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. After conducting the study required by section 3138, we determined in 2012 that outpatient costs incurred by the 11 specified cancer hospitals were greater than the costs incurred by other OPPS hospitals. For a complete discussion regarding the cancer hospital cost study, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74200 through 74201).

Based on our findings that costs incurred by cancer hospitals were greater than the costs incurred by other OPPS hospitals, we finalized a policy to provide a payment adjustment to the 11 specified cancer hospitals that reflects the higher outpatient costs as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74202 through 74206). Specifically, we adopted a policy to provide additional payments to each of the 11 cancer hospitals so that each cancer hospital's final PCR for services provided in a given calendar year is equal to the weighted average PCR (which we refer to as the ''target PCR'') for other hospitals paid under the OPPS. The target PCR is set in advance of the calendar year and is calculated using the most recent submitted or settled cost report data that are available at the time of final rulemaking for the calendar year. The amount of the payment adjustment is made on an aggregate basis at cost report settlement. 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 are assessed as usual after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period. For CY 2012, the target PCR for purposes of the cancer hospital payment adjustment is 0.91.

2. Payment Adjustment for Certain Cancer Hospitals for CY 2013

In the CY 2013 OPPS/ASC proposed rule (77 FR 45110), we proposed to continue our policy to provide additional payments to cancer hospitals so that each cancer hospital's final PCR is equal to the weighted average PCR (or ''target PCR'') for the other OPPS hospitals using the most recent submitted or settled cost report data that were available at the time of the proposed rule. To calculate the proposed CY 2013 target PCR, we used the same extract of cost report data from HCRIS, as discussed in section II.A. of the proposed rule, used to estimate costs for the CY 2013 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 estimated that, on average, the OPPS payments to other hospitals furnishing services under the OPPS were approximately 91 percent of reasonable cost (weighted average PCR of 0.91). Based on these data, we proposed a target PCR of 0.91 that would be used to determine the CY 2013 cancer hospital payment adjustment that would be paid at cost report settlement. Therefore, we proposed that the payment amount associated with the cancer hospital payment adjustment to be determined at cost report settlement would be the additional payment needed to result in a proposed target PCR equal to 0.91 for each cancer hospital.

Comment: Some commenters suggested that the PCR is only one component of the adjustment needed to account for the differences in providing cancer care. The commenters suggested that CMS utilize a methodology that they stated would ensure that the 11 cancer hospitals' losses (on a per unit PCR basis) equal the losses (on a per unit PCR basis) of the other PPS hospitals. The commenters provided details of this ''equivalent loss per unit'' methodology which they indicate would result in a target PCR equal to 0.94 for CY 2013.

Response: 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 under section 1833(t)(2)(E) of the Act, to reflect the higher costs. Because the statute requires that we provide a cancer hospital payment adjustment to reflect the higher costs, not losses, incurred at cancer hospitals, we believe that it would be inappropriate to revise our cancer hospital payment adjustment policy so that the target PCR is calculated based on the cancer hospitals' losses per unit PCR compared to the other OPPS hospitals' losses per unit PCR.

Comment: Commenters stated that CMS should not recalculate the target PCR annually because the cancer hospitals require payment stability and predictability in order to provide services to Medicare beneficiaries.

Response: We believe that annual recalculation of the target PCR will provide a timely assessment of the changes in OPPS payments relative to costs and, therefore, will enable us to provide payment adjustments to cancer hospitals that are accurate and equitable. In addition, it is unlikely that the target PCR (the weighted average PCR for the other OPPS hospitals) would fluctuate significantly from year to year. The target PCR is 0.91 for purposes of the CY 2012 cancer hospital payment adjustment and remained at 0.91 when recalculated for the CY 2013 OPPS/ASC proposed rule and this final rule with comment period. In addition to the apparent stability of the target PCR, because the target PCR is set in advance of each calendar year, cancer hospitals can easily predict the amount of their hospital-specific payment adjustment associated with the target PCR for the following year and budget accordingly.

Comment: Commenters stated that CMS must make the cancer hospital payment adjustment effective for services furnished on or after January 1, 2011, in order to comply with section 3138 of the Affordable Care Act.

Response: As explained in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71886 through 71887), we did not finalize the proposed cancer hospital adjustment for CY 2011 for a variety of reasons, including, ultimately, a determination that further study and deliberation of the issues were necessary. 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 that subsection. Several commenters on the CY 2011 OPPS/ASC proposed rule raised concerns about the agency's study of costliness conducted under section 1833(t)(18)(A) of the Act; for example, one 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, public comments arguing against implementing a cancer hospital payment adjustment for CY 2011, and our determination that further study and deliberation were necessary, we decided to not finalize a cancer hospital payment adjustment for CY 2011. We note that, because the cancer hospital payment adjustment is budget neutral, the lack of a cancer hospital payment adjustment for CY 2011 also meant that other payments were not reduced for CY 2011 to offset the increased payments from the adjustment.

Comment: One commenter noted that, although CMS indicated the estimated percent by which each cancer hospital's OPPS payments would be increased under the cancer hospital payment adjustment policy in the CY 2012 OPPS/ASC proposed and final rules, CMS did not include this information in the CY 2013 OPPS/ASC proposed rule. The commenter requested that CMS include this information in the CY 2013 OPPS/ASC final rule with comment period.

Response: We agree with the commenter that it would be informative to provide the estimated percentage increase in CY 2013 OPPS payments to each cancer hospital due to the cancer hospital payment adjustment policy. Therefore, we are including that information in the last column of Table 9 below.

After consideration of the public comments we received, we are finalizing our proposal to continue our policy to provide additional payments to cancer hospitals so that each cancer hospital's final PCR is equal to the weighted average PCR for the other OPPS hospitals using the most recent submitted or settled cost report data that were available at the time of this final rule with comment period. To calculate the final CY 2013 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 costs for the CY 2013 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 2011 claims data that we used to model the impact of the final CY 2013 APC relative weights (4,026 hospitals) because it is appropriate to use the same set of hospitals that we are using to calibrate the modeled CY 2013 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2010 to 2011. We then removed the cost report data of the 48 hospitals located in Puerto Rico from our dataset 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 the cost report data of 182 hospitals because the cost report data that were not complete (missing aggregate OPPS payments, 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 an analytic file of 3,796 hospitals with cost report data.

Using this smaller dataset of cost report data, 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). Based on these data, we will use a target PCR of 0.91 to determine the CY 2013 cancer hospital payment adjustment to be paid at cost report settlement. Therefore, the payment amount associated with the cancer hospital payment 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.

Table 9 below indicates the estimated percentage increase in OPPS payments to each cancer hospital for CY 2013 due to the cancer hospital payment adjustment policy. The actual amount of the CY 2013 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2013 payments and costs. 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 9.—ESTIMATED CY 2013 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS (WITHOUT REGARD TO TOPS) TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider Number	Hospital Name	Estimated Percentage Increase in OPPS Payments for CY 2013
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	28.2%
100271	H. Lee Moffitt Cancer Center & Research Institute	21.2%
220162	Dana-Farber Cancer Institute	44.9%
330154	Memorial Hospital for Cancer and Allied Diseases	39.5%
330354	Roswell Park Cancer Institute	30.7%
360242	James Cancer Hospital & Solove Research Institute	33.7%
390196	Hospital of the Fox Chase Cancer Center	10.0%
450076	University of Texas M. D. Anderson Cancer Center	42.0%
500138	Seattle Cancer Care Alliance	44.7%

G. Hospital Outpatient Outlier Payments

1. Background

Currently, the OPPS provides outlier payments on a service-by-service basis. In CY 2011, the outlier threshold was determined to be 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 outlier payments 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. However, 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, in our CY 2009 OPPS/ASC final rule with comment period (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 2011 OPPS payment, using available CY 2011 claims and the revised OPPS expenditure estimate for the 2012 Trustee's Report, is approximately 1.2 percent of the total aggregated OPPS payments. Therefore, for CY 2011, we estimate that we paid 0.2 percent above the CY 2011 outlier target of 1.0 percent of total aggregated OPPS payments.

As explained in the CY 2012 OPPS/ASC final rule with comment period (77 FR 74207 through 74209), we set our projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS for CY 2012. The outlier thresholds were set so that estimated CY 2012 aggregate outlier payments would equal 1.0 percent of the total estimated aggregate payments under the OPPS. Using CY 2011 claims data and CY 2012 payment rates, we currently estimate that the aggregate outlier payments for CY 2012 will be approximately 0.9 percent of the total CY 2012 OPPS payments. The difference between 1.0 percent and 0.9 percent is reflected in the regulatory impact analysis in section XXII. of this final rule with comment period. We note that we provide estimated CY 2013 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/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

2. Proposed Outlier Calculation

In the CY 2013 OPPS/ASC proposed rule (77 FR 45110), we proposed to continue for CY 2013 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, an amount equal to 0.12 percent of outlier payments (or 0.0012 percent of total OPPS payments) 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 OPPS outlier payments. As discussed in section VIII.C. of the CY 2013 OPPS/ASC 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 rate 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 2013 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 $2,400 fixed-dollar threshold.

We proposed to calculate the fixed-dollar threshold using largely the same methodology as we did in CYs 2011 and 2012 (75 FR 71887 through 71889 and 76 FR 74207 through 74209). For purposes of estimating outlier payments for the proposed rule, we used the hospital-specific overall ancillary CCRs available in the April 2012 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.

In order to estimate the CY 2013 hospital outlier payments for the proposed rule, we inflated the charges on the CY 2011 claims using the same inflation factor of 1.1406 that we used to estimate the IPPS fixed-dollar outlier threshold for the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28142). We used an inflation factor of 1.0680 to estimate CY 2012 charges from the CY 2011 charges reported on CY 2011 claims. The methodology for determining this charge inflation factor is discussed in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28142). 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, we proposed in the CY 2013 OPPS/ASC proposed rule to apply the same CCR inflation adjustment factor that we applied for the FY 2013 IPPS outlier calculation to the CCRs used to simulate the CY 2013 OPPS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2013, we proposed to apply an adjustment factor of 0.9790 to the CCRs that were in the April 2012 OPSF to trend them forward from CY 2012 to CY 2013. The methodology for calculating this proposed adjustment was discussed in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28142 through 28144). We note that, due to the issue described in the IPPS proposed rule correction notice published on June 11, 2012, the operating and capital CCR inflation factors were reversed (77 FR 34326). In estimating the proposed CY 2013 OPPS fixed-dollar outlier threshold, we applied the corrected CCR inflation factor.

Therefore, to model hospital outlier payments for the proposed rule, we applied the overall CCRs from the April 2012 OPSF file after adjustment (using the proposed CCR inflation adjustment factor of 0.9790 to approximate CY 2013 CCRs) to charges on CY 2011 claims that were adjusted (using the charge inflation factor of 1.1406 to approximate CY 2013 charges). We simulated aggregated CY 2013 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 2013 OPPS payments. We estimated that a proposed fixed-dollar threshold of $2,400, combined with the 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 $2,400 were 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 rate 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 Program requirements. For hospitals that fail to meet the Hospital OQR Program requirements, we proposed to continue the policy that we implemented in CY 2010 that the hospitals' costs will 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 XV. of this final rule with comment period.

Comment: Several commenters expressed concern with respect to the relative increase in the proposed CY 2013 OPPS fixed-dollar outlier threshold of $2,400. The commenters believed that the increase in the fixed-dollar threshold would bring about a drastic reduction in outlier payments as well as the ability to furnish services to beneficiaries. Commenters also suggested CMS to reconsider the fixed-dollar threshold value, confirm that the data used to develop the threshold were accurate, and provide data to support the increase in the threshold. Commenters also suggested alternative fixed-dollar threshold setting methodologies such as a 3-year transition to the threshold or a calculation based on prior year estimated percent OPPS outlier spending.

Response: As indicated above, we introduced a fixed-dollar threshold in order to better target outlier payments 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. While commenters have expressed concern based on the assumption that OPPS outlier payments made under an increased fixed-dollar threshold would decrease, we note that the threshold may increase or decrease from year to year, to maintain the 1.0 percent outlier spending target. While we described issues related to the charge and CCR inflation factors in the CY 2013 OPPS/ASC proposed rule, there were no other errors in the methodology (77 FR 45111). The methodology for determining the OPPS fixed-dollar threshold is described in this section, the LDS files used to model the threshold that are available for public purchase, and a detailed claims accounting document that is available online, which all support the determination of the fixed-dollar threshold. We do not believe that a transitional methodology to determine the outlier threshold or a methodology that takes into account prior spending is appropriate because the relationship between a hospital's costs and the APC payment rates changes each year.

3. Final Outlier Calculation

Consistent with historical practice, we use updated data for this final rule with comment period for our outlier calculation. For CY 2013, we are applying the overall CCRs from the July 2012 OPSF with a CCR adjustment factor of 0.9880 to approximate CY 2013 CCRs to charges on the final CY 2011 claims that were adjusted to approximate CY 2013 charges (using the final 2-year charge inflation factor of 1.0894). These are the same CCR adjustment and charge inflation factors that were used to set the IPPS fixed-dollar threshold for the FY 2013 IPPS/LTCH PPS final rule (77 FR 53695 through 53696). We simulated aggregated CY 2013 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 2013 OPPS payments. We estimate that a fixed-dollar threshold of $2,025, 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 2013, 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 $2,025 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 rate 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, and 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 2013, we are not incorporating any assumptions about the effects of reconciliation into our calculation of the OPPS fixed-dollar outlier threshold in this final rule with comment period.

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. 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 payment weight determined under section II.A. of this final rule with comment period. Therefore, the national unadjusted payment rate for most APCs contained in Addendum A to this final rule with comment period (which is 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 available via the Internet on the CMS Web site) was calculated by multiplying the CY 2013 scaled weight for the APC by the CY 2013 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 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 XV. 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.

We did not receive any public comments on the proposed calculation of an adjusted Medicare payment. Therefore, we are finalizing the calculation of an adjusted Medicare payment, where appropriate, in the manner described as follows. Individual providers interested in calculating the payment amount that they will 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 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 2013 OPPS fee schedule increase factor of 1.8 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 2013 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 extended section 508 and certain additional special exception hospital reclassifications from October 1, 2010 through September 30, 2011. Section 302 of the Temporary Payroll Tax Cut Continuation Act of 2011 (Pub. L. 112–78) as amended by section 3001 of the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96) extended section 508 and certain additional special exception hospital reclassifications from October 1, 2011 through March 31, 2012. Therefore, these reclassifications will not apply to the CY 2013 OPPS. (For further discussion of the changes to the FY 2013 IPPS wage indices, as applied to the CY 2013 OPPS, we refer readers to section II.C. of this final rule with comment period). We proposed to continue 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 available via the Internet on the CMS Web site) contains the qualifying counties and the associated wage index increase developed for the FY 2013 IPPS and listed as Table 4J in the FY 2013 IPPS/LTCH PPS final rule and available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* 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 unadjusted 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 = $Y + X_a$

Step 6. If a provider is an SCH, set forth in the regulations at § 412.92, or an EACH, which is considered to be an 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 used 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 2013 full national unadjusted payment rate for APC 0019 is $336.38. The reduced national unadjusted payment rate for a hospital that fails to meet the Hospital OQR Program requirements is $329.65. This reduced rate is calculated by multiplying the reporting ratio of 0.980 by the full unadjusted payment rate for APC 0019.

The FY 2013 wage index for a provider located in CBSA 35644 in New York is 1.2971. The labor-related portion of the full national unadjusted payment is $261.79 (.60 * $336.38 * 1.2971). The labor-related portion of the reduced national unadjusted payment is $256.55 (.60 * $329.65 * 1.2971). The nonlabor-related portion of the full national unadjusted payment is $134.55 (.40 * $336.38). The nonlabor-related portion of the reduced national unadjusted payment is $131.86 (.40 * $329.65). The sum of the labor-related and nonlabor-related portions of the full national adjusted payment is $396.34 ($261.79 + $134.55). The sum of the reduced national adjusted payment is $388.41 ($256.55 + $131.86).

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, the effective copayment rate for a covered OPD service paid under the OPPS in CY 2006, and in calendar years thereafter, shall not exceed 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.

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 2013 OPPS/ASC proposed rule (77 FR 45113), 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 national unadjusted copayment amounts for services payable under the OPPS that will be effective January 1, 2013, are shown in Addenda A and B to this final rule with comment period (which are available via the Internet on the CMS Web site). As discussed in section XV. of this final rule with comment period, for CY 2013, the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies equals 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 note that APC copayments may increase or decrease each year based on changes in the calculated APC payment rates due to updated cost report and claims data, and any changes to the OPPS cost modeling process. The CY 2013 proposed policy to base APC relative weights on geometric mean costs would also affect the APC payment rates and, through them, the corresponding beneficiary copayments. However, as described in the CY 2004 OPPS/ASC final rule with comment period, the development of the copayment methodology generally moves beneficiary copayments closer to 20 percent of OPPS APC payments (68 FR 63458 through 63459). For a more detailed discussion of the final policy to base the APC relative payment weights on geometric mean costs, we refer readers to section II.A.2.f. of this final rule with comment period.

We did not receive any public comments regarding the proposed methodology for calculating copayments for CY 2013. Therefore, for the reasons set forth in the proposed rule (77 FR 45113), we are finalizing our CY 2013 copayment methodology without modification.

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, $67.28 is 20 percent of the full national unadjusted payment rate of $336.38. 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 payment 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, 2013, are shown in Addenda A and B to this final rule with comment period (which are 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 2013 OPD fee schedule increase factor discussed in section II.B. 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.

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 surgical procedures and medical services;
- 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 public comments on these new codes and finalize our proposals related to these codes through our annual rulemaking process. As we proposed in the CY 2013 OPPS/ASC proposed (77 FR 45114), in Table 10 below (Table 13 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 the payment rates associated with codes effective July 1 were not available to us in time for incorporation into the Addenda of the proposed rule, the Level II HCPCS codes and the Category III CPT codes implemented through the July 2012 OPPS quarterly update CR 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 2012 OPPS quarterly update were included in Addendum B. Nevertheless, we requested public comments on the codes included in the July 2012 OPPS quarterly update and included these codes in the preamble of the proposed rule.

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TABLE 10.—COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April l, 2012	Level II HCPCS Codes	April 1, 2012	CY 2013 OPPS/ASC proposed rule	CY 2013 OPPS/ASC final rule with comment period
July 1, 2012	Level II HCPCS Codes	July 1, 2012	CY 2013 OPPS/ASC proposed rule	CY 2013 OPPS/ASC final rule with comment period
	Category I (certain vaccine codes) and III CPT codes	July 1, 2012	CY 2013 OPPS/ASC proposed rule	CY 2013 OPPS/ASC final rule with comment period
October 1, 2012	Level II HCPCS Codes	October 1, 2012	CY 2013 OPPS/ASC final rule with comment period	CY 2014 OPPS/ASC final rule with comment period
January 1, 2013	Level II HCPCS Codes	January 1, 2013	CY 2013 OPPS/ASC final rule with comment period	CY 2014 OPPS/ASC final rule with comment period
	Category I and III CPT Codes	January 1, 2013	CY 2013 OPPS/ASC final rule with comment period	CY 2014 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 2013 OPPS/ASC proposed rule or whether we are soliciting public comments in this CY 2013 OPPS/ASC final rule with comment period. We note that we sought public comments in the CY 2012 OPPS/ASC final rule with comment period on the new CPT and Level II HCPCS codes that were effective January 1, 2012. We also sought public comments in the CY 2012 OPPS/ASC final rule with comment period on the new Level II HCPCS codes effective October 1, 2011. These new codes, with an effective date of October 1, 2011, or January 1, 2012, 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 2012 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 2012 OPPS/ASC final rule with comment period. We are responding to public comments and finalizing our interim OPPS treatment of these codes in this CY 2013 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 2012 OPPS/ASC final rule with comment period. We respond to those comments in sections II.A., III.D., V.B., and IX of this final rule with comment period. Table 11 below lists the long descriptors for the CPT codes that were assigned to comment indicator ''NI'' for which we received public comments to the CY 2012 OPPS/ASC final rule with comment period and the specific sections where the comments are addressed.

TABLE 11.—COMMENTS TO THE CY 2012 OPPS/ASC FINAL RULE WITH COMMENT PERIOD ON NEW HCPCS CODES ASSIGNED TO COMMENT INDICATOR "NI"

CY 2012 CPT Code	CY 2012 Long Descriptor	Section In This CY 2013 OPPS/ASC Final Rule With Comment Period Where Comments Are Addressed
0278T	Transcutaneous electrical modulation pain reprocessing (eg, scrambler therapy), each treatment session (includes placement of electrodes)	III.D.4.a. (Scrambler Therapy)
0293T	Insertion of left atrial hemodynamic monitor; complete system, includes implanted communication module and pressure sensor lead in left atrium including transseptal access, radiological supervision and interpretation, and associated injection procedures, when performed	IX. (Inpatient Procedures)
0294T	Insertion of left atrial hemodynamic monitor; pressure sensor lead at time of insertion of pacing cardioverter-defibrillator pulse generator including radiological supervision and interpretation and associated injection procedures, when performed (list separately in addition to primary procedure)	
0296T	External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; recording (includes connection and initial recording)	III.D.1.e. (External Electrocardiographic Monitoring)
0297T	External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; scanning analysis with report	
0299T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound	III.D.3.a. (Extracorporeal Shock Wave Wound Treatment)
0300T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; each additional wound (list separately in addition to code for primary procedure)	

15272	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)	III.D.3.b. (Application of Skin Substitute)
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 (list separately in addition to code for primary procedure)	
15276	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)	
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 (list separately in addition to code for primary procedure)	
15777	Implantation of biologic implant (eg, acellular dermal matrix) for soft tissue reinforcement (eg, breast, trunk) (list separately in addition to code for primary procedure)	II.A.3. (Changes to Packaged Services)
64633	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or ct); cervical or thoracic, single facet joint	III.D.4.c. (Paravertebral Neurolytic Agent)
62369	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming and refill	III.D.4.d. (Programmable Implantable Pump)

62370	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming and refill (requiring physician's skill)	
77424	Intraoperative radiation treatment delivery, x-ray, single treatment session	III.D.6.e. (Intraoperative Radiation Therapy)
77425	Intraoperative radiation treatment delivery, electrons, single treatment session	
81200-81383	Tier I Molecular Pathology Procedures	III.D.9.a. (Molecular Pathology Procedures)
81400-81408	Tier 2 Molecular Pathology Procedures	
J9179	Injection, eribulin mesylate, 0.1 mg	V.A. (OPPS Transitional Pass-through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals)
Q4128	Flexhd or allopatch hd, per square centimeter	V.B. (OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status)

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1. Treatment of New CY 2012 Level II HCPCS and CPT Codes Effective April 1, 2012 and July 1, 2012 for Which We Solicited Public Comments in the CY 2013 OPPS/ASC Proposed Rule

Through the April 2012 OPPS quarterly update CR (Transmittal 2418, Change Request 7748, dated March 2, 2012) and the July 2012 OPPS quarterly update CR (Transmittal 2483, Change Request 7847, dated June 8, 2012), we recognized several new HCPCS codes for separate payment under the OPPS. Effective April 1 and July 1 of CY 2012, we made effective 13 new Level II HCPCS codes and 7 Category III CPT codes. Specifically, 5 new Level II HCPCS codes were effective for the April 2012 update and another 8 new Level II HCPCS codes were effective for the July 2012 update for a total of 13. Seven new Category III CPT codes were effective for the July 2012 update. Of the 13 new Level II HCPCS codes, we recognized for separate payment 11 of these codes, and of the 7 new Category III CPT codes, we recognized for separate payment all 7 new Category III CPT codes, for a total of 18 new Level II HCPCS and Category III CPT codes that are recognized for separate payment for CY 2013.

Through the April 2012 OPPS quarterly update CR, we allowed separate payment for each of the five new Level II HCPCS codes. Specifically, as displayed in Table 12 below, we provided separate payment for HCPCS codes C9288, C9289, C9290, C9291 and C9733.

TABLE 12.— NEW LEVEL II HCPCS CODES IMPLEMENTED IN APRIL 2012

CY 2012 HCPCS Code	CY 2012 Long Descriptor	April 2012 Status Indicator	April 2012 APC
C9288	Injection, centruroides (scorpion) immune f(ab)2 (equine), 1 vial	G	9288
C9289	Injection, asparaginase Erwinia chrysanthemi, 1,000 international units (I.U.)	G	9289
C9290	Injection, bupivacaine liposome, 1 mg	G	9290
C9291*	Injection, aflibercept, 2 mg vial	G	9291
C9733	Non-ophthalmic fluorescent vascular angiography	Q2	0397

*Level II HCPCS code C9291 (Injection, aflibercept, 2 mg vial) was deleted June 30, 2012, and replaced with HCPCS code Q2046 (Injection, aflibercept, 1 mg) effective July 1, 2012.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45115), we solicited public comments on the proposed status indicators and APC assignments for Level II HCPCS codes C9288, C9289, C9290, C9291, and C9733, which were listed in Table 14 of the proposed rule (77 FR 45115) and now appear in Tables 12 and 13 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 C9288, C9289, C9290, and C9291. However, we received several public comments on HCPCS code C9733, which are addressed in section III.D.7.a. of this final rule with comment period.

For CY 2013, the HCPCS Workgroup replaced HCPCS codes C9288, C9289, and C9291 (which was replaced with HCPCS code Q2046, effective July 1, 2012) with permanent HCPCS J-codes. Table 13 below list the replacement HCPCS J-codes for the temporary HCPCS C-codes. Consistent with our general policy of using permanent HCPCS codes 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 C9288, C9289, and C9291/Q2046, effective January 1, 2013, in Table 13.

In this final rule with comment period, we are assigning the Level II HCPCS codes listed in Table 13 below to the specific APCs and status indicators for CY 2013.

TABLE 13.—FINAL CY 2013 STATUS INDICATOR AND APC ASSIGNMENTS FOR THE LEVEL II HCPCS CODES THAT WERE NEWLY IMPLEMENTED IN APRIL 2012

CY 2012 HCPCS Code	CY 2013 HCPCS Code	CY 2013 Long Descriptor	Final CY 2013 Status Indicator	Final CY 2013 APC
C9288	J0716	Injection, centruroides immune f(ab)2, up to 120 milligrams	G	1431
C9289	J9019	Injection, asparaginase (Erwinaze), 1,000 IU	G	9289
C9290	C9290	Injection, bupivacaine liposome, 1 mg	G	9290
C9291 / Q2046	J0178	Injection, aflibercept, 1 mg	G	1420
C9733	C9733	Non-ophthalmic fluorescent vascular angiography	Q2	0397

For CY 2013, we note that we are not making any changes to the status indicators and APC assignments for HCPCS code C9290 and C9733. That is, HCPCS code C9290 will continue its pass-through status and will also continue to be assigned to APC 9290 for CY 2013. Similarly, HCPCS code C9733 will continue to be assigned to status indicator ''Q2'' and also will continue to be assigned to APC 0397 for CY 2013.

Furthermore, because HCPCS code J9019 describes the same drug and the same dosage currently designated by HCPCS code C9289, this drug will continue its pass-through status in CY 2013. Therefore, we are assigning HCPCS code J9019 to the same status indicator and APC as its predecessor HCPCS code, as shown in Table 13.

However, we note that the replacement code for HCPCS code C9291, which was replaced with HCPCS code Q2046 effective July 1, 2012, did not describe the same dosage descriptor, and consequently, the replacement HCPCS code was assigned a new APC number. Specifically, HCPCS code Q2046, which has a dosage descriptor of 1 mg, was assigned to APC 1420 effective July 1, 2012. Because the predecessor HCPCS code C9291 was assigned to pass-through status, HCPCS code Q2046 also was assigned to pass-through status for CY 2013. Similarly, the replacement code for HCPCS code C9288 does not describe the same dosage descriptor, and, consequently, its replacement HCPCS code J0716 was assigned a new APC. Specifically, HCPCS code C9288 has a dosage descriptor of 1 vial; however, its replacement HCPCS code J0716 has a dosage descriptor of ''up to 120 milligrams.'' Therefore, effective January 1, 2013, HCPCS codes J0716 is assigned to APC 1431, a different APC, to maintain data consistency for future rulemaking. Because the predecessor HCPCS code C9288 was assigned to pass-through status, HCPCS code J0716 will continue to be assigned status indicator ''G'' for CY 2013.

As discussed in the CY 2013 OPPS/ASC proposed rule (77 FR 45115 through 45116), through the July 2012 OPPS quarterly update CR, which included HCPCS codes that were made effective July 1, 2012, we allowed separate payment for 6 of the 8 new Level II HCPCS codes. Specifically, as displayed in Table 14 below (also Table 14 of the proposed rule), we provided separate OPPS payment for HCPCS codes C9368, C9369, Q2045, Q2046, Q2048, and Q2049.

TABLE 14.—NEW LEVEL II HCPCS CODES IMPLEMENTED IN JULY 2012

CY 2012 HCPCS Code	CY 2012 Long Descriptor	July 2012 Status Indicator	July 2012 APC
C9368	Grafix core, per square centimeter	G	9368
C9369	Grafix prime, per square centimeter	G	9369
Q2034	Influenza virus vaccine, split virus, for intramuscular use (Agriflu)	L	N/A
Q2045*	Injection, human fibrinogen concentrate, 1 mg	K	1414
Q2046**	Injection, aflibercept, 1 mg	G	1420
Q2047	Injection, peginesatide, 0.1 mg (for ESRD on dialysis)	A	N/A
Q2048***	Injection, doxorubicin hydrochloride, liposomal, doxil, 10 mg	K	7046
Q2049	Injection, doxorubicin hydrochloride, liposomal, imported lipodox, 10 mg	K	1421

*HCPCS code Q2045 replaced HCPCS code J1680 effective July 1, 2012. The status indicator for HCPCS code J1680 was changed to "E" (Not Payable by Medicare) effective July 1, 2012.
**HCPCS code Q2046 replaced HCPCS code C9291 effective July 1, 2012.
***HCPCS code Q2048 replaced HCPCS code J9001 effective July 1, 2012. The status indicator for HCPCS code J9001 was changed to "E" (Not Payable by Medicare) effective July 1, 2012.

We note that three of the Level II HCPCS Q-codes that were made effective July 1, 2012, were previously described by HCPCS J-codes or C-codes that were separately payable under the hospital OPPS. First, HCPCS code Q2045 replaced HCPCS code J1680 (Injection, human fibrinogen concentrate, 100 mg), beginning July 1, 2012. HCPCS code J1680 was assigned to status indicator ''K'' (Nonpass-through drugs and nonimplantable biologicals, including therapeutic radiopharmaceuticals; paid under OPPS; separate APC payment) on

January 1, 2012. However, because HCPCS code J1680 was replaced by HCPCS code Q2045 effective July 1, 2012, we changed its status indicator to ''E'' (Not Payable by Medicare) effective July 1, 2012. Because HCPCS code Q2045 describes the same drug as HCPCS code J1680, we continued its separate payment status and assigned it to status indicator ''K'' effective July 1, 2012. However, because the dosage descriptor for HCPCS code Q2045 is not the same as HCPCS code J1680, we assigned HCPCS code Q2045 to a new APC to maintain data consistency for future rulemaking. Specifically, HCPCS code Q2045 was assigned to APC 1414 effective July 1, 2012.

Second, HCPCS code Q2046 replaced HCPCS code C9291 effective July 1, 2012. HCPCS code C9291 was assigned pass-through status when it was effective April 1, 2012. Because HCPCS code Q2046 describes the same product as HCPCS code C9291, we continued its pass-through status and assigned HCPCS code Q2046 to status indicator ''G'' as well as assigned it to the same APC, specifically APC 9291, effective July 1, 2012. HCPCS code C9291 was deleted on June 30, 2012.

Third, the HCPCS Workgroup replaced HCPCS code J9001 (Injection, doxorubicin hydrochloride, all lipid formulations, 10 mg) with new HCPCS code Q2048, effective July 1, 2012. Consequently, the status indicator for HCPCS code J9001 was changed to ''E'' (Not Payable by Medicare) effective July 1, 2012. Because HCPCS code Q2048 describes the same drug as HCPCS code J9001, we continued its separate payment status and assigned HCPCS code Q2048 to status indicator ''K'' effective July 1, 2012. In addition, because, HCPCS code Q2049 is similar to HCPCS code Q2048, we assigned HCPCS code Q2049 to status indicator ''K'' effective July 1, 2012.

Of the 15 HCPCS codes that were effective July 1, 2012, we did not recognize for separate OPPS payment two HCPCS codes because they are both paid under a payment system other than OPPS. Specifically, HCPCS code Q2047 was assigned to status indicator ''A'' (Not paid under OPPS; paid by fiscal intermediaries/MACs under a fee schedule or payment system other than OPPS), and HCPCS code Q2034 was assigned to status indicator ''L'' (Not paid under OPPS; paid at reasonable cost).

In the CY 2013 OPPS/ASC proposed rule (77 FR 45116), we solicited public comments on the proposed status indicators and APC assignments for the HCPCS codes that were listed in Table 15 of the proposed rule and now appear in Table 14 and 15 of this final rule with comment period.

We did not receive any other public comments on the new Level II HCPCS codes that were implemented in July 2012. We are adopting as final, without modification, our proposal to assign the Level II HCPCS codes listed in Table 15 to the APCs and status indicators as proposed for CY 2013.

Table 15 below includes a complete list of the Level II HCPCS codes that were made effective July 1, 2012, with their final status indicators and APC assignments for CY 2013.

TABLE 15.—FINAL CY 2013 STATUS INDICATORS AND APC ASSIGNMENTS FOR THE LEVEL II HCPCS CODES THAT WERE NEWLY IMPLEMENTED IN JULY 2012

CY 2012 HCPCS Code	CY 2013 HCPCS Code	CY 2013 Long Descriptor	Final CY 2013 Status Indicator	Final CY 2013 APC
C9368	Q4132	Grafix core, per square centimeter	G	9368
C9369	Q4133	Grafix prime, per square centimeter	G	9369
Q2034	Q2034	Influenza virus vaccine, split virus, for intramuscular use (Agriflu)	L	N/A
Q2045*	J7178	Injection, human fibrinogen concentrate, 1 mg	K	1414
Q2046**	J0178	Injection, aflibercept, 1 mg	G	1420
Q2047	J0890	Injection, peginesatide, 0.1 mg (for esrd on dialysis)	A	N/A
Q2048***	J9002	Injection, doxorubicin hydrochloride, liposomal, doxil, 10 mg	K	7046
Q2049	Q2049	Injection, doxorubicin hydrochloride, liposomal, imported lipodox, 10 mg	K	1421

We note that the HCPCS Workgroup replaced HCPCS codes C9368, C9369, Q2045, Q2046, Q2047, and Q2048 with HCPCS codes Q4132, Q4133, J7178, J0178, J0890, and J9002, respectively, effective January 1, 2013. Because

HCPCS codes Q4132, Q4133, and J0178 describe the same products currently designated by HCPCS codes C9368, C9369, and Q2046, respectively, these products will continue their pass-through status in CY 2013. Therefore, we are assigning HCPCS codes Q4132, Q4133 and J0178 to the same status indicators and APCs as their predecessor HCPCS codes, which share the same dosage descriptors, as shown in Table 15. We note that because HCPCS codes Q2045 and Q2048 are assigned to status indicator ''K'' (Nonpass-Through Drugs; Paid under OPPS; Separate APC payment), their replacement HCPCS codes J7178 and J9002, which share the same code descriptors as their predecessor codes, also will continue their nonpass-through status and APC assignments in CY 2013.

Finally, HCPCS code Q2047 will be replaced with HCPCS code J0890 effective January 1, 2013. Because HCPCS code J0890 describes the same product currently designated by HCPCS code Q2047, this product will continue to be assigned to the same status indicator as its predecessor HCPCS code, as shown in Table 15.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45116), 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 CPT 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. For the July 2012 update, there were no new Category I CPT vaccine codes. Through the July 2012 OPPS quarterly update CR (Transmittal 2483, Change Request 7847, dated June 8, 2012), we allowed separate OPPS payment for all seven new Category III CPT codes effective July 1, 2012. Specifically, as displayed in Table 16 of the proposed rule and in Table 16 below, we allowed separate payment for Category III CPT codes 0302T, 0303T, 0304T, 0305T, 0306T, 0307T, and 0308T.

We received one public comment on one of the Category III CPT codes that were implemented in July 2012, specifically on CPT code 0304T, which is addressed in section II.A.2.d.(1) of this final rule with comment period. Table 16 below lists the Category III CPT codes that were implemented in July 2012, along with their final status indicators and APC assignments, for CY 2013. The final payment rates for these codes can be found in Addendum B to this CY 2013 OPPS/ASC final rule with comment period (which is available via the Internet on the CMS Web site).

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TABLE 16.—NEW CATEGORY III CPT CODES IMPLEMENTED IN JULY 2012

CY 2013 CPT Code	CY 2013 Long Descriptor	Final CY 2013 Status Indicator	Final CY 2013 APC
0302T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; complete system (includes device and electrode)	T	0089
0303T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; electrode only	T	0106
0304T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; device only	T	0090
0305T	Programming device evaluation (in person) of intracardiac ischemia monitoring system with iterative adjustment of programmed values, with analysis, review, and report	S	0690
0306T	Interrogation device evaluation (in person) of intracardiac ischemia monitoring system with analysis, review, and report	S	0690
0307T	Removal of intracardiac ischemia monitoring device	T	0105
0308T	Insertion of ocular telescope prosthesis including removal of crystalline lens	T	0234

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In the CY 2013 OPPS/ASC proposed rule (77 FR 45114 through 45117), we solicited public comments on the CY 2013 proposed status indicators and the proposed APC assignments and payment rates for the Level II HCPCS codes and the Category III CPT codes that were effective April 1, 2012, and July 1, 2012, through the respective OPPS quarterly update CRs. These codes were listed in Tables 14, 15, and 16 of the proposed rule. We proposed to finalize their status indicators and their APC assignments and payment rates, if applicable, in this CY 2013 OPPS/ASC final rule with comment period. Because the new Category III CPT and Level II HCPCS codes that become effective for July are 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 status indicators,

proposed APCs (where applicable), and proposed payment rates (where applicable) in the preamble of the proposed rule but not in the Addenda to the proposed rule. These codes were listed in Tables 15 and 16, respectively, of the proposed rule. We proposed to incorporate these codes into Addendum B to this CY 2013 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 2012 OPPS update CR and displayed in Table 14 were included in Addendum B to the proposed rule (which was available via the Internet on the CMS Web site), where their proposed CY 2013 payment rates were also shown.

We did not receive any additional public 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 were implemented or modified through the April 2012 or July 2012 OPPS update CR are found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

2. Process for New Level II HCPCS Codes That Will Be Effective October 1, 2012 and New CPT and Level II HCPCS Codes That Will Be Effective January 1, 2013 for Which We Are Soliciting Public Comments in This CY 2013 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. For CY 2013, 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. In addition, the CPT and Level II HCPCS codes that will be effective January 1, 2013, are flagged with comment indicator ''NI'' in Addendum B to the OPPS/ASC final rule with comment period. 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 2013 OPPS/ASC proposed rule (77 FR 45117 through 45118), we proposed to continue this process for CY 2013. Specifically, for CY 2013, we proposed to include in Addendum B to this CY 2013 OPPS/ASC final rule with comment period the new Category I and III CPT codes effective January 1, 2013 (including the Category III CPT codes that were released by the AMA in July 2012) that would be incorporated in the January 2013 OPPS quarterly update CR and the new Level II HCPCS codes, effective October 1, 2012, or January 1, 2013, that would be released by CMS in its October 2012 and January 2013 OPPS quarterly update CRs. As proposed, in this final rule with comment period, the October 1, 2012 and January 1, 2013 codes are flagged with comment indicator ''NI'' in Addendum B to this CY 2013 OPPS/ASC final rule with comment period to indicate that we have assigned them an interim OPPS payment status for CY 2013. 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 2014 OPPS/ASC final rule with comment period.

We did not receive any public comments on our proposal. Therefore, we are finalizing our proposal to flag new Level II HCPCS codes that become effective October 1, 2012, and new CPT and Level II HCPCS codes that become effective January 1, 2013 with comment indicator ''NI'' in Addendum B to this CY 2013 OPPS/ASC final rule with comment period to indicate that these codes have been assigned an interim OPPS payment status for CY 2013. In addition, because these codes have been assigned to comment indicator ''NI,'' their status indicators and their APC assignments and payment rates, if applicable, are open to public comment and will be finalized in the CY 2014 OPPS/ASC final rule with comment period.

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 have also 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:

(a) Use of an operating, treatment, or procedure room;

(b) Use of a recovery room;

(c) Observation services;

(d) Anesthesia;

(e) Medical/surgical supplies;

(f) 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);

(g) Incidental services such as venipuncture;

(h) 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 2012 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, multiple imaging services, and cardiac resynchronization therapy 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 cost of the services included in that APC, relative to the hospital 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 HOP Panel recommendations for specific services for the CY 2013 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 cost for an item or service in the group is more than 2 times greater than the lowest cost for an item or service within the same group (referred to as the ''2 times rule''). In the CY 2013 OPPS/ASC proposed rule (77 FR 45118), for CY 2013, we proposed to use the cost of the item or service in implementing this provision, as discussed in section II.A.2.f. of this final rule with comment period. 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 cost of the highest cost item or service within an APC group is more than 2 times greater than the cost 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 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 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 cost. In the CY 2013 OPPS/ASC proposed rule (77 FR 45118), 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 2013.

In the CY 2013 OPPS/ASC proposed rule, we identified APCs with 2 times rule violations 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 2013 OPPS/ASC proposed rule. Rather, it was published and made available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. In these cases, to eliminate a 2 times rule 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 accommodate proposed HCPCS code reassignments. In many cases, the proposed HCPCS code reassignments and associated APC reconfigurations for CY 2013 included in the proposed rule were related to changes in costs of services that were observed in the CY 2011 claims data newly available for CY 2013 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 2013. Addendum B of the CY 2013 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 2012 Addendum B Update (available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*). In contrast, Addendum B of this final rule with comment period (available via the Internet on the CMS Web site) identifies with the ''CH'' comment indicator the final CY 2013 changes compared to the codes' status as reflected in the October 2012 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 2013, we reviewed all the APCs to determine which APCs would not satisfy the 2 times rule. Then 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 utilization;

- 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 17 of the CY 2013 OPPS/ASC proposed rule listed 21 APCs that we proposed to exempt from the 2 times rule for CY 2013 based on the criteria cited above and based on claims data processed from January 1, 2011, through December 31, 2011.

We note that, for cases in which a recommendation by the HOP Panel appears to result in or allow a violation of the 2 times rule, we generally accept the Panel's recommendation because those recommendations are based on explicit consideration of resource use, clinical homogeneity, site of service, and the quality of the claims data used to determine the APC payment rates.

For the CY 2013 OPPS/ASC proposed rule, we based the listed exceptions to the 2 times rule on claims data for dates of service between January 1, 2011, and December 31, 2011, 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, 2011, and December 31, 2011, that were processed on or before June 30, 2012 and updated CCRs, if available. Thus, after considering the public comments we received on the CY 2013 OPPS/ASC proposed rule and making changes to APC assignments based on those comments, we analyzed the CY 2011 claims data used for this final rule with comment period to identify the APCs with 2 times rule violations. Based on the final CY 2011 claims data, we found that there are 19 APCs with 2 times rule violations, a cumulative decrease of 2 APCs compared to the proposed rule. We applied the criteria as described earlier to identify the APCs that are exceptions to the 2 times rule for CY 2013, and identified two additional APCs that meet the criteria for exception to the 2 times rule for this final rule with comment period:

- APC 0148 (Level I Anal/Rectal Procedures)
- APC 0254 (Level V ENT Procedures)

In addition, we also determined that four APCs no longer violated the 2 times rule:

- APC 0128 (Echocardiogram with Contrast)
- APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs)
- APC 0604 (Level 1 Hospital Clinic Visits)
- APC 0655 (Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing)

As discussed in section III.D.1.f. of this final rule with comment period, because of concerns raised regarding the 2 times rule violation for echocardiography services, and after further analysis of our claims data, we deleted APC 0128 and replaced it with two new APCs to correct the 2 times rule violation. Specifically, APC 0128 has been replaced with APC 0177 (Level I Echocardiogram with Contrast) and APC 0178 (Level II Echocardiogram with Contrast). We have not included in this count those APCs where a 2 times rule violation is not a relevant concept, such as APC 0375 (Ancillary Outpatient Services when Patient Expires), with an APC cost set based on multiple procedure claims; therefore, we have identified only final APCs, including those with criteria-based costs, such as device-dependent APCs, with 2 times rule violations.

Comment: Several commenters urged CMS to reassign HCPCS G0379 (Direct admission of patient for hospital observation care) from APC 0604 (Level 1 Hospital Clinic Visits) to APC 0608 (Level 5 Hospital Clinic Visits). In particular, the commenters requested that CMS assign HCPCS G0379 to the same APC as CPT code 99205 (Office or other outpatient visit for the evaluation and management of a new patient (Level 5)) when the Composite APC 8002 (Level I Extended Assessment & Management Composite) criteria are not met. The commenters indicated that the reassignment of HCPCS code G0379 to APC 0608 would be appropriate because it would resolve the 2 times rule violation in APC 0604 and also align the resources with a high-level hospital visit when the criteria for Composite APC 8002 are not met. The commenters suggested that continuing to assign HCPCS code G0379 to APC 0604 would result in continued underpayments to HOPDs when the services and claims processing requirements for APC 8002 are not met for a direct referral. The commenters further added that this same issue was discussed during the February 2012 HOP Panel meeting, and that after the discussion, the Panel recommended that CMS reassign HCPCS code G0379 from APC 0604 to an appropriate APC. The commenters urged CMS to accept the Panel's recommendation.

Response: Based on the recommendation of the HOP Panel at its February 2012 meeting, we reviewed our claims data for HCPCS code G0379. Our analyses revealed that the level of hospital resources used to provide HCPCS code G0379 is about the same as for CPT code 99205. In particular, our claims data show similar geometric mean costs for HCPCS code G0379 and CPT code 99205. Specifically, our claims data show a geometric mean cost of approximately $181 for HCPCS code G0379 based on 2,368 single claims (out of 3,975 total claims), and a geometric mean cost of approximately $179 based on 95,017 single claims (out of 104,246 total claims) for CPT code 99205. Based on our review of the claims data associated with HCPCS code G0379 and CPT code 99025, we agree with the commenters that the reassignment of HCPCS code G0379 to APC 0608 is appropriate. Because APC assignments are made based on consideration of both hospital resources and clinical homogeneity, we believe this reassignment improves the clinical homogeneity of APC 0608 and appropriately aligns the resource costs of HCPCS code G0379 to those procedures assigned to APC 0608.

After consideration of the public comments we received, we are finalizing our CY 2013 proposal with modification to reassign HCPCS code G0379 from APC 0604 to APC 0608, which has a final CY 2013 geometric mean cost of approximately $181.

Comment: One commenter indicated that APC 0623 violates the 2 times rule and requested that CMS review the costs associated with CPT code 36260 (Insertion of implantable intra-arterial infusion pump (eg, for chemotherapy of liver)) and reassign the CPT code to a more appropriate APC.

Response: Table 17 of the CY 2013 OPPS/ASC proposed rule listed 21 APCs that violated the 2 times rule for CY 2013. APC 0623 does not appear in Table 17 and assignment of CPT code 36260 to APC 0623 does not violate the 2 times rule. As stated above, in determining whether a 2 times rule violation exist in an APC, we consider only those HCPCS codes that are significant based on the number of claims. 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 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 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 cost. For this CY 2013 OPPS/ASC final rule with comment period, there are only 3 single claims for CPT code 36260 (each of the 3 total claims). Because CPT code 36260 does not represent a significant HCPCS code based on the number of claims, it does not violate the 2 times rule.

After consideration of the public comments we received and our review of the CY 2011 costs from hospital claims and cost report data available for this final rule with comment period, we are finalizing our proposals with some modifications. Specifically, we are finalizing our exemption of 17 of the original APCs (that appeared in Table 17 of the CY 2013 OPPS/ASC proposed rule with comment period and also appears in Table 17 below) from the 2 times rule for CY 2013. We are removing four APCs that no longer violated the 2 times rule and decreasing the number of APC exceptions from 21 to 19 APCs, as described previously in this section. Our final list of 19 APCs exempted from the 2 times rule for CY 2013 is displayed in Table 17 below.

TABLE 17.—FINAL APC EXCEPTIONS TO THE 2 TIMES RULE FOR CY 2013

Final CY 2013 APC	Final CY 2013 APC Title
0006	Level I Incision & Drainage
0012	Level I Debridement & Destruction
0045	Bone/Joint Manipulation Under Anesthesia
0057	Bunion Procedures
0060	Manipulation Therapy
0105	Repair/Revision/Removal of Pacemakers, AICDs, or Vascular Devices
0148	Level I Anal/Rectal Procedures
0152	Level I Percutaneous Abdominal and Biliary Procedures
0230	Level I Eye Tests & Treatments
0254	Level V ENT Procedures
0272	Fluoroscopy
0325	Group Psychotherapy
0330	Dental Procedures
0340	Minor Ancillary Procedures
0369	Level III Pulmonary Tests
0403	Level I Nervous System Imaging
0409	Red Blood Cell Tests
0688	Revision/Removal of Neurostimulator Pulse Generator Receiver
0690	Level I Electronic Analysis of Devices

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 Procedure, Not Discounted When Multiple) and the other set with a status indicator of ''T'' (Significant Procedure, Multiple Reduction Applies). 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 projected utilization for Medicare beneficiaries 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 2013 OPPS/ASC proposed rule (77 FR 45120), for CY 2013, we proposed 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 18 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 2013.

In the CY 2013 OPPS/ASC proposed rule, we noted that currently, in CY 2012, there are three procedures described by HCPCS G-codes receiving payment through a New Technology APC(77 FR 45121). 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 1505 (New Technology—Level V ($300–$400)); HCPCS code G0418 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 41–60 specimens) is assigned to New Technology APC 1506 (New Technology—Level VI ($400–$500)); 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 1508 (New Technology—Level VIII ($600–$700)). These HCPCS codes have been assigned to New Technology APCs since CY 2009.

Analysis of the hospital outpatient data for claims submitted in CYs 2009, 2010, and 2011 indicate that prostate needle saturation biopsy procedures are rarely performed on Medicare beneficiaries. For OPPS claims submitted from CY 2009 through CY 2011, our final rule claims data show very minimal claims for HCPCS code G0417, G0418, and G0419, as shown in Table 18.

TABLE 18.—CY 2009 THROUGH CY 2011 OPPS CLAIMS FOR HCPCS CODES G0417, G0418, AND G0419 (PROSTATE NEEDLE SATURATION BIOPSY)

HCPCS Code	Long Descriptor	CY 2009 Claims	CY 2010 Claims	CY 2011 Claims
G0417	Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 21-40 specimens	6	1	0
G0418	Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 41-60 specimens	0	0	0
G0419	Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, greater than 60 specimens	0	0	1

Given the continued lack of cost data for these HCPCS codes, we proposed to reassign these procedures to an APC that is appropriate from a clinical standpoint (77 FR 45121). Specifically, we proposed to reassign HCPCS G-codes G0417, G0418, and G0419 to clinical APC 0661 (Level V Pathology), with a proposed APC payment rate of approximately $160 for CY 2013. We stated that we believe that all three procedures, as described by HCPCS codes G0417, G0418, and G0419, are comparable clinically to other pathology services currently assigned to APC 0661 and likely require similar resources. Table 18 of the proposed rule listed the HCPCS G-codes and associated status indicators that we proposed to reassign from New Technology APCs 1505, 1506, and 1508 to APC 0661 for CY 2013.

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 these codes to APC 0661. We note that APC 0661 is the same APC to which the other HCPCS G-code for prostate needle saturation biopsy procedure, G0416 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 1–20 specimens), is assigned. In addition, for the CY 2013 update, we are revising the long descriptor for HCPCS code G0416 to read ''Surgical pathology gross and microscopic examination for prostate needle saturation biopsy sampling 10–20 specimens'' effective January 1, 2013. The final CY 2013 geometric mean cost for APC 0661 is approximately $162.

Table 19 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 2013. The final CY 2013 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 19.—REASSIGNMENT OF PROCEDURES FROM NEW TECHNOLOGY APCs FOR CY 2013

CY 2013 HCPCS Code	CY 2013 Short Descriptor	CY 2012 SI	CY 2012 APC	Final CY 2013 SI	Final CY 2013 APC
G0417	Sat biopsy prostate 21-40	S	1505	X	0661
G0418	Sat biopsy prostate 41-60	S	1506		
G0419	Sat biopsy prostate: >60	S	1508		

3. Payment Adjustment Policy for Radioisotopes Derived From Non-Highly Enriched Uranium Sources

a. Background

Radioisotopes are widely used in modern medical imaging, particularly for cardiac imaging and predominantly for the elderly (Medicare) population. Technetium-99 (Tc-99m), the radioisotope used in the majority of such diagnostic imaging services, is currently produced in legacy reactors outside of the United States using highly enriched uranium (HEU).

The Administration has established an agenda to eliminate domestic reliance on these reactors, and is promoting the conversion of all medical radioisotope production to non-HEU sources. Alternative methods for producing Tc-99m without HEU are technologically and economically viable, and conversion to such production has begun and is expected to be completed within a 5-year time period. We expect this change in the supply source for the radioisotope used for modern medical imaging will introduce new costs into the payment system that are not accounted for in the historical claims data.

Full Cost Recovery, which is routinely considered in CMS payment under Medicare, is the accounting practice used by producers and suppliers to describe the recovery of all contributing costs. Unlike legacy sources that often benefit from government subsidized multifunction facilities, the cost of these alternative methods will be increased over the cost of medical radioisotopes produced using HEU because hospitals' payments to producers and suppliers will have to cover capital expense (such as, for example, the cost of building new reactors, particle accelerators, or other very long-term investments), as well as all other new industry-specific ancillary costs (such as, for example, the cost of long-term storage of radioactive waste). Hospitals that use medical radioisotopes that are produced from non-HEU sources can expect producers and suppliers to pass on to them the full impact of these costs.

In the short term, some hospitals will be able to depend on low cost legacy producers using aging subsidized reactors while other hospitals will be forced to absorb the full cost of non-HEU alternative sources. Over several years, we believe that these cost differentials will promote increased regional shortages and create larger cost differentials and greater cost variations among hospitals. As a result, we believe this change in supply source will create a significant payment inequity among hospitals resulting from factors that are outside of normal market forces.

b. Payment Policy

In the CY 2013 OPPS/ASC proposed rule (77 FR 45121 through 45123), we proposed to exercise our authority to establish ''other adjustments as determined to be necessary to ensure equitable payments'' under the OPPS in accordance with section 1833(t)(2)(E) of the Act. We stated that we do not believe that we can ensure equitable payments to hospitals over the next 4 to 5 years in the absence of an adjustment to account for the significant payment inequities created by factors that will likely arise due to the change in supply source for the radioisotope used commonly in modern medical imaging procedures. We proposed to provide an adjustment for the marginal cost for radioisotopes produced from non-HEU sources over the costs for radioisotopes produced by HEU sources. We stated that we believe such an adjustment would ensure equitable payments in light of the Administration's HEU agenda, market influences, cost differentials, and cost variations that will create significant payment inequities among hospitals.

For CY 2013, we proposed to make an additional payment of $10, which is an amount based on the best available estimations of the incremental costs associated with non-HEU Tc-99m production as calculated using the Full Cost Recovery accounting methodology. We proposed to establish a new HCPCS code, QXXXX (Tc-99m from non-HEU source, full cost recovery add-on, per dose), to describe the Tc-99m radioisotope produced by non-HEU methods and used in a diagnostic procedure. Under the proposal, hospitals would be able to report this HCPCS Q-code once per dose along with any diagnostic scan or scans furnished using Tc-99m as long as the Tc-99m doses used can be certified by the hospital as coming from non-HEU sources and have been priced using a Full Cost Recovery accounting methodology. The HCPCS Q-code would be used to pay hospitals for the additional (incremental) cost of using Tc-99m from a non-HEU source.

Under the proposal, hospitals would not be required to make a separate certification of the non-HEU source on the claim; the inclusion of the new HCPCS code QXXXX on the claim would indicate that the hospital has met the conditions of the service definition as it does for any billed service. However, in the event of an audit, we stated that hospitals would be expected to be able to produce documentation that the individual dose delivered to the patient was completely produced from a non-HEU source. We proposed three ways in which hospitals could accomplish this.

First, the hospital could produce documentation such as invoices or patient dose labels or tracking sheets that indicated that the patient's dose was completely produced from non-HEU sources and priced based on Full Cost Recovery. In this first case, the supplier would be expected to be able to trace a specific dose of Tc-99m to a completely non-HEU batch. Current pharmacy recordkeeping is generally able to trace all components of radiopharmaceuticals back to their source production batches. A hospital would not be compliant with the HCPCS Q-code definition if the documentation indicated the supplier produced a mixed batch and labeled a fraction of the doses equal to the non-HEU fraction in the batch.

Second, a hospital could produce documentation that the entire batch of Tc-99m doses derives from non-HEU sources for a specified period of time, for example, the time that a single non-HEU based generator is in use. This approach would obviate the need for specific dose tracking from a claims audit perspective, although that information is typically required for other purposes. An attestation from the generator supplier would be sufficient evidence for the hospital, as would invoices that show that all doses of Tc-99m during a specified period came from inherently non-HEU alternative sources.

Third, if the industry was to implement labeling of generators and/or doses with labels attesting to 100 percent non-HEU sources priced based on Full Cost Recovery, documentation of labeled isotope usage using either the specific dose approach or the 100 percent hospital usage approach could provide evidence of hospital compliance. The hospital would be required to retain appropriate documentation within the hospital (including pharmacy) records but would not need to keep any specific documentation within the individual medical record. Also, we would consider a dose to be priced based on Full Cost Recovery when the supplier could attest that the supply chain adheres to usual industry practices to account for Full Cost Recovery, specifically including the capital cost of sustainable production and the environmental cost of waste management.

To reduce the administrative overhead for hospitals, we proposed not

to require hospitals to separately track additional costs for Tc-99m doses from non-HEU sources, but to include the cost of the radioisotope in the cost of the diagnostic radiopharmaceutical as usual, reporting only a token $1 charge for the HCPCS code QXXXX line. Under the proposal, we would continue to calculate the total costs of radionuclide scans using claims data, and would periodically recalculate the estimated incremental cost of Tc-99m from non-HEU sources based on Full Cost Recovery, using models relying on the best available industry reports and projections, and would adjust the payment for HCPCS code QXXXX accordingly, reducing the payment for the scans by the amount of cost paid through HCPCS code QXXXX payment. We stated that we believe this proposal allows us to continuously compensate for unanticipated changes in Tc-99m cost attributable to new non-HEU supply sources while avoiding a double payment for the increased cost.

Comment: The vast majority of commenters conceptually agreed with CMS' proposed payment policy. However, the commenters differed in opinion on how CMS should implement a proposal to encourage hospitals to switch from Tc-99m derived from HEU sources to Tc-99m derived from non-HEU sources.

Many commenters disagreed specifically with CMS' proposal to make an additional payment of $10 per dose for Tc-99m radioisotopes produced by non-HEU methods, used in a diagnostic procedure. These commenters agreed that an additional payment is necessary in order to ensure that hospitals are fully paid for the additional costs incurred for the use of non-HEU Tc-99m radioisotopes, but the commenters argued that the additional $10 payment is insufficient and inadequate to incentivize hospitals to change their current practices and transition purchases of Tc-99m to non-HEU sources. The commenters suggested that CMS instead adjust or increase the payment amount to more adequately cover any additional costs to providers.

One commenter asked that CMS conduct a study of the actual costs at a time when non-HEU Tc-99m is actually available to hospitals, and propose an adjustment that will better reflect both the marginal additional costs of the non-HEU sources and the administrative and compliance burden on hospitals.

Another commenter recommended that CMS establish HCPCS code QXXXX (Tc-99m from non-HEU sources, full cost recovery add-on, per dose) and make an interim payment of $10 per unit for CY 2013 and CY 2014. The commenter further suggested that, beginning in CY 2015, CMS calculate the cost of the service described by the recommended code based on the standard CMS payment methodology because the calculations will be based on charges for services furnished in CY 2013, and for CY 2015 and years following, CMS will have estimated costs on which to base the additional payment for the HCPCS Q-code. In addition, the commenter recommended that CMS carefully track the phase-out of the HEU sources and eliminate HCPCS code QXXXX once HEU is phased out of the market in the United States.

Overall, most of the commenters encouraged CMS to continue to work with pertinent stakeholders and providers in the industry on this issue.

Response: We agree with the commenters that $10 is not a large incentive payment to promote a conversion to non-HEU sources of Tc-99m. However, we are concerned that many commenters have mischaracterized this payment. We did not create an additional payment to promote the Administration's initiative to eliminate domestic reliance on legacy production processes producing Tc-99m from HEU, as that is outside the scope of the OPPS. Rather, the industry has conveyed to us that this conversion to non-HEU sources will occur in response to U.S. strategic policy, but that cost considerations have created barriers to that movement. One of the cost considerations is the fact that non-HEU sourced Mo-99, the Tc-99m precursor, is expected to cost more than current sources from legacy reactors, and this increased cost will adversely impact hospitals. In evaluating that concern, we determined that there is, in fact, a probability not only that costs will increase but that those costs will not be passed on uniformly as the industry converts. Therefore, we used our authority to ensure payment equity among hospitals by proposing to create this additional payment to address the incremental cost of obtaining Tc-99m from the new sources of supply. Although commenters have opined that a larger payment would be a better incentive to support non-HEU conversion, the purpose for the additional payment is limited to mitigating any adverse impact of existing payment policy and is based on the authority set forth at section 1833(t)(2)(E) of the Act.

Most of the comments raising concerns about the inadequacy of the additional payment suggested that we did not account for the administrative costs involved in implementing this additional payment at the hospital level, at the radiopharmacy level, and at the level of the generator manufacturer. However, we note that previous discussions with the industry indicated that the actual costs of conversion, distinct from the administrative costs of billing, are confined to the producer (reactor) and the processor and are passed down through the supply chain from there. In our own analysis, we concurred with that finding and calculated a payment that would readily cover the additional cost of this change in supply as it is passed down the supply chain. We do not believe that it promotes efficiency to add administrative markup to this increased cost of a supply, especially given that we believe that the administrative cost of adding a new service into the billing system should be small at the hospital and the pharmacy levels. Moreover, due to the small absolute difference in cost between non-HEU and HEU sourced Tc-99m, we do not believe that significant inequities would exist in hospital costs until a significant amount of more expensive non-HEU Mo-99 enters the system, at which point any administrative cost would be spread over a large number of claims.

Finally, we agree with commenters who stated that this additional payment should be updated as better data become available. We stated in the proposed rule that we intend to look at the amount of the add-on payment and potentially update it as better economic information becomes available. Although we did not limit ourselves to the methodology beyond a commitment to use the best available data, we also did not propose using our usual OPPS methodologies to update the payment. We had specifically advised hospitals that separate reporting of the cost of Tc-99m from non-HEU sources was not required for several reasons. First, a particular generator manufacturer could elect to provide HEU and non-HEU generators at the same averaged cost, a method that would enable the client hospitals to defray any overall cost increase as non-HEU generators became randomly available. Because there could still be an incremental cost differential incurred by doing business with that manufacturer as compared with a purely non-HEU manufacturer, our normal OPPS methods would show no incremental cost and thus could not be used to mitigate a payment inequity. Second, we noted that separate reporting of the costs of the two sources or the calculation and reporting of a cost differential would significantly increase the administrative burden on hospitals,

a burden of which we have been particularly mindful.

Comment: Several commenters asked that CMS provide separate payment for all diagnostic radiopharmaceuticals, regardless of their per day cost, as this policy would support conversion to non-HEU sources. A few commenters recommended that CMS unpackage all radiopharmaceuticals that meet the annual packaging threshold. They also suggested that CMS unpackage all radiopharmaceuticals that use Tc-99m, regardless of their per day cost. One commenter suggested that the proposed add-on payment of $10 be made in addition to separate payment for the diagnostic radiopharmaceutical.

The commenters emphasized their concern over increased costs of conversion to 100 percent non-HEU for radioisotopes. One commenter argued that separate payment would provide a direct, measurable incentive to the entire radiopharmaceutical market supply chain to support the efforts to convert from HEU to non-HEU sources. Additionally, the commenter stated that separate payment would allow CMS to obtain accurate hospital cost data on the cost of both HEU and non-HEU radiopharmaceuticals.

Response: We have already discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765 through 66768) the reasons why the agency has determined that it is appropriate to package payment for a diagnostic radiopharmaceutical into the payment for the nuclear medicine scan, and we have finalized this policy again in section II.A.3.f. of this final rule with comment period. However, specifically from the standpoint of this add-on payment to ensure equitable payments to hospitals, a separate payment for the diagnostic radiopharmaceutical would not unpackage the cost of the radioisotope from the much larger cost of the drug component, nor would it differentiate between HEU and non-HEU sources. Therefore, unpackaging the cost of the diagnostic radiopharmaceutical would not create a differential payment to ensure payment equity amongst hospitals.

Comment: Several commenters were concerned with CMS' proposal that Tc-99m doses be derived 100 percent from non-HEU sources in order to receive the additional $10 payment. A few commenters stated that it would be impossible to accurately predict the percentage of Tc-99m doses that will be comprised 100 percent from non-HEU sources. Other commenters expressed concern over the significant costs that will be incurred for segregating 100 percent non-HEU sources, especially in the radiopharmacy.

Response: We agree with the commenters that it will be impossible to accurately predict the percentage of Tc-99m doses that will be comprised of 100 percent of non-HEU sourced material, but that is because it will be impossible to predict the percentage of non-HEU Tc-99m available to manufacturers at any point in time. This presumption is one of the reasons that led us to the conclusion that payment for doses where 100 percent comes from non-HEU sources was the only reasonable option. We do not need to predict the amount of non-HEU Mo-99 available to the industry to establish a blend; instead, the HCPCS Q-code can be used whenever and wherever enough non-HEU Tc-99m is available to be kept separate down to the level of the generator or patient dose. Multiple codes to reflect different blends are not needed, and we do not need to create smaller payments for blends that reflect smaller amounts of non-HEU material. Because payment must be driven by cost, a 20-percent blend would be limited to 20 percent of the $10 cost or $2, and hospitals are already concerned that the $10 additional payment is a small payment when they consider it against the effort involved in making tracking and billing changes.

However, we do not believe that any costs created by changes in radiopharmacy procedures will be significant in the charges passed on to hospitals. We do understand that there may be some instances in which a radiopharmacy will have both a non-HEU and an HEU generator, and the pharmacy will need to determine whether it wants to keep those sources separate or blend them and eschew labeling of a non-HEU source. We also understand that this may be a larger issue at the generator manufacturer level, especially very early in the conversion when non-HEU Mo-99 is scarce. On the other hand, when non-HEU Mo-99 is scarce, the incremental cost of higher priced non-HEU Mo-99 is small and the blending of small amounts of non-HEU Mo-99 will not create payment inequities among hospitals. We expect that as conversion progresses and more non-HEU Mo-99 enters the supply chain, manufacturing processes may evolve. Ultimately, there is no requirement to use this HCPCS Q-code or label non-HEU based Mo-99; the payment exists as a tool if it is necessary to reduce payment inequities that might occur as a consequence of industry conversion to non-HEU based Mo-99.

One of the concerns about reporting doses derived from 100 percent non-HEU sources had to do with compliance concerns if, in the process of switching between an HEU and a non-HEU run, the manufacturer or pharmacy did not add in an extra step of flushing lines to ensure that cross-contamination did not occur. Our understanding is that using different sources for consecutive manufacturing runs would not create source contamination of more than 1 or 2 percent based on usual manufacturing processes. We note that it is not our intent to introduce unnecessary inefficiencies solely to support payment, and in this case we can confirm that production steps, such as cleaning lines, should be driven by FDA manufacturing requirements, not by payment artificialities. We believe that manufacturing steps that do not risk reducing the non-HEU sourced Mo-99 or Tc-99m to less than 95 percent of the generator, elution or dose (that is, do not risk reducing the content of the dose supplied to the patient to less than 95 percent non-HEU sourced Tc-99m) are consistent with a product that is completely derived from a non-HEU source. Therefore, we are modifying our proposal to state that any dose of Tc-99m that can be traced to a Mo-99 supply containing no more than 5 percent HEU sourced Mo-99 shall be considered to be completely derived from non-HEU sources for the purposes of this final rule with comment period, this additional payment, and any compliance practices that support it. It is our understanding that the normal manufacturing records will still support processes that created the non-HEU supply.

Comment: One commenter expressed concern regarding the administrative and financial burden that hospitals may incur upon adoption of this proposed policy. The commenter stated that these burdens may exceed the marginal additional cost of moving to non-HEU sources. The commenter believed that the proposed policy would result in additional administration and documentation burdens which include the following additional expenses: expenses for developing and maintaining policies to track, certify, and document HEU versus non-HEU sources in order to use the newly required HCPCS Q-code; new compliance program checks and monitoring to ensure the appropriate codes are used and documentation is maintained should an audit be conducted; additional personnel time and resources to create and maintain line items on the hospital charge master for non-HEU versus HEU codes and charges; and additional resources to

develop nuclear medicine department information technology infrastructure, as well as billing policies for documentation and use of the new HCPCS Q-code.

Another commenter also believed that this proposal would create a significant burden on hospitals by requiring them to obtain, document, and track information from the supplier and thereby create an unnecessary level of complexity for hospitals that could result in code errors and omissions on claims. The commenter urged CMS not to finalize this proposal.

Response: We do not believe that this additional payment will result in a significant administrative burden to hospitals. We note that most hospitals have computerized inventory and billing systems that are able to track low-cost items such as needles and aspirins. We have reiterated in our response to public comments in this final rule with comment period that we expect hospitals requesting this additional payment to be able to track a dose that has been labeled or claimed as ''non-HEU sourced'' and do not expect hospitals to audit the validity of such claims made by their suppliers. We also note that the cost of adding a new code to the hospital chargemaster is not large, and that a hospital is not being subject to a significant payment inequity if the cost of adding a new code to the chargemaster actually exceeds the added cost of non-HEU sourced Tc99m to the hospital. Hospitals that are not experiencing high volumes of significantly increased costs are not obligated to use this additional payment as its use is entirely optional.

Comment: One commenter asked that CMS confirm in this final rule with comment period that hospitals will not be required to audit or otherwise independently verify manufacturer or radiopharmacy documentation that a dose/injection meets the standard of non-HEU priced at Full Cost Recovery.

A few commenters expressed concern regarding the compliance and liability burden that adopting this policy may place on hospitals. These commenters stated that hospitals may be uncomfortable attesting that the supplies they receive are from non-HEU sources when there is no reliable guarantee that the products are from non-HEU sources. Further, the commenters stated that they believe that the term ''attesting'' in the ASP model is significantly different from what they believe is the original intent of this proposal. Therefore, the commenters suggested that CMS clarify the adequate documentation necessary to confirm that the provider obtained a dose that is 100 percent from non-HEU sources.

Response: We are aware that providers must exert considerable effort to conscientiously perform their compliance responsibilities over such a vast health care system, and we specifically attempted to offer examples of acceptable compliance steps to alleviate that burden in this instance. We acknowledge that the end product used by hospitals is effectively homogenous, and there is no practical way for a hospital to prove chemically that a supply purported to be derived from a non-HEU source truly meets those requirements. On the other hand, the radiopharmaceutical industry is a heavily regulated industry closely monitored by the Food and Drug Administration, and it is our understanding that if a supplier indicates that a source is non-HEU, manufacturing records will be able to confirm that. We are confident that claims by suppliers as to the source of the Tc-99m used can be satisfactorily audited through usual manufacturing processes without creating additional requirements for hospitals. We do not expect hospitals to assay doses of drugs to ensure that they received what the invoice claimed, and we do not expect any chemical or physical verification here. It was our intent in the proposed rule to indicate that providers are expected to exercise due diligence, and to ensure that their claims are supported by internal records of some type, but that facilities could accept any tracking mechanism by a supplier (invoice, label, contract, among others) regarding a non-HEU source as satisfactory proof for the purposes of the facility.

We also note that any use of the word ''attestation'' in the proposed rule was meant only to indicate a formal statement by one party to assure another party of the source and composition. We further note that these were examples in the proposed rule rather than requirements.

Comment: Several commenters asked that CMS publish the methodology and data used to establish the additional payment amount of $10 for Tc-99m derived from non-HEU sources.

Response: There are two data sources on which we relied. First, the Organization for Economic Cooperation and Development—Nuclear Energy Agency (OECD–NEA) has published several economic analyses of the world market for Tc-99m, which are pertinent for the United States because, at present, our entire supply comes from foreign sources. Although some members of the industry have opined that these data are not accurate because the data include little information from U.S. suppliers, the fact remains that there is currently no supply available domestically. Thus, while the data we used may not reflect all of the unique market forces present in the domestic market, this data source provides the best estimation of the costs of non-HEU sources compared to HEU sources because the manufacturing steps are primarily performed overseas and therefore reflect the global market. Nonetheless, as an additional data source, we invited industry entities to submit additional information regarding their manufacturing and supply costs, production levels, and prices. However, given that the industry is small with limited numbers of competitors at each level of the supply chain, most American companies were reluctant to provide information and were insistent on confidentiality (as protected by FOIA Exemption 4) to safeguard the sensitive (business competitive) information that they did share. Therefore, we accepted supplemental information from the industry and pledged to maintain its confidentiality, and consequently are unable to provide details of the additional information. We can disclose our methodology and refer readers to the OECD–NEA models that form the basis of our model, noting that the supplemental information submitted to date has not significantly altered the conclusions drawn by the OECD–NEA.

To estimate costs, we tracked costs through the entire supply chain, using a building block approach to add the cost of each step onto the steps that occurred before it. Because the OECD–NEA provided ranges rather than point estimations, we used an averaging approach to factor in the possible low cost, the possible high cost, and the most likely ''expected'' cost. This is a common estimation technique used in business when significant uncertainty exists. By avoiding optimistic assumptions, we were able to model a payment that reflects not only the likely costs but ones that would also be adequate to cover unexpected costs in one or more of the manufacturing steps.

In response to the request to provide as much detail about our methodology as possible, we are detailing that methodology here. We used a supply chain model to accumulate costs through the Tc-99m supply chain based on—

(Unit Cost of Supply/Production Efficiency) + Unit Production Cost + ((Fixed Production Costs + Overhead)/ Units Produced) = Unit Production Cost = Downstream Unit Cost of Supply.

In tracking units (efficiency), we allowed for product loss during production and for product loss as a

function of time (decay). We applied this model across a supply chain that consisted of—

Irradiator/Producer > Processor > Generator Manufacturer > Nuclear Pharmacy > Hospital > Patient.

Using a Program Evaluation and Review Technique (PERT) 3-point estimation applied to costs, we based the upper and lower bounds on the OECD–NEA economic models for Full Cost Recovery (2011) and non-HEU Conversion (2012), given that U.S. supply is based on the global market. We then varied the expected value to model a range of outcomes. Finally we calculated the incremental cost of process changes by subtracting current costs. Almost all of the incremental costs of switching to non-HEU sources occur in the irradiation and the processing steps, with very little impact on generator assembly, generator elution, or the preparation of the patient dose. We noted that any artificial costs of tracking during conversion would not be reflected in the final post-conversion costs of supply. Due to the wide variation in cost projections, we rounded up to the nearest $5 as most of the estimators could not be regarded as sufficiently precise to justify a more precise value until actual cost data become available. This methodology resulted in a projection that fully accounts for the cost of conversion in almost all probable scenarios and that also accounts for or significantly offsets the costs of Full Cost Recovery under most combinations of assumptions. Therefore, the $10 value can be expected to offset any payment inequities under most likely combinations of cost changes within the Tc-99m supply chain.

Comment: One commenter stated that suppliers of Mo-99 are currently working toward full conversion to non-HEU sources by 2015. However, the commenter stated that it is estimated that only 10 percent of the Tc-99m doses used in the United States could be produced from 100 percent non-HEU sources in 2013. The commenter further believed that the proposed policy will cause a substantial increase in material costs, require duplicative effort in the preparation of radiopharmaceutical doses, add additional administrative costs, increase the costs for non-HEU products, and create a disincentive for hospitals that cannot purchase non-HEU products as they would be unwilling to pay higher prices for their nuclear pharmaceutical products when they are not receiving any additional benefits.

The commenter instead suggested that these impacts can be reduced by establishing a threshold amount of Mo-99 that must be used by a generator manufacturer for CY 2013, based on information provided by the OECD–NEA and other pertinent stakeholders. The commenter stated that this amount could then be adjusted upward in later years. The commenter further explained that, in order for a technetium generator to be considered ''compliant'' with the requirements for the additional payment, the manufacturer of that generator would need to certify to providers that it used at least the established threshold amount of non-HEU sourced Mo-99 in the production of its generators for CY 2013 and for subsequent quarters. In turn, the hospitals that purchased the Tc-99m doses prepared by complaint manufactures would receive separate payment during that specific period. The commenter stated that this approach would require a downward adjustment to the proposed $10 additional payment to reflect the lower amount of non-HEU Mo-99.

Response: We acknowledge the desirability of a simplified payment for non-HEU sourced material in the generators, and agree that the proposed blended payment would be much easier to implement. However, we note that we do not have the authority to create that type of payment. Within the OPPS, we depend on reported costs, as calculated from claims and cost report information, to set prospective payments. Our authority to deviate from this system in this instance is based on the authority of the Secretary to adjust payments if necessary to ensure payment equity among hospitals. A payment adjustment based on industry-wide thresholds would not create a payment differential among those hospitals with predominantly higher cost non-HEU sources and those hospitals with predominantly lower cost HEU sources. However, although we lack the authority to create a special payment to cover rising costs at the industry or manufacturer level, we note that the normal OPPS payment mechanism does exactly that: as costs rise, those costs will be passed on globally to hospitals and reflected in their charges adjusted to costs and, therefore, ultimately reflected in the prospective payments calculated by our usual methodology. This add-on payment merely ensures equitable payments to hospitals through the transition where non-HEU sources are not uniformly distributed, while our established OPPS mechanisms will ensure that the total costs of new sources are incorporated into final payments year by year. We also have previously stated that we believe that costly changes in manufacturing solely to facilitate a transitional payment are not likely to occur, and that instead the payment can be expected to trigger small administrative changes. We expect that expensive changes in industry processes will not be driven by an interim payment but will occur only when those changes will continue to be necessary or desirable after the transition is complete.

Comment: A few commenters suggested that CMS, at a minimum, allow a payment adjustment for lower percentages (less than 100 percent) of non-HEU sources and institute a multiyear phase-in period. One commenter suggested that CMS establish a ''threshold quotient'' of non-HEU content in Tc-99m radiopharmaceuticals during CY 2013 and allow partial payment of the $10 additional payment amount. The commenter explained that this would require CMS to accept a given percentage amount of non-HEU source content and pay a corresponding percentage of the proposed $10 additional payment amount. The commenter gave the example of a payment of $1.50 for Tc-99m sources that contain 15 percent non-HEU, as $1.50 is 15 percent of the $10 proposed additional payment amount. The commenter also suggested that CMS could further promote the conversion to 100 percent non-HEU sources by adopting industry-wide targets for conversion, which would include conversion to 25 percent in CY 2013, 50 percent in CY 2014, 75 percent in CY 2015, and 100 percent in CY 2016.

Another commenter suggested that a 10-percent industry threshold program be considered for CY 2013 in lieu of the 100 percent non-HEU sources proposed requirement. The commenter stated that a payment of no less than $10 could be given for non-HEU documented doses and that this would be more reflective of the short-term non-HEU Mo-99 supply.

Response: As noted above, our authority to establish this additional payment is based on the necessity to ensure equitable payments to hospitals, an authority that does not allow us to develop payments to promote the conversion of the industry to non-HEU sources. Therefore, our ability to create industry-wide payments is limited. We considered using one or more thresholds ranging from 10 percent to 80 percent to pay for blended sources that were not derived entirely from non-HEU sourced Mo-99, but determined that to be impractical for several reasons. First, the use of multiple codes to describe different mixtures of HEU and non-HEU

sourced Mo-99 is immeasurably more complex than a simple single all or nothing coding choice, and many commenters were concerned about the complexity of even our proposed coding schema. Second, any blend of HEU and non-HEU sourced material will, as mentioned by the commenters, have reduced additional costs in proportion to the percentage of the blend. Because many commenters were concerned that $10 was small compared to the administrative effort they believed might be involved, we did not believe that a significantly smaller payment would be acceptable to that level of the supply chain.

Comment: Several commenters suggested that CMS extend the $10 additional payment for non-HEU sources for at least 5 years. The commenters stated that this period of time will be required to convert fully to non-HEU sources. Another commenter requested clarification of the proposed implementation date and methodology for calculating the total costs of radionuclide scans using claims data and the periodic recalculation of the estimated marginal cost of non-HEU Full Cost Recovery sources using models relying on the best available industry reports and projections, resulting in an adjustment in the payment of the proposed HCPCS code QXXXX accordingly, reducing the payment for the scans by the amount of cost paid through the HCPCS code QXXXX payment.

Response: Although we typically propose only the payments for the subsequent calendar year except in the case of adjustments that need to be phased in over multiple years, we did state our current expectations of the state of the industry and our expectations of a probable need for this additional payment over multiple years. We stated that our current expectation is that the transition to non-HEU sourced Mo-99 will be completed within 4 to 5 years. Therefore, we expect there may be a need to make differential payments for a period of 4 to 5 years. We will reassess, and propose, on an annual basis, whether such an adjustment under section 1833(t)(2)(E) of the Act continues to be necessary and whether any changes to the adjustment are needed. Again, our current expectation is that this additional payment will be needed for the duration of the industry's conversion to alternative methods to producing Tc-99m without HEU, which is expected to be completed within 4 to 5 years.

With respect to the request for clarification regarding future adjustments of this proposed payment, we note that the payment is being applied in addition to the standard procedure payment amount for nuclear medicine scans, including the diagnostic radioisotope and pharmaceutical, that is paid based on reported costs. As more non-HEU sourced Mo-99 is used, the costs reported by hospitals will contain costs associated with non-HEU conversion. Because the HCPCS code QXXXX is the indicator of non-HEU Mo-99 use and is also the vehicle for the additional payment, the rate at which extra payments are made will exactly follow the rate at which non-HEU sources are reported with their attendant additional costs. Therefore, even as we increase the payment for the nuclear medicine scan with radioisotope in the future due to increasing radioisotope costs, we expect to offset (reduce) the payment by the amount of the non-HEU add-on payment to avoid paying twice for non-HEU costs. This approach has the effect of using the add-on payment to make an additional payment for the cost of non-HEU sourced Mo-99 in the year that the cost appears, rather than waiting 18 months until the cost is reflected in the claims data. Consistent with our OPPS methods, though, we will still be basing the final payments for the nuclear medicine scans on the aggregate costs of the scan and its radioisotopes and pharmaceuticals as reported by hospitals. For example, suppose that 20 percent of hospitals in CY 2013 report non-HEU Tc-99m usage billed with HCPCS code QXXXX. The OPPS payment for the scan with its diagnostic radioisotope will still reflect 100 percent of the reported CY 2011 costs. The $10 from HCPCS code QXXXX will represent additional money because the higher cost non-HEU Tc-99m was not reflected in the CY 2011 cost data. However, when we set the rates for CY 2015, those 20 percent of the hospitals who used non-HEU Tc-99m in CY 2013 will have reported higher costs for scans in the CY 2013 claims data because they had an additional cost from the non-HEU Tc-99m that they used. To eliminate a double payment, we will need to make an adjustment, such as removing the total dollars paid by HCPCS code QXXXX in CY 2013 (that is, the estimated additional cost of the non-HEU sourced isotope in those 20 percent of the claims) from the total reported procedure dollars in CY 2013 before setting the base procedure rate for CY 2015. We note that this offset does not reduce the payment for the scan below its current level; it only keeps the payment from going up as the cost of the radioisotope rises, because the increased cost of the radioisotope is being paid separately using HCPCS code QXXXX. In fact, in CY 2015, the utilization of non-HEU sourced Tc-99m should have continued to climb well beyond 20 percent. As in CY 2013, the dollars associated with increased utilization, that is, HCPCS code QXXXX billing in excess of the 20 percent, will again represent additional money over the total costs reflected in the CY 2013 claims.

Comment: A few commenters suggested that CMS alter the description of the proposed HCPCS code QXXXX by adding the word ''study'' into the descriptor in order to make this definition more consistent with the arcana of the radiopharmaceutical industry. The commenters stated that the descriptor for the HCPCS Q-code therefore would be HCPCS code QXXXX (Tc-99m from non-HEU source, full cost recovery add-on, per study dose). The commenters stated that it would be logical to add the word ''study'' because several nuclear cardiology procedures could require multiple Tc-99m doses administered alone with one CPT procedure code. Thus, they believed that providers would purchase one to three study doses. The commenters further suggested that CMS clarify in this final rule with comment period that the add-on payment would apply to each per study dose of the complete service as described by the CPT procedure code. Therefore, the commenters stated, providers would be able to bill the HCPCS Q-code with multiple units and be paid $10 per the number of study doses provided during the procedure described by the CPT code, as appropriate.

Response: We acknowledge that it was our intent that this additional payment would be applied per study dose, such as the dose for the study performed at rest and the dose for the study performed with exercise. Therefore, we accept these recommendations and are modifying the proposed HCPCS definition to include the word ''study'' as follows: HCPCS code Q9969 (Tc-99m from non-highly enriched uranium source, full cost recovery add-on, per study dose).

Comment: Several commenters requested that CMS clarify the proposal which requires a reduction to the payment for the scans by the amount of cost paid through the proposed HCPCS code QXXXX. The commenters were not sure whether the payment offset would be applied uniformly to all hospitals or only to those hospitals reporting non-HEU source doses. The commenters further requested that no reduction in

payment for nuclear scans by made as a result of the additional $10 payment amount.

Response: Although commenters were not making this comment in the context of budget neutrality, the considerations that caused us to create a payment offset were driven by precisely that statutory constraint. As discussed above, because hospitals will not be required to separately report costs for non-HEU radioisotopes, all increased costs will be reported as part of the charges for the nuclear scans. To preserve budget neutrality, an additional payment in one place must be accompanied by an offset somewhere else. To prevent double payment for the radioisotope, this offset will have to come from the payment for nuclear scans. Because all hospitals use the same codes for scans, and because parallel families of codes for scans using HEU and non-HEU sourced Tc-99m were not feasible, the offset will be applied to all hospitals. However, this offset will not occur until the claims data show non-HEU payments, at which time reported charges will presumably also reflect these increases in radioisotope costs. Thus, under the current expectations, if 10 percent of CY 2013 claims for a given nuclear scan show a $10 non-HEU add-on payment, $1 (10 percent of $10) will be offset in CY 2015 from the nuclear scan payment. However, if the 10 percent of hospitals claiming the $10 add-on payment also had $10 in increased costs, the calculated cost of a scan using CY 2013 data will have increased by $1 (10 percent of $10). The payment for CY 2015 would therefore increase by $1 because of the new costs in the claims data, and that new $1 will then be removed (offset) to go exclusively to the hospitals that are actually using the non-HEU sourced Tc-99m and are carrying the added cost. Therefore, we note that we are not reducing payments to all hospitals to offset the cost of this payment; rather, we are ensuring that the added costs of the non-HEU sourced Tc-99m go only to the hospitals incurring the costs and that their payments are not diluted by increased payments to uninvolved facilities. In this way, we are not offsetting the current nuclear scan payment by the $10 non-HEU add-on payment even though we currently plan to offset future payment increases to the extent necessary to avoid double payments, as those increased costs will be included in the costs reported by hospitals.

Comment: Several commenters suggested that CMS use the average sales price (ASP) methodology to establish the additional payment amount for Tc-99m based on non-HEU sources. One commenter suggested that CMS use the ASP data when available as a benchmark for determining costs that are packaged. A few commenters suggested that payment based on the ASP methodology be applied in the same manner CMS pays for therapeutic radiopharmaceuticals. The commenters stated that this will establish transparency in the ratesetting for radioisotopes derived from non-HEU sources.

Response: We note that the ASP methodology does not apply to the Tc-99m radioisotope but only to the radiopharmaceutical that results from the combination of the isotope with the pharmaceutical moiety. Moreover, the ASP methodology is particularly unsuited to use on the radioisotope component alone because the isotope does not have an ASP. The radioisotope is typically produced by a generator and, whereas the ASP of a generator can be determined, the cost of a single dose is highly dependent on the number and timing of elutions of the generator, information that is not captured in the ASP. In fact, ASP is marginally valuable for Tc-99m radiopharmaceuticals only because the cost of the drug component is typically large compared to the cost of the isotope. This fact also argues against the comment that ASP would increase ''transparency'' of the cost of Tc-99m: There is no additional transparency of an isotope packaged into a payment with the drug than there is for an isotope packaged into a payment with the scan. Finally, the use of the ASP methodology would not differentiate between the cost of a non-HEU sourced Tc-99m and the cost of using an HEU source, which is the purpose of this payment. The proposed additional payment accounts for the increased cost of the isotope, which meets both incremental payment and transparency goals.

Comment: A few commenters recommended that CMS establish parallel codes for the use of HEU and non-HEU sourced radiopharmaceuticals to collect cost data for future ratesetting. Most of the commenters were concerned with the complexity involved in adding and reporting a single code.

Response: We do not believe that an entire set of parallel codes would lessen the complexity or the administrative cost and, in fact, we believe it would significantly increase them. We acknowledge that this, like many other options we have had on other issues, could significantly improve the accuracy of our ratesetting. However, based on other comments from the hospitals that would have to use these parallel codes, we do not believe that we or the hospitals would consider the increased administrative cost to be worth the slight increase in payment precision.

Comment: A few commenters requested that CMS clarify the meaning of ''calculation by 'Full Cost Recovery' ''. Some commenters also requested clarification of what this method encompasses.

Response: Full Cost Recovery is a concept that is well known to the producers, processors, and manufacturers but is not commonly discussed by radiopharmacies and hospitals. Unlike other supplies, radioisotopes typically require nuclear reactors for initial production, and many of the capital and environmental costs are not captured in the prices. For example, some reactors were built decades ago for other purposes and can be used (relatively) ''free of charge'' because it costs almost the same to run the reactor and do nothing as it does to run the reactor and irradiate some uranium. This has implications on the accounting of capital costs, which, in many cases, were or are recovered by other uses to which the reactors were put. Similarly, moderately enriched uranium left over from previous programs may be cheaply downgraded and provided at a ''low'' cost because the alternative is to allow it to decay in storage with no consequent benefit. In both cases, the Tc-99m produced is obtained by hospitals at a bargain price, but not at a price that is sustainable because the old reactors will need to be replaced and the enriched uranium will be depleted. There are other unique costs for radioisotopes, such as the need to make arrangements for long-term storage of radioactive waste. Failure to account for those costs can lower the price of the radioisotope for some hospitals today but creates a long-term problem in that other hospitals must pick up the costs. Full Cost Recovery is the accounting principle that ensures that all of these long-term costs are included in cost calculations.

Full Cost Recovery is obviously not important to the hospitals although, because it is critically important in providing for the long-term supply of the radioisotope, it is actually a major underlying cause of payment inequities associated with this transition. From the standpoint of this final rule with comment period then, Full Cost Recovery is coupled to the non-HEU criterion for purposes of the additional payment. Just as manufacturers will indicate that certain Tc-99m doses are derived from non-HEU sources, it is our expectation that the irradiator (reactor) and the processor of the non-HEU Mo-

99 will be able to confirm that Full Cost Recovery accounting was used in setting the price of the non-HEU sourced Mo-99, an accounting principle that is considered integral to the conversion to non-HEU sources. We expect the generator manufacturer to affirm to the radiopharmacy that its source is non-HEU, with this designation including accounting according to Full Cost Recovery. As mentioned earlier, we consider this affirmation to be sufficient for the radiopharmacy and the hospital, regardless of whether the affirmation is in the form of a letter or statement, a notation on the invoice, or a label on the vial or tracking slip. We do not believe that independent verification is necessary or even possible for the radiopharmacy and the hospital and require only their due diligence in accepting claims made by their suppliers. The costs of new capital expenses such as new reactors, including all their associated costs, are factored into the manufacturer's price of the Tc-99m and passed down to hospitals, and the additional payment is made to account for those unique costs that the hospitals will incur.

Comment: One commenter asked that CMS delay finalizing the proposal until CY 2014 so that hospitals have adequate time to implement the proposed change. Another commenter recommended that CMS postpone the implementation of the proposed policy until CY 2015, so that hospitals could avoid the complexities of handling and segregating HEU sources versus non-HEU sources. Another commenter expressed doubt that hospitals would be able to obtain Tc-99m derived from non-HEU sources in CY 2013. Therefore, they requested that the proposal be deferred until CY 2014.

One commenter expressed concern about the availability of non-HEU sources because they were told by their suppliers that a 100 percent non-HEU source supply is unavailable for CY 2012 and also will be unavailable by CY 2013. The commenter questioned whether this issue should be addressed by a payment system and suggested that this issue instead be addressed by the Administration as opposed to CMS. The commenter further suggested that the implementation of this proposal be delayed until there is some availability of 100 percent non-HEU sourced isotopes in this country.

Response: We considered the timing of this proposed additional payment after advice and consultation from both the Mo-99 industry and other U.S. agencies. We were initially advised that it is the understanding of the industry that conversion to non-HEU sources is already underway and is expected to be completed by the end of 2016. We understand this remains the case. We are aware that currently commercial Tc-99m is not readily available in the United States as it is in the world market, but that there also has not been a demand from within the United States. We do understand there is an expectation that it will make an appearance in CY 2013.

We acknowledge that the supply of non-HEU sourced Mo-99 may be small in CY 2013. However, we believe, as the industry believes, that conversion to non-HEU sourced Tc-99m is inevitable and will occur over the next several years. From the standpoint of the Medicare payment system, it is important for us to have some mechanism in place to mitigate any adverse impact on hospitals. If the supply is very low, hospitals will not be significantly disadvantaged and may elect to not make use of this additional payment in CY 2013. Conversely, if the supply starts to increase, some hospitals may be forced to shoulder a disproportionate share of the cost due to supplier relationships and contract status; this additional payment will create an opportunity for those hospitals to mitigate that cost. We fully expect that utilization of this additional payment will be small in CY 2013 but will increase in CYs 2014, 2015, and 2016 as this conversion occurs. We reiterate that the normal mechanisms of the OPPS will ultimately incorporate increased costs into APC calculations with resultant increased payments for the nuclear scans that use this radioisotope that will allow us to retire or modify this payment and incorporate the entire additional cost into the base payment. This additional payment will enable hospitals to avoid any inequities caused by suddenly rising local costs that are not able to be captured in a timely fashion by usual methods. Based on the timetable for conversion and the rescue nature of the payment, we believe that a delay until CY 2014 or CY 2015 is unnecessary.

Comment: Several commenters suggested that an additional separate payment be given in other Medicare settings, including the physician's office and ASC, for radioisotopes derived from non-HEU sources. One commenter recommended that these additional payments also be made under Medicaid, the Department of Defense/Veterans Affairs, Indian Health Services health programs, and any other government health programs where nuclear medicine procedures are covered. This commenter acknowledged that its comments are outside the scope of the OPPS/ASC final rule with comment period.

Response: We agree with the commenter that addressing additional payments for radioisotopes derived from non-HEU sources in other settings and payment systems, such as the Physician's Office, Medicaid, the Department of Defense/Veterans Affairs, Indian Health Services health programs, and any other government health programs where nuclear medicine procedures are covered, is outside the scope of the proposed rule and cannot be addressed in this final rule with comment period. In addition, we note that the Medicare authority for this additional payment is based on the need to establish equitable payments for hospitals. The authority to make equitable adjustments under section 1833(t)(2)(E) of the Act does not extend to the ASC setting. We do use a HCPCS Q-code as the vehicle for this additional payment so that other payers and other payment systems could use this code if desired.

After consideration of the public comments we received, we are finalizing our proposed policy with the modifications discussed above. Specifically, we are modifying the policy to provide that a product identified as non-HEU sourced must be at least 95 percent derived from non-HEU sources. We also are finalizing our proposal to establish a HCPCS code for Tc-99m from non-HEU sources with a revised code definition. The number and title of the new HCPCS code is HCPCS code Q9969 (Tc-99m from non-highly enriched uranium source, full cost recovery add-on, per study dose) for CY 2013. HCPCS code Q9969 is assigned to APC 1442 (Non-HEU TC–99M Add-On/Dose) with a status indicator of ''K'' and a CY 2013 payment rate of $10.

D. OPPS APC-Specific Policies

1. Cardiovascular and Vascular Services

a. Cardiac Telemetry (APC 0213)

For CY 2013, we proposed to reassign CPT code 93229 (External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ecg data storage (retrievable with query) with ecg triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; technical support for connection and patient instructions for use, attended surveillance, analysis and physician prescribed transmission of daily and emergent data reports) from APC 0209 (Level II Extended EEG,

Sleep, and Cardiovascular Studies), which had a proposed rule payment rate of approximately $808, to APC 0340 (Minor Ancillary Procedures), which had a proposed rule payment rate of approximately $49.

Comment: One commenter disagreed with CMS' proposal to reassign CPT code 93229 to APC 0340 because the service described by CPT code 93229 involves the use of sophisticated technology requiring 24-hour, 7 days a week monitoring by a technician for up to 30 days, which according to the commenter, is not a minor procedure. According to the commenter, the proposed rule payment rate of approximately $49 is significantly lower than the MPFS payment rate of $694, and much lower than the average contractual arrangement charge to hospitals of $674. The commenter explained that while this procedure is performed primarily by independent diagnostic testing facilities (approximately 98 percent), this service is provided in the HOPD setting under contractual arrangements with hospitals. The commenter stated that the CPT code is fairly new because it was effective January 1, 2009, and suggested that the low geometric mean cost for the service could be attributed to miscoding by hospitals. The commenter believed that hospitals may be reporting CPT code 93229 incorrectly when they are actually performing other remote cardiac tests, such as the services described by CPT code 93226 (External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; scanning analysis with report) or CPT code 93271 (External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; transmission and analysis), that require fewer resources. In addition, the commenter questioned the validity of the claims data, given the low number of claims billed under the OPPS. The commenter requested that CMS delay the reassignment of the service described by CPT code 93229 to APC 0340, and urged CMS to maintain CPT code 93229 in APC 0209 until more data are available to determine an appropriate payment for the service.

Response: The commenter is correct that CPT code 93229 was effective January 1, 2009. However, we believe that since that time hospitals have familiarized themselves with how to code this service appropriately. We have no reason to believe that hospitals are incorrectly reporting the service described by CPT code 93229, and note that we do not specify the methodologies that hospitals must use to set charges for this, or any other, procedure. The calculation of OPPS relative payment weights that reflect the relative resources required for HOPD services is the foundation of the OPPS. We rely on hospitals to bill all HCPCS codes accurately in accordance with their code descriptors and CPT and CMS instructions, as applicable, and to report charges on claims and charges and costs on their Medicare hospital cost report appropriately.

We do not agree with the commenter that it is necessary to delay the reassignment of CPT code 93229 to APC 0340. We examined our claims data for the last 3 years, given the concerns raised by the commenter regarding the low number of claims. Our analysis revealed that the claims submitted for the service described by CPT code 93229 have steadily increased since CY 2009, but the cost for the procedure has been significantly lower than the APC payment rate. Specifically, the cost for the service described by CPT code 93229 in CY 2009 was approximately $287, based on 103 single claims (out of 114 total claims), approximately $260 in CY 2010, based on 184 single claims (out of 184 total claims), and approximately $172 for CY 2011, based on 1,949 single claims (out of 1,949 total claims). Based on the claims data, we have no reason to believe that the claims data used to calculate the cost for CPT code 93229 for CY 2013 does not appropriately reflect the hospitals cost for providing this service.

In addition, because of concerns raised by the commenter regarding reassigning CPT code 93229 to an APC that is labeled ''Minor Ancillary Procedures,'' further review of our claims data for this final rule with comment period showed that CPT code 93229 would be more appropriately assigned to APC 0213 (Level I Extended EEG, Sleep, and Cardiovascular Studies) than APC 0340 based on its clinical homogeneity and resource costs in relation to the other procedures assigned to APC 0213. Our claims data show a geometric mean cost of approximately $172 for CPT code 93229, which is relatively similar to the final geometric mean cost of approximately $178 for APC 0213.

Further, we recognize that the MPFS pays separately for CPT code 93229, but the MPFS and the OPPS are very different payment systems. Each system is established under a different set of statutory and regulatory principles, and the policies established under the MPFS do not have bearing on the payment policies under the OPPS.

In summary, after consideration of the public comment we received, we are finalizing our CY 2013 proposal, with modification. Specifically, we are reassigning CPT code 93229 from APC 0209 to APC 0213 (instead of the proposed APC 0340) for CY 2013. The final CY 2013 geometric mean cost for APC 0213 is approximately $178.

b. Mechanical Thrombectomy (APC 0653)

For CY 2013, we proposed to continue to assign CPT code 36870 (Thrombectomy, percutaneous, arteriovenous fistula, autogenous or nonautogenous graft (includes mechanical thrombus extraction and intra-graft thrombolysis)) to APC 0653 (Level I Hand Musculoskeletal Procedures), which had a proposed rule payment rate of approximately $2,445.

Comment: Some commenters expressed concern regarding the proposed 19.7 percent reduction in the payment rate for the APC in which the procedure describing a mechanical thrombectomy by arteriovenous access, CPT code 36870, is assigned. The commenters believed that such a reduction would impede Medicare beneficiary's access to the procedure. In addition, the commenters stated that CMS offered no explanation for the payment rate reduction, nor permitted adequate notice for a meaningful opportunity to comment. The commenters requested that CMS delay its proposal to reduce the payment rate for mechanical thrombectomy by AV access until stakeholders have been given a meaningful opportunity to comment.

Response: On an annual basis, CMS evaluates hospital outpatient claims data to determine the cost of procedures and services paid under the OPPS to ensure appropriate APC assignment for the following year. This evaluation generally results in establishing new APCs, reassigning procedures and services to more appropriate APCs, or deleting APCs that are no longer applicable. In addition, this evaluation may result in revising relative payment weights, as well as wage and other adjustments, to take into account changes in medical practices, changes in technology, the addition of new services, new cost data, and other relevant information and factors. The OPPS proposed rule is published annually in the summer and is the mechanism used by CMS to inform the public of the proposed changes for the upcoming year and provide an opportunity for comment. As has been

our practice, we encourage the public to submit their comments on issues addressed in the proposed rule. Comments received in response to the proposed rule are addressed in the final rule with comment period, which is also published annually in the winter.

For the CY 2013 update, our analysis of the latest hospital outpatient data for claims submitted for services provided during CY 2011 shows a geometric mean cost for CPT code 36870 of approximately $2,662, based on 539 single claims (out of 50,476 total claims), which is relatively similar to the proposed rule payment rate of approximately $2,748 for APC 0653. Based on our claims data, we believe that APC 0653 is the most appropriate APC assignment for CPT code 36870 based on its clinical homogeneity and resource costs in relation to the other procedures assigned to the APC. Consistent with our policy of reviewing APC assignments annually, we will again reevaluate the cost of CPT code 36870 and its APC assignment in CY 2013 for the CY 2014 rulemaking cycle.

After consideration of the public comments we received, we are finalizing our CY 2013 proposal without modification. We will continue to maintain CPT code 36870 in APC 0653 for CY 2013. The final CY 2013 geometric mean cost for APC 0653 is approximately $2,748.

c. Non-Congenital Cardiac Catheterization (APC 0080)

For CY 2011, the AMA's CPT Editorial Panel restructured the Cardiac Catheterization section of the CPT codebook so that combinations of services that were previously reported using multiple codes are now reported with one CPT code. This revision deleted several non-congenital cardiac catheterization-related CPT codes from the 93500 series and created new CPT codes in the 93400 series and in the 93500 series. We discussed these coding changes in detail in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71846 through 71849), 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. As discussed in that 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 costs 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 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 the services that were reported by the 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 non-congenital catheterization-related CPT codes in APC 0080 (Diagnostic Cardiac Catheterization), to calculate CPT code level costs and the payment rate for APC 0080 of approximately $2,698. We noted that, because the CPT codes listed in Table 11 were new for CY 2011, they were identified with comment indicator ''NI'' in Addendum B to that final rule with comment period to indicate that the interim APC assignment was subject to public comment. We specifically requested public comment on our methodology for simulating the costs for these new CY 2011 CPT codes, in addition to public comments on the payment rates themselves (75 FR 71848).

For CY 2012, we continued to use the CY 2011 methodology in determining the APC assignments for the new cardiac catheterization CPT codes. That is, we continued to use the CY 2011 methodology in determining the APC assignments for the cardiac catheterization CPT codes by using the existing hospital outpatient claims and the cost report data from the predecessor cardiac catheterization CPT codes to simulate an estimated cost for the new cardiac catheterization CPT codes in determining the appropriate APC assignments. Specifically, we used the CY 2010 hospital outpatient claims data and the most recent cost report data to create simulated costs for the new separately payable CPT codes for CY 2012 to determine the payment rates for the APC to which the cardiac catheterization CPT codes were assigned. For CY 2012, we did not make any changes to the CY 2011 APC assignments of any of the CPT codes assigned to APC 0080 because the claims data supported continuation of these APC assignments.

As we discussed in the CY 2013 OPPS/ASC proposed rule, because the cardiac catheterization CPT codes were new for CY 2011, CY 2013 is the first year that claims data are available for ratesetting for these specific CPT codes (77 FR 45084 through 45085). For CY 2013, our analysis of the CY 2011 claims data available for the proposed rule showed no violation of the 2 times rule for the cardiac catheterization CPT codes because the lowest cost of a CPT code with significant claims data in APC 0080 was approximately $1,716 (for CPT code 93451), while the highest cost of a CPT code with significant claims data was approximately $3,308 (for CPT code 93461). We stated in the proposed rule that we believe that the cardiac catheterization CPT codes continue to be appropriately assigned to APC 0080 based on clinical homogeneity and resource costs. Therefore, for CY 2013, we proposed to continue to assign the cardiac catheterization CPT codes to APC 0080.

Comment: One commenter pointed out that CPT codes 93463 (Pharmacologic agent administration (eg, inhaled nitric oxide, intravenous infusion of nitroprusside, dobutamine, milrinone, or other agent) including assessing hemodynamic measurements before, during, after and repeat pharmacologic agent administration, when performed (list separately in addition to code for primary procedure)) and 93464 (Physiologic exercise study (eg, bicycle or arm ergometry) including assessing hemodynamic measurements before and after (list separately in addition to code for primary procedure)), which appeared in Table 5 (Proposed APCs to Which Non-Congenital Cardiac Catheterization CPT Codes Would Be Assigned for CY 2013) of the CY 2013 OPPS/ASC proposed rule do not appear to represent cardiac catheterization procedures.

Response: CPT codes 93463 and 93464 are packaged procedures. These CPT codes appeared in Table 5 of the CY 2013 OPPS/ASC proposed rule because these procedures are performed

in conjunction with cardiac catheterization procedures. CPT code 93463 is an add-on code that describes a pharmacologic agent that may be administered when a cardiac catherization procedure is performed. Similarly, CPT code 93464 is an add-on code that describes a physiologic exercise test that may be combined with a cardiac catheterization. Because these procedures are used in conjunction with cardiac catherization procedures, we believe that listing them in Table 5 of the CY 2013 OPPS/ASC proposed rule was appropriate.

After consideration of the public comment that we received, we are finalizing our proposal, without modification, to continue to assign the cardiac catheterization CPT codes to APC 0080 for CY 2013, as listed below in Table 20 below. The final CY 2013 geometric mean cost for APC 0080 is approximately $2,726.

TABLE 20.—APCs TO WHICH NON-CONGENITAL CARDIAC CATHETERIZATION CPT CODES ARE ASSIGNED FOR CY 2013

CY 2013 HCPCS Code	CY 2013 Short Descriptor	CY 2012 SI	CY 2012 APC	CY 2013 SI	CY 2013 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
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

d. 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 under the Endovascular Revascularization section of the 2011 CPT codebook 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 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 the most recent cost report data to create simulated costs for 12 of the 16 new separately payable CPT codes for CY 2011. Because the endovascular revascularization CPT codes were 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 costs, we selected claims that we believe met 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 costs for the new CPT 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 the 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 costs for the procedures, we assigned each CPT code to appropriate APCs based on their clinical homogeneity and resource use. Of the 16 CPT 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 the remaining 2 CPT codes. Table 8 of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71845) displayed their final CY 2011 APC assignments and CPT code costs. We noted that, because these CPT codes were new for CY 2011, they were assigned comment indicator ''NI'' in Addendum B to the CY 2011 OPPS/ASC final rule with comment period to identify them as new interim APC assignments for CY 2011, and subject to public comment. We specifically requested public comment on our methodology for simulating the costs for these new CY 2011 CPT codes in addition to public comments on the payment rates themselves (75 FR 71845).

As stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74156), for CY 2012, we continued to use the CY 2011 methodology to determine the APC assignments for the CPT codes that describe endovascular revascularization of the lower extremity. Because previous endovascular revascularization CPT codes were in existence prior to CY 2011 and assigned to designated APCs, we continued to use existing hospital outpatient claims and cost report data from the established CPT codes to simulate estimated costs for the endovascular revascularization CPT codes to determine the appropriate APC assignments for CY 2012, as we did for CY 2011. In the CY 2012 OPPS/ASC final rule with comment period, we also revised the title of APC 0083 from ''Coronary or Non-Coronary Angioplasty and Percutaneous Valvuloplasty'' to ''Coronary Angioplasty, Valvuloplasty, and Level I Endovascular Revascularization of the Lower Extremity''; revised the title of APC 0229 from ''Transcatheter Placement of Intravascular Shunts and Stents'' to ''Level II Endovascular Revascularization of the Lower Extremity''; and revised the title of APC 0319 from ''Endovascular Revascularization of the Lower Extremity'' to ''Level III Endovascular Revascularization of the Lower Extremity''.

Because the endovascular revascularization of the lower extremity CPT codes were new for CY 2011, CY 2013 is the first year of claims data that are available for ratesetting for these specific CPT codes. For CY 2013, review of the procedures with significant claims data in APCs 0083, 0229, and 0319 did not show 2 times rule violations in these APCs. In the CY 2013 OPPS/ASC proposed rule, we stated that we believe that the endovascular revascularization CPT codes assigned to APCs 0083, 0229, and 0319 continue to be appropriately assigned based on clinical homogeneity and resource costs. Therefore, we proposed to continue to assign the endovascular revascularization CPT codes to APCs 0083, 0229, and 0319 for CY 2013 (77 FR 45083 through 45084).

Comment: Several commenters believed that the assignment of CPT code 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 imaging guidance and documentation) and 37210 (Uterine fibroid embolization (ufe, embolization of the uterine arteries to treat uterine fibroids, leiomyomata), percutaneous approach inclusive of vascular access, vessel selection, embolization, and all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the procedure) to APC 0229 (Level II Endovascular Revascularization of the Lower Extremity) violated the 2 times rule. The commenter believed that these two codes should be reassigned to APC 0083 (Coronary Angioplasty, Valvuloplasty, and Level I Endovascular Revascularization of the Lower Extremity).

Response: As stated above, in determining whether a 2 times rule violation exists in an APC, we consider only those HCPCS (both CPT and Level II Alphanumeric HCPCS codes) codes that are significant based on the number of claims. For purposes of identifying significant HCPCS codes for examination to determine if they violate 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 cost to be significant (75 FR 71832). This longstanding definition of when a 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 costs. Similarly, a code for which there are fewer than 99 single claims and which comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC cost.

For this CY 2013 OPPS/ASC final rule with comment period, our analysis of the CY 2011 claims data showed that CPT code 37183 had 211 single claims (out of 302 total claims) while CPT code 37210 had 211 single claims (out of 254 total claims). Of the 12 procedures assigned to APC 0229, only 5 procedures meet the definition of significant claims. Specifically, CPT codes 37205 (Transcatheter placement of an intravascular stent(s) (except coronary, carotid, vertebral, iliac, and lower extremity arteries), percutaneous; initial vessel), 37221 (Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed), 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), and 37229 (Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with atherectomy, includes angioplasty within the same vessel, when performed) have significant claims data to determine whether a violating of the 2 times rule exists within APC 0229. Review of the procedures assigned to APC 0229 revealed that the range of the CPT geometric mean costs for the procedures with significant claims data is between approximately $7,013 (for CPT code 37205, which represents 14 percent of the single claims) and approximately $9,915 (for CPT code

37229, which represents 5 percent of the single claims). Taking into consideration all of the codes with significant claims that are assigned to APC 0229, CPT codes 37183 and 37210 do not meet the definition of significant claims to determine if there is a violation of the 2 times rule within APC 0229.

Therefore, based on the clinical similarity to other procedures currently assigned to APC 0229, and because there is no determination of a violation of the 2 times rule, we are continuing to assign CPT codes 37183 and 37210 to APC 0229 for CY 2013. For CY 2013, APC 0229 has a final geometric mean cost of approximately $8,905.

Comment: Several commenters recommended the reassignment of add-on 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 (list separately in addition to code for primary procedure)) from APC 0083 to APC 0229 because the proposed geometric mean cost of the procedure is similar to the geometric mean costs of procedures assigned to APC 0229 (although the commenters also pointed out that the cost data calculated from single claims for CPT code 37223 are unreliable because CPT code 37223 is an add-on code and would not appear by itself on a claim). Some commenters also argued that the assignment of CPT code 37223 to APC 0083 results in a violation of the 2 times rule. The commenters stated that the reassignment of CPT code 37223 to APC 0229 would be consistent with CMS' policy of assigning add-on codes to the same APC as their base codes. In addition, the commenters asserted that this reassignment would not only ensure patient access for this therapeutic procedure, but also would promote clinical homogeneity and similar resource cost of procedures assigned to APC 0229 and provide accurate payment for the procedure.

Response: Although there are many add-on codes that have been assigned to the same APC as their base code, there are some procedures that are add-on codes that have been assigned to different APCs from their base or primary codes. In establishing an appropriate APC assignment, we take into consideration the clinical homogeneity and similarity in resource use associated with the procedure or service. This determination may result in the same APC assignment for both the base code and the add-on code, or in different APC assignments, as illustrated in Table 21 below. Therefore, we disagree with the commenters' assertion that we should reassign CPT code 37223 to APC 0229 so that it is in the same APC as its base code.

We also do not agree with commenters that the composition of APC 0083 constitutes a violation of the 2 times rule because CPT code 37223 does not have sufficient single claims to qualify as a significant procedure for purposes of applying the 2 times rule, as described earlier in this section. Based on our understanding of the procedure, we continue to believe that APC 0083 is the most appropriate assignment for CPT code 37223 based on clinical considerations and similarity in resource use to other procedures assigned to APC 0083, as we have stated in the past (76 FR 74156).

TABLE 21.—EXAMPLES OF BASE AND ADD-ON CPT CODES THAT ARE ASSIGNED TO DIFFERENT APCs

CY 2013 CPT Code	CY 2013 Short Descriptor	CY 2013 SI	CY 2013 APC
11000	Debride infected skin	T	0016
11001*	Debride infected skin add-on	T	0013
11044	Deb bone 20 sq cm/<	T	0020
11047*	Deb bone add-on	T	0019
11100	Biopsy skin lesion	T	0015
11101*	Biopsy skin add-on	T	0013
13101	Repair of wound or lesion	T	0135
13102*	Repair wound/lesion add-on	T	0134
56605	Biopsy of vulva/perineum	T	0189
56606*	Biopsy of vulva/perineum	T	0188
64479	Inj foramen epidural c/t	T	0207
64480*	Inj foramen epidural add-on	T	0206

*Add-on procedure code.

Further, in response to the commenters' concerns regarding providing accurate payment for the procedure described by CPT code 37223 to ensure patient access, we believe that the payment rate for the procedure does not inhibit HOPDs from performing the procedure. The OPPS, like other Medicare payment systems, is budget neutral and overall increases in payments are limited to the 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 payment rates are adequate to ensure access to services.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue to assign CPT code 37223 to APC 0083 for CY 2013.

Comment: One commenter believed that CPT codes 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)), 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 (list separately in addition to code for primary procedure)) are inappropriately assigned to APC 0083, and recommended that they be reassigned to APC 0229. The commenter indicated that these procedures involve both angioplasty with stent placements, similar to the procedure described by 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), which is assigned to APC 0229. The commenter also stated that CPT codes 37234 and 37235 are similar to the stent procedures described by CPT codes 37205 (Transcatheter placement of an intravascular stent(s) (except coronary, carotid, vertebral, iliac, and lower extremity arteries), percutaneous; initial vessel) and 37206 (Transcatheter placement of an intravascular stent(s) (except coronary, carotid, vertebral, iliac, and lower extremity arteries), percutaneous; each additional vessel (list separately in addition to code for primary procedure)), which are assigned to APC 0229. The commenter concluded that the payment rate for APC 0083 does not reflect the resources associated with placement of a cardiovascular stent; therefore, CPT codes 37234 and 37235 should be reassigned to APC 0229.

Response: We continue to believe that APC 0083 is the most appropriate assignment for these CPT codes based on clinical and resource considerations. We do not agree that the procedures described by CPT codes 37234 and 37235 are dissimilar to other procedures in APC 0083 because they involve a stent. In addition, an analysis of CY 2011 claims data shows only one single claim for CPT code 37234 (out of 153 total claims) and no single claims (out of 31 total claims) for CPT code 37235. Therefore, the outpatient claims data do not support an APC reassignment of these CPT codes. Because these CPT codes were made effective January 1, 2011, CY 2011 is the first year of claims data available for CPT codes 37234 and 37235. Consistent with CMS' policy of reviewing APC assignments annually, we will reevaluate the cost of these procedures and their APC assignments next year for the CY 2014 rulemaking cycle.

After consideration of the public comment we received, we are finalizing our CY 2013 proposal, without modification, to continue to assign CPT codes 37234 and 37235 to APC 0083, which has a CY 2013 final geometric mean cost of approximately $4,139.

Table 22 below provides the list of endovascular revascularization CPT codes assigned to APCs 0083, 0229, and 0319 for CY 2013.

TABLE 22.—APCs TO WHICH ENDOVASCULAR REVASCULARIZATION OF THE LOWER EXTREMITY CPT CODES WILL BE ASSIGNED FOR CY 2013

CY 2013 CPT Code	CY 2013 Short Descriptor	CY 2012 SI	CY 2012 APC	CY 2013 SI	CY 2013 APC
37220	Iliac revasc	T	0083	T	0083
37221	Iliac revasc w/stent	T	0229	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

e. External Electrocardiographic Monitoring (APC 0097)

In the CY 2012 OPPS/ASC final rule with comment period, we assigned new CPT codes 0296T (External electrocardiographic recording) and 0297T (External electrocardiographic recording; scanning analysis with report) on an interim basis to APC 0097 (Level I Non-Invasive Physiologic Studies), which has a CY 2012 payment rate of approximately $68 and a CY 2013 proposed payment rate of approximately $67.

Comment: One commenter who responded to the CY 2012 OPPS/ASC final rule with comment period supported our placement of CPT code 0296T in APC 0097. The commenter stated that the service described by CPT code 0296T is clinically similar to other services in that APC. However, the commenter believed that CPT code 0297T would be more appropriately assigned to APC 0692 (Level II Electronic Analysis of Devices), which has a CY 2013 proposed rule cost of approximately $113). The commenter argued that CPT code 0297T is similar in nature and in required resources to CPT code 93271 (Electrocardiographic monitoring and analysis), which is assigned to APC 0692, because it has a similar monitoring period and requires similar network and information technology resources.

Response: Based on our understanding of the resources that are required to furnish the services described by CPT codes 93271 and 0297T, we do not agree with the commenter. The service described by CPT code 93271 includes 24-hour attended monitoring, while the service described by CPT 0297T does not. Therefore, we believe that CPT code 0297T is more clinically similar to the services assigned to APC 0097. Therefore, for CY 2013, we will continue to assign this service to APC 0097, which has a final CY 2013 geometric mean cost of approximately $68. We will reevaluate the APC placement using our standard ratesetting methodology when we receive claims data for these services.

f. Echocardiography (APCs 0177, 0178, 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 procedures without contrast followed by procedures 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 2013, we proposed payment rates for these APCs of approximately $571, $212, $392, and $558, respectively.

Comment: One commenter expressed concern regarding the APC assignment of the procedures for fetal echocardiography to APC 0697. The commenter believed that this APC classification and payment rate are inconsistent with the resources required to perform fetal echocardiography studies. These resources, the commenter noted, substantially exceed the resources generally needed for adult services. Therefore, the commenter recommended that CMS reassign fetal echocardiography 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) to the same APC as adult echocardiography procedures, APC 0269 (Level II Echocardiogram Without Contrast).

Response: For the CY 2013 OPPS/ASC proposed rule, we proposed to assign CPT codes 76825 and 76826 to APC 0697, which had a proposed payment rate of $211.71. As we stated in the CY 2012 OPPS/ASC final rule with comment period, because these codes have been in existence for almost 20 years, and have been reportable under the 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 beneficiaries. Analysis of our claims data from past years revealed that these procedures are relatively low volume procedures. CPT code 76825 has had fewer than 330 single claims for ratesetting for each year with a cost that has ranged between approximately $88 and approximately $140. Similarly, CPT code 76826 has had fewer than 50 single claims for ratesetting for each year with a cost that has ranged between approximately $85 and approximately $92. For this CY 2013 OPPS/ASC final rule with comment period, CPT codes 76826 and 76825 are assigned APCs with payment rates that exceed their respective individual geometric mean costs. Therefore, based on our claims data, we believe that CPT codes 76825 and 76826 are appropriately assigned to APC 0697 for CY 2013 based on their clinical homogeneity and resource costs of the other procedure assigned to APC 0697.

Comment: Several commenters expressed concern regarding a violation of the 2 times rule for APC 0128 and urged CMS not to finalize an exemption from the 2 times rule for APC 0128. The commenters stated that the assignment of HCPCS codes C8924 (Transthoracic echocardiography with contrast, or without contrast followed by with contrast, real-time with image documentation (2d), includes m-mode recording, when performed, follow-up or limited study) and C8930 (Transthoracic echocardiography, with contrast, or without contrast followed by with contrast, real-time with image documentation (2d), includes m-mode recording, when performed, during rest and cardiovascular stress test using treadmill, bicycle exercise and/or pharmacologically induced stress, with interpretation and report; including performance of continuous electrocardiographic monitoring, with physician supervision) to APC 0128 results in a violation of the 2 times rule in particular, and that the other procedures assigned to APC 0128 are not clinically comparable in nature, therefore resulting in an APC payment rate that does not reflect the wide range of resources utilized for the procedures assigned to APC 0128. The commenters further recommended that CMS reconfigure APC 0128 so that the procedures are clinically similar with respect to resources. One commenter recommended that CMS adopt three levels of contrast-enhanced APCs that parallel the three APCs that have been established for non-contrast enhanced procedures.

Response: As stated above, we have four separate APCs to which echocardiography services are assigned. Procedures that utilize contrast agents are currently assigned to APC 0128, while procedures without contrast agents are assigned to one of three APCs, specifically APC 0270, APC 0269, or APC 0697. In the CY 2013 OPPS/ASC proposed rule, we proposed a payment rate for APC 0128 of approximately $571 for CY 2013. As we do every year, we reviewed our claims data for the services assigned to APC 0128. Based on our review, and taking into consideration the public comments received in response to the final rule with comment period, we agree with commenters that APC 0128 has a 2 times violation that cannot be exempted for this CY 2013 OPPS/ASC final rule with comment period. As we have stated in section III.B. of this final rule with comment period, we make exemptions to the 2 times rule's limit on the variation of costs within each APC group in unusual cases, such as low volume items and services. In deciding to propose exemptions to the 2 times rule, we look at the respective APC's resource homogeneity, clinical homogeneity, hospital outpatient setting, frequency of service (volume), and opportunity for upcoding and code fragmentation. We believe that, for this CY 2013 OPPS/ASC final rule with comment period, it would be inappropriate to exempt APC 0128 from the 2 times rule and to continue to assign echocardiography services utilizing contrast agents to one APC, based on our evaluation of the aforementioned criteria. Therefore, for CY 2013, we are splitting APC 0128 to create two new level APCs: APC 0177 (Level I Echocardiogram with Contrast) and APC 0178 (Level II Echocardiogram with Contrast).

After consideration of the public comments we received, we are finalizing our proposals, with the modifications mentioned above, to continue to calculate the costs of the HCPCS codes describing the non-contrast echocardiography procedures based on APCs 0697, 0269, and 0270, and to calculate the costs for the HCPCS codes describing contrast echocardiography procedures based on new APCs 0177 and 0178. 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 (72 FR 68542 through 68544), and the CY 2010 OPPS/ASC final rule with comment period (74 FR 60374 through 60383).

Table 23 below shows the procedure assignments and the final geometric mean cost assigned to echocardiography APCs, including the new Level I and Level II Echocardiogram with Contrast APCs.

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TABLE 23.—APC ASSIGNMENTS FOR ECHOCARDIOGRAPHY PROCEDURES FOR CY 2013

APC	HCPCS Code	Short Descriptor	Final CY 2013 Geometric Mean Cost
0177 (Level I Echocardiogram With Contrast)	C8924	2D TTE w or w/o fol w/con,fu	$446.38
	C8922	TTE w or w/o fol w/cont, f/u	
	C8923	2D TTE w or w/o fol w/con,co	
	C8927	TEE w or w/o fol w/cont, mon	
0178 (Level II Echocardiogram With Contrast)	C8921	TTE w or w/o fol w/cont, com	$594.96
	C8925	2D TEE w or w/o fol w/con,in	
	C8926	TEE w or w/o fol w/cont,cong	
	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	$218.76
	76826	Echo exam of fetal heart	
	93308	Tte f-up or lmtd	
0269 (Level II Echocardiogram Without Contrast)	93304	Echo transthoracic	$401.69
	93306	Tte w/doppler complete	
	93307	Tte w/o doppler complete	
	93313	Echo transesophageal	
	93315	Echo transesophageal	
	93350	Stress tte only	
0270 (Level II Echocardiogram Without Contrast)	93303	Echo transthoracic	$574.69
	93312	Echo transesophageal	
	93316	Echo transesophageal	
	93318	Echo transesophageal intraop	
	93351	Stress tte complete	

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2. Gastrointestinal Services

a. Laparoscopic Adjustable Gastric Band (APC 0132)

Effective January 1, 2006, the AMA's CPT Editorial Panel established CPT code 43770 (Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)) to describe the bariatric placement of an adjustable band by laparoscopy. From January 1, 2006 through December 31, 2011, CPT code 43770 was assigned to status indicator ''C'' to indicate that the procedure was not paid separately under the OPPS because the procedure was considered an ''inpatient'' procedure. However, in the CY 2012 OPPS/ASC final rule (76 FR 74355), we stated that we received a comment requesting that this CPT code be removed from the inpatient list and assigned to a separately payable APC, effective January 1, 2012. Based on input from our physicians and review of our claims data, we determined that it was appropriate to remove CPT code 43770 from the inpatient list because patients undergoing this procedure can typically be managed postoperatively as outpatients. Consequently, we assigned CPT code 43770 to APC 0131 (Level II Laparoscopy), effective January 1, 2012.

At the August 2012 HOP Panel meeting, a presenter requested that the Panel recommend to CMS the reassignment of CPT code 43770 from APC 0131 to a new APC. The commenter expressed concern about the existing APC assignment and indicated that APC 0131 does not adequately cover the costs of performing the procedure. After discussion of the

procedure and review of the hospital outpatient claims data, the Panel recommended that CPT code 43770 remain in APC 0131 for the CY 2013 update.

For CY 2013, we proposed to continue to assign CPT code 43770 to APC 0131, which had a proposed rule payment rate of approximately $3,497.

Comment: Several commenters disagreed with the proposal to continue to assign CPT code 43770 to APC 0131 because the procedure is different from other procedures assigned to this APC. According to one commenter, the procedures assigned to APC 0131 are less intensive (for example, resource cost) than CPT code 43770. Another commenter stated that the procedures assigned to APC 0131 are not similar to CPT code 43770 because this procedure includes the implantation of a gastric band device as well as a port device, while the other procedures assigned to this APC do not. In addition, some commenters believed that assignment of CPT code 43770 to APC 0131 violates the 2 times rule. According to the commenters, there is no existing APC that includes procedures that are comparable to the procedures described by CPT code 43770, both clinically and in terms of resource utilization. Therefore, they requested that CMS establish a new APC for CPT code 43770 to ensure the most appropriate payment for this procedure.

However, we received conflicting statements on the issue of clinical comparability from some of the commenters. One commenter stated that, although there is no existing APC that accurately fits with CPT code 43770, the commenter mentioned that APC 0132 (Level III Laparoscopy) does include some procedures that are more clinically comparable to CPT code 43770 than the procedures assigned to APC 0131, and suggested that APC 0132 would be an appropriate APC assignment for this procedure. Another commenter considered suggesting a reassignment of CPT code 43770 to APC 0132 but stated that the procedures assigned to APC 0132 are not comparable in terms of resource utilization. Although most of the commenters agreed that establishing a new APC for CPT code 43770 would be more appropriate, some commenters suggested assigning the procedure to APC 0132 as an interim APC assignment if a new APC cannot be established for the CY 2013 update.

Response: We do not agree with the commenters' assertion that assigning CPT code 43770 to APC 0131 violates the 2 times rule. In determining whether a 2 times rule violation exists in an APC, we consider only those HCPCS codes that are significant based on the number of claims. 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 comprise at least 2 percent of the single major claims used to establish the costs of the procedures assigned to an APC 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 costs. Similarly, a HCPCS code for which there are fewer than 99 single claims and which comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the costs of the procedures in an APC. For the CY 2013 OPPS/ASC proposed rule, claims data for CPT code 43770 showed 171 single claims out of 216 total claims and comprised less than 1 percent of the claims for procedures within APC 0131. Although CPT code 43770 had more than 99 single major claims, it did not contribute to at least 2 percent of the single major claims for procedures within APC 0131. Therefore, in the CY 2013 OPPS/ASC proposed rule, we determined that assigning CPT code 43770 to APC 0131 did not violate the 2 times rule because it did not meet the definition of a significant HCPCS code.

As stated above, the HOP Panel made a recommendation to continue to assign CPT code 43770 to APC 0131 for the CY 2013 update. However, after the Panel meeting, we reviewed our more recent claims data for this final rule with comment period, and our analysis revealed that the procedure would be more appropriately assigned to APC 0132 (Level III Laparoscopy). Specifically, our analysis showed 213 single claims (out of 262 total claims) for CPT code 43770 with a geometric mean cost of approximately $7,410. Furthermore, our analysis revealed that CPT code 43770 meets the definition of significant claims because the procedure represents more than 99 single major claims and contribute to at least 2 percent of the claims for procedures within APC 0132. Consequently, we do not agree with the Panel's recommendation, and are reassigning CPT code 43770 to APC 0132.

In summary, after consideration of the public comments we received, we are revising the APC assignment for CPT code 43770 from APC 0131 to 0132 for CY 2013. The final CY 2013 geometric mean cost for APC 0132 is approximately $5,268.

b. Transoral Incisionless Fundoplication (APC 0422)

For CY 2013, we proposed to continue to assign CPT code C9724 (Endoscopic full-thickness plication in the gastric cardia using endoscopic plication system (eps); includes endoscopy) to APC 0422 (Level III Upper GI Procedures), which had a proposed payment rate of approximately $1,878.

We note that at the August 2012 HOP Panel meeting, a presenter requested that the Panel recommend to CMS the reassignment of HCPCS code C9724 from APC 0422 to a new APC, or alternatively, to establish a new APC with a descriptor of ''Level IV Upper GI Procedures.'' The commenter stated that the payment rate for APC 0422 does not cover the cost of providing the procedure. After discussion of the procedure and review of the hospital outpatient claims data, the Panel recommended that HCPCS code C9724 remain in APC 0422 for the CY 2013 update.

Comment: Several commenters disagreed with the proposal to continue to assign HCPCS code C9724 to APC 0422. The commenters stated that the proposed payment rate for APC 0422 would not cover the cost of performing the procedure. According to the commenters, the cost of performing the procedure is approximately $5,000. The commenters urged CMS to either reassign HCPCS code C9724 to APC 1565 (New Technology—Level XXVIII ($5000-$5500)), which had a proposed payment rate of approximately $5,250, or establish a new APC titled ''Level IV Upper GI Procedures'' with a payment rate of approximately $5,000.

Response: HCPCS code C9724, which was established by CMS effective April 1, 2005, describes an endoscopic full-thickness plication procedure for the treatment of gastroesophageal reflux disease (GERD). Since April 2005, HCPCS code C9724 has been assigned to APC 0422. Because this code has been in existence since April 2005, we have claims data for several years. For this final rule with comment period, which is based on claims submitted from January 1, 2011 through December 31, 2011, our data show a geometric mean cost of approximately $5,728 based on 24 single claims (out of 120 total claims) for HCPCS code C9724. In addition, we agree with the Panel's recommendation to maintain HCPCS code C9724 in APC 0422 for the CY 2013 update. Based on the clinical similarity to other

procedures currently assigned to APC 0422, and because there is no violation with the 2 times rule, we will continue to assign HCPCS code C9724 to APC 0422. Consistent with CMS' policy of reviewing APC assignments annually, we will reevaluate the cost of HCPCS code C9724 and its APC assignment for the CY 2014 rulemaking cycle.

In addition, because of concerns related to the current descriptor for HCPCS code C9724, we are revising the long descriptor to read ''Endoscopic full-thickness plication of the stomach using endoscopic plication system (eps); includes endoscopy,'' effective January 1, 2013. This change in the long descriptor is necessary to accurately describe how the procedure is currently performed.

After consideration of the public comments we received, we are finalizing our CY 2013 proposal without modification and will continue to maintain HCPCS code C9724 in APC 0422. The final CY 2013 geometric mean cost for APC 0422 is approximately $1,921.

c. Gastrointestinal Transit and Pressure Measurement (APC 0361)

The AMA's CPT Editorial Panel created CPT code 0242T (Gastrointestinal tract transit and pressure measurement, stomach trough colon, wireless capsule, with interpretation and report) effective January 1, 2011. For CY 2011, we initially assigned CPT code 0242T to APC 0361 (Level II Alimentary Tests), with a payment rate of $282.48.

For CY 2012, we maintained the assignment of CPT code 0242T to APC 0361 with a payment rate of $285.59. We noted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74242) that we routinely make assignments of new CPT codes to clinical APCs before we have claims data that are indicative of the resource 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 stated in the CY 2012 OPPS/ASC final rule with comment period that, as was the case when we made the initial assignment for CY 2011, we continued to believe that there are relevant clinical similarities between the service described by CPT code 0242T and other services assigned to APC 0361 to continue to justify this APC assignment. The service described by CPT code 0242T and the services assigned to APC 0361 all involve tests of the alimentary canal. We believed that the clinical attributes and CY 2012 costs of the services assigned to APC 0361 supported the initial assignment of CPT code 0242T to APC 0361. We indicated that we routinely make assignments of new CPT codes to clinical APCs before we have claims data to indicate the procedural resource costs, and that we generally wait until claims data are available before reassignment to a new APC. For CY 2012, we maintained our assignment of CPT code 0242T to APC 0361, which has a final median cost of $285.89, and we stated that we would review this assignment for CY 2013 when some claims data should be available for this procedure.

For CY 2013, we proposed to maintain the assignment of CPT code 0242T to APC 0361, which had a proposed rule geometric mean cost of approximately $311 and a proposed payment rate of approximately $303. We now have a small number of claims for use in CY 2013 for CPT code 0242T, which had a proposed rule geometric mean cost of approximately $613. The range of procedure level costs in APC 0361 for the CY 2013 proposed rule was approximately $214 to approximately $633. This range of costs does not constitute a 2 times rule violation because the range of costs for procedures with significant volume in the APC is approximately $302 to approximately $406.

We did not receive any public comments on our proposed APC assignment of CPT code 0242T to APC 0361.

At the August 2012 meeting of the HOP Panel, the Panel recommended that CMS assign CPT code 0242T to APC 0142 (Level I Small Intestine Endoscopy), based on the procedure's proposed rule mean cost of approximately $613, with a frequency of 8 claims.

Our CY 2013 final rule claims data show a cost of approximately $497 for CPT code 0242T, based on 8 claims. Our analysis comparing the proposed rule data and the final rule data for CPT code 0242T shows that one claim was dropped and another added, resulting in the fluctuation in geometric mean costs for the small number of claims between the proposed rule dataset and the final rule dataset for this procedure. The CY 2013 final geometric mean cost for APC 0361 is approximately $311, which includes a range of costs for procedures in the APC of approximately $209 to approximately $633. The CY 2013 final geometric mean cost for APC 0142 is approximately $772, which includes a range of costs for procedures in the APC of approximately $569 to approximately $826. Therefore, based on the final rule geometric mean cost for CPT code 0242T, assignment of the code to APC 0361 is appropriate. We also continue to believe that CPT code 0242T is similar clinically to other procedures assigned to APC 0361. Therefore we are maintaining our assignment of the CPT code 0242T procedure to APC 0361 for CY 2013.

We note that the CPT Editorial Panel is replacing the CPT code for the procedure described by CPT code 0242T with a Category I CPT code, CPT code 91112 (Gastrointestinal transit and pressure measurement, stomach trough colon, wireless capsule, with interpretation and report), effective January 1, 2013. Therefore, we are deleting CPT code 0242T from the OPPS effective January 1, 2013, and assigning replacement CPT code 91112 to APC 0361 for this procedure.

3. Integumentary System Services

a. Extracorporeal Shock Wave Wound Treatment (APC 0340)

In the CY 2012 OPPS/ASC final rule with comment period, we assigned new CPT codes 0299T (Extracorporeal shock wave for integumentary wound healing, initial wound) and 0300T (Extracorporeal shock wave for integumentary wound healing, each additional wound) on an interim basis to APC 0340 (Minor Ancillary Procedures), which has a CY 2012 payment rate of approximately $46 and a CY 2013 proposed rule payment rate of approximately $49.

Comment: One commenter objecting to the interim APC assignment of CPT codes 0299T and 0300T believed that the assignment is not consistent clinically or in terms of the resources associated with the shock wave treatment procedures. The commenter stated that these services are more similar clinically and in related resources to the high-energy shock wave procedure for musculoskeletal conditions that is assigned to APC 0050 (Level II Musculoskeletal Procedures Except Hand and Foot), which has a CY 2012 payment rate of approximately $2,269. The commenter believed that assignment of these codes to a New Technology APC would be appropriate to gather cost data, and indicated that they would submit an application for new technology payments for these codes to CMS.

We received other similar comments to the proposed rule from several clinicians in the field who were involved in the initial clinical trial of the extracorporeal shock wave procedure. These commenters discussed

the clinical trial and the clinical attributes of this treatment, indicating that it offers significantly greater clinical benefit than other wound healing therapies at a considerably lower cost. They objected to CMS' assignment of CPT codes 0299T and 0300T to APC 0340. The commenters believed that the payment rate for this APC would inhibit the use of this emerging technology and would prevent patient access to the treatment.

Response: We agree with the commenters that it may be more appropriate in terms of clinical and resource similarity to assign CPT codes 0299T and 0300T to an APC other than APC 0340. However, we do not agree that CPT codes 0299T and 0300T should be assigned to APC 0050. Having considered the information provided by the commenters, and based on our evaluation of clinical and resource similarity to existing services, we believe that placement in APC 0133 (Level I Skin Repair) would be more appropriate for these services until claims data are available. For CY 2013, we are placing CPT codes 0299T and 0300T in APC 0133, which has a final geometric mean cost of approximately $88. We will reevaluate the APC placement when claims data are available for CY 2014.

b. Application of Skin Substitute (APCs 0133 and 0134)

For CY 2012, we made assignments for several new (replacement) CPT codes for the application of skin substitutes. We assigned CPT code 15272 (Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm or part thereof) and CPT code 15276 (Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet and/or multiple digits, total wound surface area up to 100 sq cm; each additional 25 sq cm or part thereof) to APC 0133 (Level I Skin Repair), which has a CY 2012 payment rate of approximately $84 and a CY 2013 proposed payment rate of approximately $86. We assigned CPT code 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 or part thereof) and CPT code 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 or part thereof) to APC 0134 (Level II Skin Repair), which has a CY 2012 payment rate of approximately $228 and a CY 2013 proposed payment rate of approximately $252.

Comment: One commenter stated that CMS should have assigned the new codes to the APC that includes their predecessor base codes so that a 2 times rule violation is avoided. They requested that for CY 2013, CMS reassign CPT codes 15272 and 15276 to APC 0134, crosswalking them to the predecessor add-on CPT code 15341 and assign them to the same APC as the former base CPT code 15340. Similarly, the commenter requested that CMS reassign CPT codes 15274 and 15278 to APC 0135 (Level III Skin Repair) which includes their applicable base codes (CPT codes 15273 and 15277).

Response: As we indicated in the CY 2012 OPPS/ASC final rule (76 FR 74269), we assigned these four replacement CPT codes for CY 2012 based on their clinical and estimated resource similarity to the services in their assigned APCs. We also took into account the size descriptions in the new codes' long descriptors. There was not a one-to-one crosswalk between the old skin substitute application codes and the new CPT codes, as suggested by the commenter. Several of the old CPT codes map to a single new code. Therefore, we made the most appropriate assignment based on clinical homogeneity and estimated resource similarity, taking into account all of the former procedures that are now encompassed by a single code and the new coding structure for the family of codes.

For CY 2013, we will continue to assign CPT codes 15272 and 15276 to APC 0133, which has a final geometric mean cost of approximately $88, and CPT codes 15274 and 15278 to APC 0134, which has a final geometric mean cost of approximately $259. We will reevaluate the placement of these codes when claims data become available in the CY 2014 rulemaking cycle.

c. Low Frequency, Non-Contact, Non-Thermal Ultrasound (APC 0015)

Effective January 1, 2008, the CPT Editorial Panel created CPT code 0183T (Low Frequency, Non-Contact, Non-Thermal Ultrasound). Since that time, we have assigned this service to either APC 0013 (Level II Debridement and Destruction) or APC 0015 (Level III Debridement and Destruction). Initially, for CY 2008 and CY 2009, we placed this service in the higher Level III APC 0015, with a payment rate of approximately $100. Based on our review of the first year of hospital claims data (CY 2008 claims), for CY 2010 we reassigned the service to the lower Level II APC 0013, with a payment rate of approximately $59. For CY 2011 and CY 2012, due to a change in the estimated cost of CPT code 0183T, we reassigned it to the higher level APC 0015, with a payment rate of approximately $105 in CY 2011 and approximately $103 in CY 2012.

For CY 2013, we proposed to reassign CPT 0183T to APC 0013 because its proposed rule geometric mean cost of approximately $89 was closer to the proposed rule geometric mean cost of APC 0013 (approximately $73) than the proposed rule geometric mean cost of APC 0015 (approximately $110).

Comment: One commenter objected to the reassignment of CPT code 0183T to APC 0013 because the commenter's estimated cost of furnishing this service of approximately $101 would be greater than its proposed payment. The commenter believed that procedures currently assigned to APC 0013 and those assigned to APC 0015 are not homogeneous clinically or in terms of resource requirements. The commenter requested that CMS split APC 0013 and APC 0015 to create a third APC, such that APC 0013 would include the services with costs less than $80; the new APC would include services with costs between $80 and $110; and APC 0015 would include services with costs greater than or equal to $110.

Another commenter recommended that CMS merge APC 0013 and APC 0015, arguing that both APCs are for skin procedures and noting that the proposed cost for the highest volume service in APC 0013, described by CPT code 17000 (Destruction of premalignant lesions; first lesion), is more than half of the cost of the highest volume service in APC 0015, described by CPT code 97597 (Open wound debridement; first 20 sq cm or less).

Response: The final rule geometric mean cost of CPT code 0183T and APC 0013 (approximately $88 and $74, respectively) did not change significantly from their proposed rule costs and remain very similar. There also is no significant change in the final rule geometric mean cost of APC 0015 (approximately $110). We note that merging the two APCs as one commenter suggested would create several 2-times rule violations, and we see no clinical or other need to further split the APCs. Therefore, because the geometric mean cost of CPT code 0183T continues to be closer to the geometric mean cost of APC 0013 than that of APC 0015, and because merging the APCs would create several 2 times rule violations, for CY 2013, we are finalizing our proposal to reassign CPT code 0183T to APC 0013.

4. Nervous System Services

a. Scrambler Therapy (APC 0275)

For the CY 2012 update, the AMA's CPT Editorial Panel established Category III CPT code 0278T (Transcutaneous electrical modulation pain reprocessing (eg, scrambler therapy), each treatment session (includes placement of electrodes)) effective January 1, 2012. CPT code 0278T describes a transcutaneous electrical modulation pain reprocessing procedure and involves the use of four to five electrodes that deliver electrical stimulation to treat chronic chemo-induced neuropathic pain. Based on the nature of the procedure, which can be performed by physicians, nurses, or physical therapists, the therapy involves 10 sessions (1 session per day for 10 days), and each session takes approximately between 30 and 45 minutes.

In Addendum B of the CY 2012 OPPS/ASC final rule with comment period, we assigned CPT code 0278T to APC 0215 (Level I Nerve and Muscle Tests) which has a CY 2012 payment rate of approximately $44. We also assigned this CPT code comment indicator ''NI'' to indicate that the code was new for CY 2012 with an interim APC assignment that was subject to public comment following the publication of the final rule with comment period. Specifically, the code's APC assignment and status indicator were subject to public comment. We received one public comment regarding the interim APC assignment for CPT code 0278T which we address below in this section.

We note that we do not discuss APC or status indicator assignments for new codes for the upcoming year in the proposed rule because the new codes are not available when we publish the proposed rule. Rather, as has been our practice in the past, we implement new HCPCS codes in the OPPS final rule with comment period, at which time we invite public comments regarding the treatment of the new codes. We subsequently respond to those comments in the final rule with comment period for the following year's OPPS update.

As has been our practice since the implementation of the OPPS in 2000, we carefully review all new procedures before assigning them to an APC. In determining the APC assignment for CPT code 0278T, we took into consideration the clinical and resource characteristics involved with Scrambler Therapy. Based on our initial review of the components of these services and consultation with our medical advisors, we assigned CPT code 0278T to APC 0215 for CY 2012.

At the February 2012 HOP Panel meeting, a presenter requested the reassignment of CPT code 0278T from APC 0215 to APC 0206 (Level II Nerve Injections) based on resource cost and clinical homogeneity. The presenter stated that the assignment of CPT code 0278T to APC 0215 is not appropriate because the procedures in this APC are primarily diagnostic in nature, whereas CPT code 0278T represents a therapeutic procedure. The presenter further added that the time and cost involved with providing the service associated with CPT code 0278T is considerably greater than the time and cost involved for procedures assigned to APC 0215, and recommended that the Scrambler Therapy would be more appropriately assigned to APC 0206 because the procedures in APC 0206 are mostly therapeutic in nature and represent similar costs. At the February 2012 meeting, the Panel made no recommendation to reassign CPT code 0278T from its current APC 0215 assignment for CY 2013.

In Addendum B of the CY 2013 OPPS/ASC proposed rule, we proposed to continue to assign CPT code 0278T to APC 0215. At the August 2012 HOP Panel meeting, the same presenter at February 2012 Panel meeting made the same request to the Panel to recommend to CMS to reassign CPT code 0278T to a more appropriate APC. Specifically, at the August 2012 HOP Panel meeting, the requester recommended that CPT code 0278T be reassigned to APC 0204 (Level I Nerve Injections) based on clinical and cost considerations. During the discussion, one of the Panel members pointed out that the procedures assigned to APC 0204 represent nerve injections, which is in contrast to how the procedure described by CPT code 0278T is delivered because the procedure associated with the Scrambler Therapy does not involve injections. After discussion of the issue, the HOP Panel recommended that CMS assign CPT code 0278T to APC 0218 (Level II Nerve and Muscle Tests).

Comment: One commenter to the CY 2012 OPPS/ASC final rule with comment period recommended the reassignment of CPT code 0278T from APC 0215 to APC 0206 based on the commenter's cost analysis. Alternatively, the commenter recommended assignment of CPT code 0278T to APC 0204 because this is the APC assigned to unlisted CPT code 64999 (Unlisted procedure, nervous system), which would be used to report the Scrambler Therapy if CPT code 0278T had not been established.

Response: As a new Category III CPT code for CY 2012, we do not yet have hospital claims data for the procedure. Category III CPT codes are temporary codes that describe emerging technology, procedures, and services, and are created by the AMA to allow for data collection for new services or procedures. Under the OPPS, we generally assign a payment rate to a new Category III CPT code based on input from a variety of sources, including but not limited to, review of resource costs and clinical homogeneity of the service to existing procedures, information from specialty societies, input from CMS medical advisors, and other information available to us. Based on our review of the clinical characteristics of the service described by CPT code 0278T and the information provided by the commenter, we do not believe that we have sufficient clinical or cost information to justify a reassignment to a different APC at this time. As we do every year for other services and procedures under the OPPS, we will review the claims data for CPT code 0278T for CY 2012 for the CY 2014 rulemaking cycle. Because CPT code 0278T was a new code for CY 2012, the first time we will have claims data for this procedure is next year for the CY 2014 update, and at which time we will reevaluate the APC assignment for this code.

Comment: Some commenters recommended a range of the appropriate payment for CPT code 0278T based on their internal analysis. One commenter recommended that CPT code 0278T be assigned to an APC that has a payment rate of between $124 to $144 based on their analysis, by taking into consideration the site of service, staff time involved, and system costs associated with providing the therapy. Another commenter stated that the total cost of providing Scrambler Therapy is approximately $274; however, an initial payment of approximately $184 may be adequate for hospitals to initiate treatment. The commenter further stated that the proposed payment rate of approximately $81 for APC 0218, which was recommended by the HOP Panel at the August 2012 meeting, is adequate. However, the commenter asserted that the proposed payment rate of approximately $150 for New Technology APC 1540 (New Technology—Level III ($100—$200)) would be more appropriate.

Response: After further review of the HOP Panel recommendation at the August 2012 meeting and consideration of the public comments that we received on this particular procedure, we believe that we should continue to assign the

Scrambler Therapy to APC 0215. Therefore, we are not accepting the Panel's recommendation to reassign CPT code 0278T to APC 0218. In addition, we do not agree with the commenter that CPT code 0278T should be assigned to New Technology APC 1540. Based on our understanding of the procedure, we believe that APC 0215 is the most appropriate APC assignment for CPT code 0278T based on its similarity to other procedures assigned to APC 0215. We will review the claims data for CPT 0278T next year for the CY 2014 rulemaking to determine whether an APC reassignment for the Scrambler Therapy is necessary.

After consideration of the public comments received, we are finalizing our CY 2013 proposal, without modification, to continue to assign CPT code 0278T to APC 0215 for CY 2013. The final CY 2013 geometric mean cost for APC 0215 is approximately $44.

b. Transcranial Magnetic Stimulation Therapy (TMS) (APC 0216)

Since July 2006, CPT codes have existed to describe Transcranial Magnetic Stimulation Therapy (TMS) therapy. The initial CPT codes were temporary Category III CPT codes, specifically, CPT code 0160T (Therapeutic repetitive transcranial magnetic stimulation treatment planning) and 0161T (Therapeutic repetitive transcranial magnetic stimulation treatment delivery and management, per session), that were effective July 1, 2006. For CY 2011, the CPT Editorial Panel deleted CPT code 0160T on December 31, 2010, and replaced it with CPT code 90867 (Therapeutic repetitive transcranial magnetic stimulation (tms) treatment; initial, including cortical mapping, motor threshold determination, delivery and management) effective January 1, 2011. Similarly, CPT code 0161T was deleted on December 31, 2010, and was replaced with CPT code 90868 (Therapeutic repetitive transcranial magnetic stimulation (tms) treatment; subsequent delivery and management, per session) effective January 1, 2011. In CY 2012, the AMA's CPT Editorial Panel established an additional TMS therapy code, specifically CPT code 90869 (Therapeutic repetitive transcranial magnetic stimulation (tms) treatment; subsequent motor threshold re-determination with delivery and management), that was effective January 1, 2012.

In Addendum B of the CY 2013 OPPS/ASC proposed rule, we proposed to continue to assign CPT codes 90867, 90868, and 90869 to APC 0218 (Level II Nerve and Muscle Tests), which had a proposed payment rate of approximately $81.

Comment: One commenter disagreed with the proposed APC assignment and stated that the TMS therapy codes are not similar to the services assigned to APC 0218. The commenter recommended three options on the appropriate APC assignment.

Under the first option, the commenter recommended the reassignment of CPT codes 90867, 90868, and 90869 to APC 0216 (Level III Nerve and Muscle Tests), which had a proposed payment rate of approximately $182. The commenter also recommended the revision of the APC title description to read ''Level III Nerve and Muscle Tests & TMS''. The commenter stated that the TMS therapy services are similar to the services described by CPT codes 95961 (Functional cortical and subcortical mapping by stimulation and/or recording of electrodes on brain surface, or of depth electrodes, to provoke seizures or identify vital brain structures; initial hour of physician attendance), 95962 (Functional cortical and subcortical mapping by stimulation and/or recording of electrodes on brain surface, or of depth electrodes, to provoke seizures or identify vital brain structures; each additional hour of physician attendance (list separately in addition to code for primary procedure)), and 96000 (Comprehensive computer-based motion analysis by video-taping and 3d kinematics), which are assigned to APC 0216.

Under the second option, the commenter recommended the establishment of a new APC for the three TMS therapy CPT codes, and further recommended revising the APC title description to read ''Transcranial Magnetic Stimulation''.

Under the third option, the commenter suggested assigning CPT codes 90867, 90868, and 90869 to APC 0320 (Electroconvulsive Therapy), which had a proposed payment rate of approximately $441. Although TMS therapy is clinically related to electroconvulsive therapy (ECT), the commenter stated that its resource costs are lower than ECT.

Response: We appreciate the commenter's thoughtful suggestions on the APC assignments for CPT codes 90867, 90868, and 90869. We do not agree with the commenter that the procedures described by CPT codes 90867, 90868, and 90869 would be appropriately assigned to 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. However, based on the latest claims data used for this rulemaking, we do agree with the commenter's suggestion that APC 0216 would be the more appropriate APC assignment for the three TMS therapy CPT codes. Analysis of our more recent claims data revealed that the resources associated with CPT codes 90867, 90868, and 90869 are similar to those services assigned to APC 0216. Specifically, for claims submitted during CY 2011, which were used for this final rule with comment period, CPT code 90867 showed a geometric mean cost of approximately $190 based on 15 single claims (out of 18 total claims), and a geometric mean cost of approximately $233 for CPT code 90868 based on 609 single claims (out of 614 total claims). In addition, review of the procedures assigned to APC 0216 showed that the range of the geometric mean cost for the procedures with significant claims data is between approximately $146 (for CPT code 92584 (Electrocochleography)) and approximately $233 (for CPT code 90868 (Tcranial magn stim tx deli)). Based on the clinical and resource similarity to other procedures currently assigned to this APC, we believe it is appropriate to reassign the TMS therapy services to APC 0216. Although CPT code 90869 is a new code for CY 2012, we believe that it is appropriate to reassign this service to APC 0216, similar to the APC assignment of CPT codes 90867 and 90868. Because of this reassignment, we also are revising the APC title descriptions of APCs 0215, 0216, and 0218 to appropriately reflect the services within each APC. Specifically, we are revising the APC title description of APC 0215 from ''Level I Nerve and Muscle Tests'' to ''Level I Nerve and Muscle Services''; the title description of APC 0218 from ''Level II Nerve and Muscle Tests'' to ''Level II Nerve and Muscle Services''; and the title description of APC 0216 from ''Level III Nerve and Muscle Tests'' to ''Level III Nerve and Muscle Services''.

After consideration of the public comment we received, we are finalizing our CY 2013 proposal, with modification. That is, we are reassigning CPT codes 90867, 90868, and 90869 from APC 0218 to APC 0216, which has a final CY 2013 geometric mean cost of approximately $189. Table 24 below shows the final APC assignments for CPT codes 90867, 90868, and 90869 for CY 2013.

TABLE 24.—FINAL APC ASSIGNMENTS FOR TMS THERAPY FOR CY 2013

CY 2012 HCPCS Code	CY 2012 Short Descriptor	CY 2012 SI	CY 2012 APC	Final CY 2013 SI	Final CY 2013 APC
90867	Tcranial magn stim tx plan	S	0218	S	0216
90868	Tcranial magn stim tx deli	S	0218	S	0216
90869	Tcran magn stim redetemine	S	0218	S	0216

c. Paravertebral Neurolytic Agent (APC 0207)

Effective January 1, 2012, the AMA's CPT Editorial Panel created CPT code 64633 (Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or ct); cervical or thoracic, single facet joint). For CY 2012, we assigned new CPT code 64633 on an interim basis to APC 0207 (Level III Nerve Injections). This interim APC assignment was consistent with our standard process for dealing with new CPT codes effective on January 1 for the upcoming calendar year, which is to assign each code to the APC that we believe contains services that are comparable with respect to clinical characteristics and resources required to furnish the service. CPT code 64633 was assigned a comment indicator of ''NI'' in Addendum B to the CY 2012 OPPS/ASC final rule with comment period to identify it as a new interim APC assignment for the new year and the APC assignment for this new code was open to public comment for 60 days following the publication of the CY 2012 OPPS/ASC final rule with comment period. For CY 2013, we proposed to continue to assign CPT code 64633 to APC 0207, which had a proposed payment rate of approximately $568.

Comment: One commenter who responded to the CY 2012 OPPS/ASC final rule with comment period objected to the assignment of CPT code 64633 to APC 0207 because the commenter believed that the payment rate for APC 0207 substantially underpays providers for this service.

Response: Due to the lack of any claims data for CPT code 64633, we have no way to validate or substantiate the claim made by the commenter. We expect to have CY 2012 claims data for CPT code 64633 available in CY 2013 in preparation for the CY 2014 rulemaking cycle and will reevaluate the APC assignment of CPT code 64633 at that time.

After consideration of the public comments we received, we are finalizing our CY 2013 proposal, without modification, to continue to assign CPT code 64633 to APC 0207, which has a final CY 2013 APC geometric mean cost of approximately $582.

d. Programmable Implantable Pump (APC 0691)

Effective January 1, 2012, the AMA's CPT Editorial Panel created two new CPT codes that combine pump refill and programming/analysis procedures: CPT code 62369 (Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drub prescription status); with reprogramming and refill) and CPT code 62370 (Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drub prescription status); with reprogramming and refill (requiring physician's skill)). For CY 2012, CPT codes 62369 and 62370 received a new interim APC assignment to APC 0691 (Level III Electronic Analysis of Devices), consistent with our standard process for dealing with new CPT codes effective on January 1 for the upcoming calendar year, which is to assign each code to the APC that we believe contains services that are comparable with respect to clinical characteristics and resources required to furnish the service. CPT codes 62369 and 62370 were both given a comment indicator of ''NI'' in Addendum B to the CY 2012 OPPS/ASC final rule with comment period to identify it as a new interim APC assignment for the new year and the APC assignment for these two new codes was open to public comment for 60 days following the publication of the CY 2012 OPPS/ASC final rule with comment period. For CY 2013, we proposed to continue to assign CPT codes 62369 and 62370 to APC 0691, which had a proposed payment rate of approximately $192.

Comment: Commenters who responded to the CY 2012 OPPS/ASC final rule with comment period objected to the assignment of CPT codes 62369 and 62370 to APC 0691 because they believed that the payment rate for APC 0691 substantially underpays providers for these services.

Response: Due to the lack of any claims data for CPT codes 62369 and 62370, we have no way to validate or substantiate the claim made by commenters. We expect to have CY 2012 claims data for CPT codes 62369 and 62370 in CY 2013 in preparation for the CY 2014 rulemaking cycle and will reevaluate the APC assignment of CPT codes 62369 and 62370 at that time.

After consideration of the public comments we received, we are finalizing our CY 2013 proposal, without modification, to continue to assign CPT codes 62369 and 62370 to APC 0691, which has a final CY 2013 APC geometric mean cost of approximately $197.

e. Revision/Removal of Neurostimulator Electrodes (APC 0687)

For CY 2013, we proposed to continue to assign CPT code 64569 (Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator) to APC 0687 (Revision/Removal of Neurostimulator Electrodes), which had a proposed CY 2013 payment rate of approximately $1,576.

Comment: Commenters objected to the assignment of CPT code 64569 in APC 0687 because they stated that this code is used to report both the revision and the replacement of neurostimulator electrodes. The commenters believed that hospital resources are substantially greater when neurostimulator electrodes are being replaced rather than revised. The commenters asked CMS to reassign CPT code 64569 to device-dependent APC 0040 (Level I Implantation/Revision/Replacement of

Neurostimulator Electrodes) or assign new HCPCS codes to differentiate between electrode replacements (with a new electrode) and electrode revisions (without a new electrode) so that electrode revisions map to APC 0687 and electrode replacements map to APC 0040. The commenters noted that, like CPT code 64569, the procedures currently assigned to APC 0040 involve the implantation of a new electrode, either as an initial implant or as a replacement, while all of the procedures currently assigned to APC 0687, with the exception of CPT code 64569, are defined as ''revision or removal'' or simply ''removal'' of electrodes. The commenters stated that the resources associated with the procedure described by CPT code 64569 are similar to the resources associated with the procedures assigned to APC 0040.

Response: We agree with the commenters that the resources associated with the procedure described by CPT code 64569 are similar to the resources associated with procedures assigned to APC 0040, and that these procedures share clinical characteristics. We note that the CY 2013 final rule geometric mean cost for CPT code 64569 of approximately $5,473 is more consistent with the CY 2013 final rule geometric mean cost of APC 0040 of approximately $4,526 than with the CY 2013 final rule geometric mean cost of APC 0687 of approximately $1,554. Therefore, we are modifying our proposal and assigning CPT code 64569 to APC 0040 for CY 2013.

5. Ocular Services: Placement of Amniotic Membrane (APC 0233)

In CY 2011, 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's 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's CPT Editorial Panel established 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 65778 to APC 0239 (Level II Repair and Plastic Eye Procedures), which had a payment rate of approximately $559, and CPT code 65779 to APC 0255 (Level II Anterior Segment Eye Procedures), which had a payment rate of approximately $519.

In addition, consistent with our longstanding policy for new codes, we assigned these two new CPT codes to interim APCs for CY 2011. Specifically, we assigned 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 the codes were new with interim APC assignments that were subject to public comment. In accordance with our longstanding policy, our interim APC assignment for each code was based on our understanding of the resources required to furnish the service as defined in the code descriptor and input from our physicians.

At the Panel's February 28–March 1, 2011 meeting, a presenter requested the reassignment of CPT codes 65778 and 65779 to APC 0244 (Corneal and Amniotic Membrane Transplant), 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 65778 and 65779 were previously reported under the original version of CPT code 65780, which did not specify ''multiple layers,'' and as such these new CPT codes should continue to be assigned to APC 0244. Further, the presenter stated that the costs of the procedures described by CPT codes 65778 and 65779 are very similar to the cost of the procedure described by CPT code 65780.

The Panel recommended that CMS reassign the APC assignments for both CPT codes 65778 and 65779. Specifically, the Panel recommended the reassignment of CPT code 65778 from APC 0239 to APC 0233 (Level III Anterior Segment Eye Procedures), and the reassignment of CPT code 65779 from APC 0255 to APC 0233. In addition, the Panel recommended that CMS furnish data when data become available for these two codes. We noted at that time that because these CPT codes were effective January 1, 2011, the first available claims data for these codes would be for the CY 2013 OPPS rulemaking cycle.

We accepted the Panel's recommendations. However, in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74247), we indicated that, while we agreed with the Panel's recommendation to reassign CPT codes 65778 and 65779 to APC 0233, we believed that CPT code 65778 should be assigned to a conditionally packaged status indicator of ''Q2'' to indicate that the procedure would be packaged when it is reported with another procedure that is also assigned to status indicator ''T''; but in all other circumstances, the CPT code would be paid separately. Because the procedure described by CPT code 65778 would rarely be provided as a separate, stand-alone service in the HOPD, and because the procedure would almost exclusively be provided in addition to and following another procedure or service, we proposed to reassign CPT code 65778 a conditionally packaged status indicator of ''Q2.'' In addition, 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.

At the August 10–11, 2011 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 status indicator ''T.'' Based on information presented at the meeting, and after further discussion of the issue, the Panel recommended that CMS reassign the status indicator for CPT code 65778 from conditionally packaged ''Q2'' to status indicator ''T.'' Several commenters also urged CMS not to finalize its proposal to conditionally package CPT code 65778 by assigning it status indicator ''Q2'' and instead adopt the Panel's recommendation to assign status indicator ''T.''

After consideration of the Panel's August 2011 recommendation and the public comments that we received in response to the CY 2012 OPPS/ASC

proposed rule, we finalized our proposal and reassigned the status indicator for CPT code 65778 from ''T'' to ''Q2'' effective January 1, 2012 (76 FR 74246). Given the clinical characteristics of this procedure, we believed that conditionally packaging CPT code 65778 was appropriate under the OPPS.

For the CY 2013 OPPS update, we proposed (77 FR 45123) to continue to assign CPT code 65778 a conditionally packaged status indicator of ''Q2.'' Similarly, we stated that we believe that we should assign CPT code 65779 to a conditionally packaged status indicator of ''Q2.'' Therefore, for CY 2013, we proposed to revise the status indicator for CPT code 65779 from status indicator ''T'' to ''Q2'' to indicate that the procedure would be packaged when it is reported with another procedure that is also assigned status indicator ''T,'' but in all other circumstances, the CPT code would be paid separately. This reassignment would enable hospitals to perform either procedures (CPT code 65778 or 65779) when appropriate, and would not differentiate one procedure from the other because of the status indicator assignment under the OPPS.

As indicated at the February 28-March 1, 2011 Panel meeting, because CPT codes 65778 and 65779 were effective January 1, 2011, the first available claims data for these codes would be in CY 2012 for the CY 2013 OPPS rulemaking. We now have claims data for CPT codes 65778 and 65779, and our data show that both procedures are performed in the HOPD setting. Analysis of the CY 2011 claims data available for the proposed rule, which was based on claims processed from January 1 through December 31, 2011, revealed that the estimated cost for CPT code 65778 is approximately $1,025 based on 33 single claims (out of 130 total claims), and the estimated cost for CPT code 65779 is approximately $2,303 based on 35 single claims (out of 260 total claims). Based on the clinical similarity to other procedures currently assigned to APC 0233, and because there was no violation with the 2 times rule, we stated that we believe that we should continue to assign both CPT codes 65778 and 65779 to APC 0233, which had a payment rate of approximately $1,150. Review of the procedures assigned to APC 0233 showed that the range of the cost for the procedures with significant claims data is between approximately $859 (for CPT code 65400 (Removal of eye lesion)) and approximately $1,397 (for CPT code 66840 (Removal of lens material)).

In summary, for CY 2013, we proposed to continue to assign CPT code 65778 to a conditionally packaged status indicator of ''Q2'' and to reassign the status indicator for CPT code 65779 from ''T'' to ''Q2,'' similar to CPT code 65778. In addition, we proposed to continue to assign both CPT codes 65778 and 65779 to APC 0233, which had a proposed geometric mean cost of approximately $1,150. Both procedures and their CY 2013 APC assignments were displayed in Table 19 of the proposed rule.

At the August 2012 HOP Panel Meeting, a presenter urged the Panel to recommend to CMS not to conditionally package CPT code 65779 for CY 2013, and instead, assign status indicator ''T'' to the code. Based on the information presented at the meeting, and after further discussion of the issue, the HOP Panel made no recommendation to revise the status indicator assignment for CPT code 65779.

Comment: One commenter urged CMS not to finalize its proposal to conditionally package CPT code 65779 by assigning it status indicator ''Q2,'' and recommended that CMS continue to assign the code status indicator ''T.'' The commenter expressed concern that assigning a ''Q2'' status indicator to CPT code 65779 would impede access to this procedure because, in a majority of the cases (84 percent), hospitals perform this procedure with another procedure. Consequently, a ''Q2'' status indicator would result in no payment for CPT code 65779. The commenter further recommended that CMS assign CPT code 65779 to APC 0244, or another APC that better reflects the resources associated with the procedure, such as APC 0241 (Level IV Repair and Plastic Eye Procedures) or APC 0234 (Level IV Anterior Segment Eye Procedures).

Response: We believe that the revision in status indicator for CPT code 65779 would enable hospitals to perform either procedures (CPT code 65778 or 65779) when appropriate, and would not differentiate one procedure from the other because of the status indicator assignment under the hospital OPPS. In addition, because CPT codes 65778 and 65779 were new for CY 2011, CY 2013 is the first year of claims data that we have available for ratesetting for both CPT codes. Analysis of the CY 2011 claims data revealed a geometric mean cost of approximately $989 for CPT code 65778 based on 36 single claims (out of 142 total claims), and approximately $2,314 for CPT code 65779 based on 37 single claims (out of 280 total claims). Review of the procedures assigned to APC 0233 showed that the range of the CPT geometric mean cost for the procedures with significant claims data is between approximately $867 (for CPT code 65400 (Removal of eye lesion)) and approximately $1,390 (for CPT code 66840 (Removal of lens material)). Based on the clinical similarity to other procedures currently assigned to APC 0233, and because there is no violation with the 2 times rule, we believe that we should continue to assign CPT code 65779 to APC 0233, which has a final geometric mean cost of approximately $1,162 for CY 2013.

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. For CPT codes 65778 and 65779, we will again reevaluate their APC assignments for the CY 2014 OPPS rulemaking cycle.

After consideration of the public comment that we received, we are finalizing our CY 2013 proposal, without modification, to assign status indicator ''Q2'' to CPT code 65779. When the service is furnished with a separately payable surgical procedure with status indicator ''T'' on the same day, payment for CPT code 65779 is packaged. Otherwise, payment for CPT code 65779 is made separately through APC 0233, which has a final CY 2013 geometric mean cost of approximately $1,162. The amniotic membrane procedures and their CY 2013 final APC assignments are displayed in Table 25 below.

TABLE 25.—FINAL APC ASSIGNMENTS FOR CPT CODES 65778 AND 65779 FOR CY 2013

CY 2012 HCPCS Code	CY 2012 Short Descriptor	CY 2012 SI	CY 2012 APC	Final CY 2013 SI	Final CY 2013 APC
65778	Cover eye w/membrane	Q2	0233	Q2	0233
65779	Cover eye w/membrane suture	T	0233		

6. Radiology Oncology

a. Proton Beam Therapy (APCs 0664 and 0667)

APC 0664 (Level I Proton Beam Radiation Therapy) includes two procedures: CPT code 77520 (Proton treatment delivery; simple, without compensation), which had a CY 2013 proposed rule cost of approximately $331 (based on 185 single claims of 185 total claims submitted for CY 2011); and CPT code 77522 (Proton treatment delivery; simple, with compensation), which had a proposed rule cost of approximately $1,191 (based on 14,279 single claims of 15,405 total claims submitted for CY 2011). APC 0667 (Level II Proton Beam Radiation Therapy) also includes two procedures: CPT code 77523 (Proton treatment delivery, intermediate), which had a proposed rule cost of approximately $920 (based on 3,009 single claims out of 3,202 total claims submitted for CY 2011), and CPT code 77525 (Proton treatment delivery, complex), which had a proposed rule cost of approximately $483 (based on 1,400 single claims out of 1,591 total claims submitted for CY 2011). Based on these CY 2011 claims data, under the current APC structuring the proposed rule cost of APC 0664 was approximately $1,171, and the proposed rule cost of APC 0667 was approximately $750.

Because only a few hospitals bill Medicare for these services, their payment rates, which are set annually based on claims data according to the standard OPPS ratesetting methodology, may fluctuate significantly from year to year. For CY 2013, under the current APC assignments, the proposed rule cost of APC 0664 was approximately the same as its CY 2012 payment rate of $1,184. However, the proposed rule cost of APC 0667 decreased substantially from the CY 2012 payment rate. We also observed that for CY 2013, as in several prior years, the lower level APC 0664 did not include the lower cost services among the four CPT codes. For CY 2013, we proposed to improve the resource homogeneity within the proton beam therapy APCs by including the services requiring fewer resources in APC 0664 (Level I) and the services requiring greater resources in APC 0667 (Level II). Specifically, we proposed to reassign CPT code 77522 to APC 0667 and to reassign CPT code 77525 to APC 0664. Under the proposed reassignment, the estimated cost of APC 0664 was approximately $462, and the estimated cost of APC 0667 was approximately $1,138. We invited public comments on this proposal.

Comment: Several commenters indicated that the decrease in the cost of APC 0667 is attributable to inaccurate coding and cost reporting during part of CY 2010 and part of CY 2011, on the part of one hospital. The commenters stated that one hospital's services that should have been billed as CPT code 77523 were instead billed as CPT code77525, which has a lower estimated cost. They stated that these services were also reported under an unintended cost center in the hospital's cost report, and argued that the current APC configuration better reflects the clinical similarity and relative resources used to furnish proton beam therapy services. We received a comment from the hospital in question indicating the same. This provider also stated that these issues were corrected and do not affect any claims in CY 2012. These commenters requested that we therefore forego using the CY 2011 claims data to set CY 2013 rates because they are based in part on inaccurate data reported by one of the few billing providers. They requested that CMS maintain both the CY 2012 payment rates and the current CY 2012 APC configuration through CY 2013, and the HOP Panel agreed with this recommendation at its August 2012 public meeting.

One commenter recommended that CMS obtain corrected data from the provider in question and use the corrected data in updating the CY 2012 proton beam therapy payment rates for CY 2013. The commenter recommended that if CMS could not accomplish this in time for publication of the CY 2013 final rule, CMS exclude the reportedly erroneous data from its ratesetting process and update the CY 2012 payments for proton beam services for CY 2013 using the remaining claims data. In either event, the commenter recommended that we not restructure the APCs this year because despite what the cost data show, simple and complex proton beam therapy services are not clinically homogenous.

Another commenter supported the proposed reduction in payments for proton beam services. The commenter stated that given the cost of establishing and staffing proton beam centers, proton beam therapy does not yield commensurate benefit over other therapies.

Response: We appreciate the public comments and the HOP Panel's recommendation. After consideration of the public comments we received, we are updating the payment rates for proton beam therapy for CY 2013 to reflect the most recently available claims data from all providers. Therefore, we are not maintaining the CY 2013 payment rates at CY 2012 levels, and we are not excluding the reportedly erroneous data from the ratesetting process. However, we are maintaining the current APC structure for CY 2013 and will reevaluate the costs and appropriateness of the APC structuring for proton beam services next year. Using the current APC assignments for proton beam services, the CY 2013 final geometric mean cost of APC 0664 (including CPT codes 77520 and 77522) is approximately $1,169. The CY 2013 final geometric mean cost of APC 0667 (including CPT codes 77523 and 77525) is approximately $702.

b. Device Construction for Intensity Modulated Radiation Therapy (IMRT) (APC 0305)

Effective January 1, 2010, the CPT Editorial Panel created CPT code 77338 (Construction of multi-leaf collimator (MLC) device(s) for IMRT per IMRT plan) to report all of the devices furnished under a single IMRT treatment plan. The code was created as part of an effort to consolidate the reporting of multiple services or units of service into a single code. For CY 2011, we assigned CPT 77338 to APC 0310 (Level III Therapeutic Radiation Treatment Preparation) based on a simulated cost of approximately $792 that we calculated using CY 2009 claims data for the predecessor CPT code 77334 ((Treatment devices, design and construction; complex (irregular blocks, special shields, compensators, wedges, molds or casts)).

For CY 2012, using our standard ratesetting methodology and the first year of available claims data for CPT code 77338, and based upon a final rule cost of approximately $188, we reassigned this service from APC 0310 to APC 0305 (Level II Therapeutic Radiation Treatment Preparation) with a final payment rate of approximately $264. In our response to public comments, we noted several possible reasons for the discrepancy in the reported cost of the service relative to its predecessor code. We stated that it is not unusual for providers to bill a given service in a manner that is inconsistent with what we would expect based on the definition of a new code. We also noted potential clinical reasons for the apparent anomaly, such as the inclusion of labor-intensive physical blocks, shields, and molds in the service described by CPT code77334, and 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. We stated that we saw no basis to ignore our robust set of single procedure claims submitted by a significant number of hospitals by continuing to simulate a cost for CPT code 77338.

In the CY 2013 OPPS/ASC proposed rule Addenda, based on a proposed rule cost of approximately $293, we proposed to continue the current assignment of CPT code 77338 for CY 2013 to APC 0305, and to add this service to the bypass list which would increase the number of claims that could be used in setting its payment rate.

Comment: One commenter objected to the continued assignment of CPT code 77338 to APC 0305. The commenter again noted the low estimated cost of this service compared to its predecessor code, and continued to believe that providers are inappropriately coding the service. They requested that for CY 2013, we simulate the cost of this service using the alternative methodology that we used in CY 2011, and that we reassign the service to APC 0310, which has a final rule cost of approximately $1,013.

Response: As we noted last year, we see no reason to discard the reported claims data for CPT code 77338, which has a CY 2013 final rule geometric mean cost of approximately $297. For the reasons previously discussed, for CY 2013 we will continue assigning this CPT code to APC 0305, which has a final geometric mean cost of approximately $299. We will reevaluate whether this placement is appropriate next year when additional claims data are available.

c. Other Radiation Oncology Services (APCs 0310 and 0412)

Comment: One commenter addressed the proposed payment rates for the following services: CPT code 77418 (Radiation treatment delivery intensity modulated radiotherapy), which is assigned to APC 0412 (Level II Radiation Therapy) and is separately paid; CPT code 77295 (3–D Therapeutic radiology simulation-aided field setting), which is assigned to APC 0310 (Level III Therapeutic Radiation Treatment Preparation) and is also separately paid; CPT code 77373 (Stereotactic body radiation therapy delivery), which has a status indicator of ''B'' (Not covered under the OPPS); and CPT code 77014 (CT scan for therapy guidance), which has status indicator of ''N'' and is packaged. The commenter expressed concern about perceived decreases in payment for these services.

Response: Under our standard ratesetting methodology, we proposed a slight payment increase for CPT 77418 from approximately $459 in CY 2012 to approximately $484 in CY 2013, based on a CY 2013 proposed rule geometric mean cost of $497. Similarly, we proposed a slight payment increase for CPT 77295 from approximately $953 in CY 2012 to approximately $985 in CY 2013, based on a CY 2013 proposed rule geometric mean cost of $988. The final CY 2013 geometric mean cost of CPT 77418 is approximately $498, and the final CY 2013 geometric mean cost of CPT 77295 is approximately $991.

Since 2007, we have not recognized CPT code 77373 under the OPPS, and hospitals should instead report this service using HCPCS code G0251 (Linear accelerator based stereotactic radiosurgery, delivery). HCPCS code G0251 is assigned to APC 0065 (Level I Stereotactic Radiosurgery, MRgFUS, and MEG), whose payment rate also increased from CY 2012 (final CY 2012 payment of approximately $902) to CY 2013 (final CY 2013 geometric mean cost of approximately $1,007). CPT code 77014 has been packaged under the OPPS since 2008 when we implemented our guidance services policy.

d. Stereotactic Radiosurgery (SRS) Treatment Delivery Services (APCs 0065, 0066, 0067, and 0127)

For CY 2013, 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), which had a CY 2013 proposed payment rate of approximately $8,011.

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 2013. 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), which had a CY 2013 proposed payment rate of approximately $3,294; 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), which had a CY 2013 proposed payment rate of approximately $967; 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), which had a CY

2013 proposed payment rate of approximately $2,361.

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 urged CMS to reevaluate the APC assignments for the linear accelerator-based (LINAC) and robotic Cobalt-60 based stereotactic radiosurgery (r-SRS) HCPCS codes. The commenter stated that no clinical data exist to support the need for differential payments for LINAC-based and Cobalt-60 r-SRS procedures. The commenter further explained that there is no clinical evidence to suggest that one system is superior to the other, and the costs of purchasing and maintaining the devices are similar. The commenter recommended that CMS assign HCPCS code G0339 and CPT code 77371 to the same APC, thereby establishing payment parity for the complete course of treatment for intracranial and other head and neck r-SRS, regardless of equipment or energy source. In addition, the commenter argued that this APC reevaluation is necessary to protect the Medicare program and beneficiaries from excessive costs associated with Cobalt-60-based system, when both the LINAC-based and Cobalt-60-based systems are similar in clinical homogeneity and resource costs.

Response: We disagree with the commenter's argument that the LINAC-based and Cobalt-60 based systems have similar resource costs. For the past several years, we have seen resource differences based on the geometric mean costs for the LINAC-based and Cobalt-60-based systems, and analysis of our claims data show that the geometric mean costs for LINAC-based and Cobalt-60-based SRS procedures differ significantly. Since CY 2007, when CPT code 77371 became effective, our claims data have shown consistently a cost of more than $7,000 for the service associated with the Cobalt-60-based system, which is higher than the mean cost of approximately $3,500 for the LINAC-based system (described by HCPCS G-code G0339).

Analysis of the updated CY 2011 claims data used for this final rule with comment period indicates that the code-specific geometric mean costs for the LINAC-based and Cobalt-60-based systems continue to differ. Our updated claims data on the hospital outpatient claims available for CY 2013 ratesetting show a geometric mean cost of approximately $8,138 for CPT code 77371 based on 410 single claims (out of a total of 4,598 claims), which is significantly higher than the geometric mean costs associated with HCPCS codes G0173, G0251, G0339, and G0340. Specifically, our claims data indicate a geometric mean cost of approximately $2,605 for HCPCS code G0173 based on 923 single claims (out of a total of 1,597 claims), a geometric mean cost of approximately $1,007 for HCPCS code G0251 based on 12,965 single claims (out of a total of 13,746 claims), a geometric mean cost of approximately $3,497 for HCPCS code G0339 based on 8,287 single claims (out of a total of 10,462 claims), and a geometric mean cost of approximately $2,423 for HCPCS code G0340 based on 25,444 single claims (out of a total of 25,708 claims). Because the geometric mean costs of HCPCS code G0339 and CPT code 77371 differ significantly, we do not believe it would be appropriate to provide OPPS payment through a single APC for these r-SRS treatment delivery services in CY 2013. We continue to believe that APC 0127 is an appropriate APC assignment for CPT code 77371, and, similarly, that APC 0067 is an appropriate APC assignment for HCPCS code G0339 based on consideration of the clinical characteristics associated with these procedures and based on the geometric mean costs for these services calculated from the most recently available hospital outpatient claims and cost report data. Consistent with our current policy to annually assess the appropriateness of the APC assignments for all services under the hospital OPPS, we will continue to monitor our claims data for the SRS treatment delivery services in the future.

As we have stated in the past (74 FR 60456), the OPPS is a prospective payment system, where APC payment rates are based on the relative costs of services as reported to us by hospitals according to the most recent claims and cost report data as described in section II.A. of this final rule with comment period. The 2 times rule specifies that the mean cost of the highest cost item or service within a payment group may be no more than 2 times greater than the mean cost of the lowest cost item or service within the same group. Based on the 2 times rule, HCPCS code G0339 and CPT code 77371 could not be assigned to the same APC and, because hospitals continue to report very different costs for these services, we believe it is appropriate to maintain their assignments to different payment groups for CY 2013. As a matter of payment policy, the OPPS does not set payment rates for services based on considerations of clinical effectiveness. Furthermore, in accordance with the statute, we budget neutralize the OPPS each year in the annual update so that projected changes in spending for certain services are redistributed to payment for other services.

After consideration of the public comments we received, we are finalizing our CY 2013 proposals, without modification, to continue to assign CPT code 77371 to APC 0127, which has a final CY 2013 APC geometric mean cost of approximately $8,138, and to continue to assign HCPCS code G0339 to APC 0067, which has a final CY 2013 APC geometric mean cost of approximately $3,395.

e. Intraoperative Radiation Therapy (IORT) (APC 0412)

(1) Background

The AMA's CPT Editorial Panel created three new Category I CPT codes for intraoperative radiation therapy (IORT), effective January 1, 2012: CPT codes 77424 (Intraoperative radiation treatment delivery, x-ray, single treatment session); 77425 (Intraoperative radiation treatment delivery, electrons, single treatment session); and 77469 (Intraoperative radiation treatment management). As with all new CPT codes for CY 2012, these three codes were included in Addendum B to the CY 2012 OPPS/ASC final rule with comment period (available via the CMS Web site), effective on January 1, 2012. In accordance with our standard practice each year, our clinicians review the many CPT code changes that will be effective in the forthcoming year and make decisions regarding status indicators and/or APC assignments based on their understanding of the nature of the services. We are unable to include proposed status indicators and/or APC assignments in the proposed rule for codes that are not announced by the AMA's CPT Editorial Panel prior to the issuance of the proposed rule. Therefore, in accordance with our longstanding policy, we include, in the final rule with comment period, interim status indicators and/or APC assignments for all new CPT codes that are announced by the AMA's CPT Editorial Panel subsequent to the issuance of the OPPS/ASC proposed

rule to enable payment for new services as soon as the codes are effective.

We identified the new codes for IORT for CY 2012 in Addendum B to the CY 2012 OPPS/ASC final rule with comment period as being open to public comment by showing a comment indicator of ''NI'' and made interim status indicator assignments for each of these new IORT codes, based on our understanding of the clinical nature of the services they describe. Specifically, for CY 2012, we packaged these IORT service codes with the surgical procedures with which they are billed, assigning them interim status indicators of ''N'' (Items and Services Packaged into APC Rates). We did so based on a policy that was adopted in the CY 2008 OPPS final rule with comment period (72 FR 66610 through 66659) to package services that are typically ancillary and supportive of a principal diagnostic or therapeutic procedure, which would generally include intraoperative services. Because IORT are intraoperative services furnished as a single dose during the time of the related surgical session, we packaged them into the payment for the principal surgical procedures with which they are performed based on claims data used for the CY 2012 OPPS/ASC final rule with comment period.

Subsequent to issuance of the CY 2012 OPPS/ASC final rule with comment period, stakeholders provided comments on the interim status of these IORT service codes for CY 2012, asserting that these services are not ancillary to the surgical procedures, urging us to unpackage these codes, and requesting that we assign them to an APC reflective of the resources used to provide the IORT services. Commenters who responded to the CY 2012 OPPS/ASC final rule with comment period argued that IORT services described by CPT codes 77424 and 77425 are separate, distinct, and independent radiation treatment services from the surgical services to remove a malignant growth. According to the commenters, IORT is performed separately by a radiation oncologist and a medical physicist when there is concern for residual unresected cancer because of narrow margins related to the surgical resection. A number of the commenters provided varied estimates of the cost of IORT as between $4,000 and $7,000 per treatment, and some commenters cited a hospital survey of per treatment costs for the procedure described by CPT code 77424 of $4,441.17 and for the procedure described by CPT code 77425 of $6,897.50.

One commenter stated that the x-ray intraoperative service described by CPT code 77424 has previously been reported with CPT code 0182T (High dose rate electronic brachytherapy, per fraction), which is a separately paid OPPS service. However, the commenter pointed out that it would not be proper to report intraoperative radiation therapy with CPT code 0182T because now CPT codes 77424 and 77425 more specifically and accurately describe the intraoperative radiation services. One commenter recommended that CPT code 77425 be mapped to a new technology APC.

(2) CY 2013 Proposals for CPT Codes 77424, 77425, and 77469

Based on the public comments and information received on the IORT policies contained in the CY 2012 OPPS/ASC final rule with comment period, and after further review and consideration of those public comments and the clinical nature of the IORT procedures, we agreed that IORT services are not the typical intraoperative services that we package, as they are not integral to or dependent upon the surgical procedure to remove a malignancy that precedes IORT. Therefore, for CY 2013, we proposed to unpackage CPT codes 77424 and 77425 and assign them to APC 0412, currently titled ''IMRT Treatment Delivery'' (77 FR 45124). We stated that IORT treatment services are clinically similar to other radiation treatment forms, such as IMRT treatment, which are assigned to APC 0412. Furthermore, we proposed to change the title of APC 0412 to ''Level III Radiation Therapy'' to encompass a greater number of clinically similar radiation treatment modalities. The CY 2013 proposed rule geometric mean cost for APC 0412, based on CY 2011 claims data, was approximately $496. We also proposed to monitor hospitals' costs for furnishing the services described by CPT codes 77424 and 77425.

In the CY 2013 proposed rule, we stated that we believe that CPT code 77469 should receive equal treatment to other radiation management codes, such as CPT code 77431 (Radiation therapy management with complete course of therapy consisting of 1 or 2 fractions only) and CPT code 77432 (Stereotactic radiation treatment management of cranial lesion(s) (complete course of treatment consisting of 1 session)), which are assigned status indicator ''B'' (Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x)) and are not paid under the OPPS. Therefore, we proposed that the appropriate status indicator code assignment for CPT code 77469 be ''B'' for nonpayable status under the OPPS for CY 2013, a change from its current CY 2012 status indicator assignment of ''N'' for packaged payment status.

At its August 2012 meeting, the HOP Panel recommended that CMS assign CPT code 77424 and CPT code 77425 to APC 0313 (Brachytherapy), and consider renaming the APC ''Brachytherapy and Intraoperative Radiation Therapy.'' The Panel also recommended that CMS present to the Panel cost data regarding CPT codes 77424 and 77425, when available or by the August 2013 Panel meeting.

Comment: Many commenters supported the proposal to unpackage CPT codes 77424 and 77425, but objected to the proposed assignment of these codes to APC 0412. The commenters asserted that APC 0412 is neither reflective of the clinical characteristics nor the resources needed to perform the IORT services described by CPT codes 77424 and 77425. The commenters pointed out the clinical differences between IORT and IMRT, in that IORT provides a much higher dose of radiation during a single fraction (session) lasting about 45 minutes, while IMRT provides lower doses over multiple fractions lasting about 15 minutes. The commenters asserted that IMRT's cost over the full course of therapy is $17,000 to $20,000, much higher than IORT's cost.

Many commenters requested that CMS assign CPT codes 77424 and 77425 to an appropriate APC based on clinical similarity to other radiation treatments and suggested that CMS use external cost data to estimate the costs of IORT, because cost data from hospital claims are not yet available for these new CPT codes. Some commenters recommended that CPT codes 77424 and 77425 be assigned to APC 0313 (Brachytherapy), which has a proposed payment rate of approximately $685, because the IORT services are more similar to brachytherapy services than the IMRT services currently assigned to APC 0412. These commenters asserted that both IORT and brachytherapy involve placement of a radiation source inside or next to the area of the body requiring treatment, while IMRT, which is a form of external beam radiation therapy, delivers radiation from outside the body. The commenters opined that CPT codes 77424 and 77425 and the APC 0313 brachytherapy procedures have similar resource costs, particularly because the X-ray based IORT procedure is comparable to high dose rate (HDR) brachytherapy, and the X-ray based IORT system may be used for the delivery of fractionated breast brachytherapy, often billed with CPT

code 0182T (High dose rate electronic brachytherapy, per fraction), which is assigned to APC 0313.

Several other commenters stated that IORT is very different than HDR brachytherapy, as well as IMRT and multi-fraction stereotactic radiosurgery, in terms of both clinical characteristics and resource costs. Commenters stated that IORT capital equipment can only be used for IORT in the operating room, and not for other forms of radiation therapy, resulting in less patient utilization over which to spread costs. These commenters recommended that CMS assign CPT codes 77424 and 77425 to APC 0067 (Level III Stereotactic Radiosurgery, MRgFUS, and MEG), which has a proposed payment rate of approximately $3,294. These commenters believed that IORT is more similar clinically to stereotactic radiosurgery (SRS) than IMRT, pointing out that SRS may be delivered in single or multiple fraction therapy and has many fewer (that is, 2 to 5) fractions, making it more similar to IORT, in that regard. A few commenters recommended that CMS assign IORT to a New Technology APC, with a wide range of recommended payment rates, from approximately $4,000 to approximately $7,000, citing various data estimates and sources including a survey of hospitals.

Regarding our proposal to change the status indicator for CPT code 77469 to ''B'' and make the service non-payable, one commenter supported the proposed change on the basis that it is consistent with our policy regarding other radiation treatment management codes.

Response: We appreciate all of the feedback we received on the CY 2012 interim status indicator assignment of ''N'' to CPT codes 77424 and 77425 and the CY 2013 proposal to assign these CPT codes to APC 0412. As stated in the CY 2013 OPPS/ASC proposed rule and described above, we agree with the commenters that IORT services are not the typical intraoperative services that we package, as they are not integral to or dependent upon the surgical procedure to remove a malignancy that precedes IORT.

We agree with commenters that the resource costs of APC 0412 do not fit well with single fraction radiation therapy technologies, such as IORT. However, we believe the resource costs of IORT can be accommodated by one of the existing APCs for radiation therapy, and therefore, a new technology APC assignment is not needed. From a clinical standpoint, we agree with commenters that the procedures described by CPT codes 77424 and 77425 share important characteristics with SRS, particularly because SRS may be a single fraction therapy or involve many fewer fractions than IMRT. Based on the range of claimed costs provided by the commenters, which are all based on external costs, as we do not yet have claims data, there is clearly a wide range of reported or estimated costs for IORT services, and, as some commenters indicate, there may be a difference in the cost structures of CPT codes 77424 and 77425.

After consideration of the public comments we received, we believe that an appropriate initial APC assignment for CPT codes 77424 and 77425 is APC 0065 (Level I Stereotactic Radiosurgery, MRgFUS, and MEG), in terms of clinical characteristics, and the range of estimated costs for IORT services. Therefore, for CY 2013, we are assigning CPT codes 77424 and 77425 to APC 0065, which has a CY 2013 final geometric mean cost of approximately $1,006. We will review the APC assignment of CPT codes 77424 and 77425, individually, once we have OPPS hospital claims data. Regarding the Panel recommendation that we present to the Panel cost data regarding CPT codes 77424 and 77425, we agree to provide cost data from claims for these service codes when available.

7. Imaging

a. Non-Ophthalmic Fluorescent Vascular Angiography (APC 0397)

Effective April 1, 2012, we created HCPCS code C9733 (Non-ophthalmic fluorescent vascular angiography (FVA)) for a service that became known to us via the new technology APC application process. We assigned HCPCS code C9733 to APC 0397 (Vascular Imaging), which has a CY 2012 payment rate of $154.87 and a status indicator assignment of ''Q2.'' The ''Q2'' status indicator provides that the service will have packaged APC payment if billed on the same date of service as a HCPCS code assigned status indicator ''T''; and in all other circumstances, there is a separate APC payment for the service. We proposed to continue to assign HCPCS code C9733 to APC 0397 for CY 2013, which had a CY 2013 proposed payment rate of $192.21, and to continue the assignment of the code to the ''Q2'' status indicator.

The HOP Panel, at its August 2012 meeting, recommended that CMS maintain a status indicator of ''Q2'' for HCPCS code C9733, while making no recommendation as to its APC assignment. The proposed payment rate for APC 0397 was $197.08, with a range in individual procedure geometric mean costs from $140.78 to $202.97. We proposed the assignment of HCPCS code C9733 to APC 0397 because we believed that the service described by HCPCS code C9733 is similar in clinical characteristics to other vascular imaging services. We do not have claims cost data available for HCPCS code C9733 because it was made effective on April 1, 2012. For new HCPCS codes, our longstanding policy is to wait until we have claims data on new services before considering them for reassignment to clinical APCs other than the originally assigned APC.

Comment: A number of commenters were appreciative that CMS created a new HCPCS code for non-ophthalmic FVA, but were concerned with the packaged status that would result from assigning HCPCS code C9733 status indicator ''Q2'' because the procedure is usually performed with a service having a ''T'' status indicator. A few commenters pointed out that FVA is effective in assessing perfusion in tissue, and is particularly useful when vascular function is diminished. A number of commenters pointed out that the procedure is performed intraoperatively for this purpose, and is a valuable tool to assist the surgeon with clinical decision-making. Commenters also pointed out that the non-ophthalmic FVA procedure has been used primarily in the hospital inpatient setting, and only recently offered in the hospital outpatient setting; therefore, outpatient data are only beginning to accumulate. However, commenters believed that because the ''Q2'' status indicator will typically result in packaging the cost of the procedure, the procedure will not be performed at many hospitals. The commenters asserted that it was very important that CMS change the status indicator of HCPCS code C9733 to ''S,'' which is the same status indicator as all other procedures assigned to APC 0397. Moreover, some commenters stated that other vascular imaging procedures, such as Doppler Ultrasound, fluoroscopy, and magnetic resonance angiography (MRA), are alternatives to the procedure described by HCPCS code C9733 and are assigned status indicator ''S'' rather than status indicator ''Q2.'' Another commenter noted that other modalities used for tissue perfusion screening in the hospital outpatient setting are assigned to APC 0096 (Level II Noninvasive Physiologic Studies), and these procedures also are assigned status indicator ''S.'' The commenter opined that assignment of status indicator ''Q2'' will encourage outpatient clinics to schedule multiple

visits to avoid the packaging of HCPCS code C9733. One commenter claimed that only a small number of APCs have more than one status indicator for their assigned procedures, and that no other HCPCS C-codes have a status indicator of ''Q2.'' The commenter asserted that packaged status should only be assigned to procedures where data indicate that the costs and services associated with the procedure are integral to existing procedures.

One commenter asserted that the assignment of HCPCS code C9733 to APC 0397 is not appropriate based on the costs of the procedure, and estimated that the cost is approximately $2,100 per procedure. The commenter stated that this estimate is based on a $6,000 monthly lease payment of the system's capital with 5 times per month use, disposable kit costs of approximately $800, plus $100 in indirect costs. The commenter recommended the assignment of HCPCS code C9733 to APC 0279 (Level II Angiography and Venography), which has a CY 2013 proposed payment rate of approximately $2,219, or assignment of the C-code to New Technology APC 1522 (Level XXII New Technology), which has a CY 2013 proposed payment rate of $2,250, for at least a 3-year transitional period, until the costs to perform the non-ophthalmic FVA procedure are known, in order to package the procedure.

A few commenters were concerned that the HOP Panel, and perhaps CMS as well, were confusing the HCPCS code C9733 technology with a ''Wood's Lamp.'' The commenters explained the differences in the two technologies, indicating that there are clinically significant differences as a result of the properties of the fluorescent dyes with which they are used.

Response: We believe that, when the non-ophthalmic FVA procedure is performed with a surgical procedure, it is ancillary to the surgical service, providing imaging services that are supportive and adjunctive to the surgical service. As a number of commenters stated, the procedure is used intraoperatively to assist the surgeon. In those instances when the service described by HCPCS code C9733 is performed as a stand-alone service, it is separately paid. Therefore, we believe the ''Q2'' status indicator is appropriate. Regarding the comment that there are only a few APCs that have more than one status indicator, we assign status indicators to HCPCS codes, not to APCs. APCs are sometimes composed of procedures that have similar roles in the overall provision of services (for example, they are either major or minor services, serve an adjunct role), but this is not always the case. We disagree that the ''Q2'' status indicator will encourage multiple clinic visits. In cases where surgery requires intraoperative imaging to assess tissue perfusion, the procedure described by HCPCS code C9733 cannot be provided separate from the surgery. Regarding the estimated cost of the procedure that a commenter provided, we note that the assumptions regarding the use of the capital equipment markedly affects the estimate of the cost of the procedure. The commenter's assumed use of the equipment at 5 times per month, results in the $1,200 monthly capital cost. However, an assumed monthly use of 20 times results in $300 monthly costs, and 30 times per month results in $200 monthly capital costs, and so on. Low utilization of a new technology can result in aberrantly high per case cost estimates and illustrates why it is important for us to wait until hospital outpatient claims data become available to us for use in ratesetting. We understand the differences between the non-ophthalmic FVA and Wood's Lamp technologies, and assure the commenters that our decision is not based on any confusion regarding the two technologies.

After consideration of the public comments we received, we are finalizing our CY 2013 proposal to assign HCPCS code C9733 to APC 0397 and to continue to assign the code to status indicator ''Q2.'' APC 0397 has a CY 2013 final geometric mean cost of approximately $340, which we note is a significant increase over the CY 2012 proposed rule mean cost.

b. Level II Nervous System Imaging (APC 0402)

For CY 2013, we proposed to continue to assign CPT code 78607 (Brain imaging, tomographic (spect)) in APC 0402 (Level II Nervous System Imaging), which had a proposed payment rate of approximately $477.

Comment: Some commenters requested that CMS assess the accuracy of the payment rate calculation for APC 0402. One commenter stated that the proposed 22-percent payment reduction does not appear to be due to any significant reduction in hospital charges for the procedures included in the APC or the shift from the use of medical charges to the use of the geometric mean cost. Another commenter requested that CMS reassess its APC payment rate calculation, including the proposed geometric mean cost of brain SPECT, which is described by CPT code 78607, and only phase in a change to the APC payment rate if the data support a reduction.

Response: We reviewed our claims data and, for the CY 2013 update, used more claims to determine the payment rate for APC 0402, as compared to the CY 2012 update. For the CY 2012 final rule with comment period, there were 2,593 single claims (out of 4,643 total claims), while for the CY 2013 proposed rule, there were 3,062 single claims (out of 4,793 total claims) used to calculate the proposed payment rate for APC 0402. Also, as indicated in the file that we made available with the proposed rule entitled ''CY 2013 OPPS Comparison Between Proposed Geometric Mean and Median Based Payments,'' the proposed payment rate using either payment methodology shows a decrease in the payment rate for APC 0402 for the CY 2013 update. That is, the CY 2013 proposed payment rate for APC 0402, based on the median cost methodology, was approximately $497, while the geometric mean cost methodology resulted in a CY 2013 proposed payment rate of approximately $477. While the proposed payment rate decreased for APC 0402, overall, the use of the geometric mean methodology has been positive for many services. In addition, basing the OPPS payment calculations on geometric means aligns the metric used in the ratesetting methodology for the OPPS with that used for the IPPS.

Further examination of the claims data used for this final rule with comment period revealed an increase in services assigned to APC 0402. Specifically, our claims data show a geometric mean cost of approximately $472 based on 3,446 single claims (out of 5,345 total claims). Similarly, we saw the same pattern of increase in services and cost for CPT code 78607 from the proposed rule claims data to this final rule claims data. That is, for the CY 2013 OPPS/ASC proposed rule, the proposed geometric mean cost for CPT code 78607 was approximately $490 based on 2,295 single claims (out of 2,573 total claims), while the final rule geometric mean cost is approximately $468 based on 2,592 single claims (out of 2,902 total claims). We note that CPT code 78607 represents 75 percent of the claims for services assigned to APC 0402. Because of the robust claims, we believe that our claims data accurately reflect the resource costs of the procedures assigned to APC 0402, including the service described by CPT code 78607. We do not believe that applying a phase-in change to the APC payment rate for the brain SPECT CPT code 78607 is necessary, given the significant claims data for this procedure.

After consideration of the public comments we received, we are finalizing our CY 2013 proposal, without modification, to continue to assign CPT code 78607 to APC 0402. The final CY 2013 geometric mean cost for APC 0402 is approximately $472.

c. Computed Tomography of Abdomen/Pelvis (APCs 0331 and 0334)

For CY 2011, the AMA's CPT Editorial Panel established three new CPT codes to describe computed tomography of the abdomen and pelvis. CPT codes 74176 (Computed tomography, abdomen and pelvis; without contrast material), 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) were effective January 1, 2011. As shown in Table 26, for CY 2011, these services were paid under one of two methods under the OPPS. They were either paid separately through a single APC or through a composite APC. We assigned CPT code 74176 to APC 0332 (Computed Tomography Without Contrast), CPT code 74177 to APC 0283 (Computed Tomography With Contrast), and CPT code 74178 to APC 0333 (Computed Tomography Without Contrast Followed By Contrast). We also assigned CPT code 74176 to composite APC 8005 (CT and CTA Without Contrast Composite), and CPT codes 74177 and 74178 to composite 8006 (CT and CTA With Contrast Composite). We assigned the CPT codes to status indicator ''Q3'' to indicate that they were eligible for composite payment under the multiple imaging composite APC methodology when they are furnished with other computed tomography procedures performed on the same patient on the same day.

TABLE 26.—CY 2011 OPPS APC ASSIGNMENTS FOR THE COMPUTED TOMOGRAPHY OF ABDOMEN AND PELVIS CPT CODES

CY 2011 CPT Code	CY 2011 Short Descriptor	CY 2011 SI	CY 2011 Single Code APC	CY 2011 Single Code APC Payment Rate	CY 2011 Composite APC	CY 2011 Composite APC Payment Rate
74176	Ct abd & pelvis	Q3	0332	$193.85	8005	$420.85
74177	Ct abd & pelv w/contrast	Q3	0283	$299.81	8006	$628.61
74178	Ct abd & pelv 1/> regns	Q3	0333	$334.24	8006	$628.61

Consistent with our longstanding policy for new codes, in Addendum B of the CY 2011 OPPS/ASC final rule with comment period, we assigned these new CPT codes to interim APCs for CY 2011, with comment indicator ''NI'' to denote that the codes were new and the interim APC assignment would be open to public comment. In accordance with our longstanding policy to provide codes to enable payment to be made for new services as soon as the code is effective, our interim APC assignment for each code was based on our understanding of the resources required to furnish the service and its clinical characteristics as defined in the code descriptor.

As we described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74259), in general, stakeholders who provided comments on the interim APC assignments of these CPT codes for CY 2011 stated that the most appropriate approach to establishing payment for these new codes was to assign the procedures described by the codes 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 services under the OPPS than 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. In addition, at the February 28-March 1, 2011 Panel meeting, several presenters expressed their concern and disagreement with our single APC assignments for these new codes. The presenters stated that the payment rates for the single APC assignments reflected only half of the true costs of these services based on their internal calculated costs. Similar to the public commenters, the presenters indicated that, prior to CY 2011, these services were reported using a combination of codes, and suggested that CMS revise the methodology to include these combinations of codes to determine accurate payment rates for these services. Specifically, the presenters indicated that simulating the costs for CPT codes 74176, 74177, and 74178 using historical claims data from the predecessor codes would result in the best estimates of costs for these CPT codes and, therefore, the most accurate payment rates.

After examination of our claims data for the predecessor codes, and after considering the various concerns and recommendations that we received on this issue (specifically, the views of the stakeholders who met with us to discuss this issue, the comments received in response to the CY 2011 OPPS/ASC final rule with public comment period, and input from the Panel at its February 28-March 1, 2011 meeting), we proposed to revise our payment methodology for CPT codes 74176, 74177, and 74178 for CY 2012 (76 FR 42235). That is, we proposed to simulate the costs for CPT codes 74176, 74177, and 74178 using historical claims data from the predecessor codes to determine the most accurate payment rates for these CPT codes. This new proposed payment methodology necessitated establishing two new APCs, specifically, APC 0331 (Combined Abdominal and Pelvis CT Without Contrast) to which CPT code 74176 would be assigned, and

APC 0334 (Combined Abdominal and Pelvis CT With Contrast) to which CPT codes 74177 and 74178 would be assigned. In addition, we proposed to continue to assign CPT code 74176 to composite APC 8005 and CPT codes 74177 and 74178 to composite APC 8006 for CY 2012.

Based on the feedback that we received from the Panel at its August 10–11, 2011 meeting, and the public comments received in response to the CY 2012 OPPS/ASC proposed rule in support of the proposed revised payment methodology for CPT codes 74176, 74177, and 74178, we finalized our proposals in the CY 2012 OPPS/ASC final rule with comment period. Specifically, we reassigned CPT code 74176 from APC 0332 to APC 0331, CPT code 74177 from APC 0283 to APC 0334, and CPT code 74178 from APC 0333 to APC 0334. (We refer readers to the CY 2012 OPPS/ASC final rule with comment period for a detailed description of the methodology we used to simulate the costs of these procedures using claims data for the predecessor CPT codes (76 FR 74259 through 74262).) We also continued with our composite APC assignments for these codes. Specifically, we continued to assign CPT code 74176 to composite APC 8005 and CPT codes 74177 and 74178 to composite APC 8006. Table 27 below shows the payment rates for these CPT codes for the CY 2012 update.

TABLE 27.—CY 2012 OPPS APC ASSIGNMENTS FOR THE COMPUTED TOMOGRAPHY OF ABDOMEN AND PELVIS CPT CODES

CY 2012 CPT Code	CY 2012 Short Descriptor	CY 2012 SI	CY 2012 Single Code APC	CY 2012 Single Code APC Payment Rate	CY 2012 Composite APC	CY 2012 Composite APC Payment Rate
74176	Ct abd & pelvis	Q3	0331	$405.17	8005	$431.60
74177	Ct abd & pelv w/contrast	Q3	0334	$580.54	8006	$721.12
74178	Ct abd & pelv 1/> regns	Q3	0334	$580.54	8006	$721.12

We stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74262) that we would reassess whether there is a continued need for these APCs for the CY 2013 OPPS/ASC update once we have actual charges for these services. Because CPT codes 74176, 74177, and 74178 became effective on January 1, 2011, we have hospital claims data available for these codes that we can use for ratesetting for the first time. In the CY 2013 OPPS/ASC proposed rule (77 FR 45086), we stated that analysis of the latest CY 2011 hospital outpatient claims data for the CY 2013 OPPS/ASC proposed rulemaking update, which was based on claims processed with dates of service from January 1, 2011 through December 31, 2011, revealed a decrease in costs for the three procedures, compared to the costs simulated using the predecessor CPT codes for CY 2012. CPT code 74176 showed a proposed geometric mean cost of approximately $314 based on 312,493 single claims (out of 713,662 total claims), while CPT code 74177 showed a proposed geometric mean cost of approximately $476 based on 367,002 single claims (out of 951,296 total claims). In addition, CPT code 74178 showed a proposed geometric mean cost of approximately $537 based on 184,580 single claims (out of 267,401 total claims). Because we used hospital claims data specific to CPT codes 74176, 74177, and 74178, we stated that we believe these costs accurately reflect the resources associated with providing computed tomography of the abdomen and pelvis as described by these CPT codes in the HOPD.

Furthermore, our analysis of the CY 2011 claims data available for the proposed rule showed no 2 times rule violation for either APC 0331 or APC 0334. Therefore, for CY 2013, we proposed to continue to assign CPT code 74176 to APC 0331 and CPT codes 74177 and 74178 to APC 0334. (Because we have claims data available for these three CPT codes, we will no longer simulate their costs using the predecessor codes as we did in CY 2012.) In addition, we proposed to continue to assign these codes to their existing composite APCs for CY 2013. Specifically, we proposed to continue to assign CPT code 74176 to composite APC 8005, and to assign CPT codes 74177 and 74178 to composite APC 8006.

Comment: Several commenters expressed concern with the decreased payment rates for APCs 0331 and 0334, and suggested that the coding changes that occurred in CY 2011 for CPT codes 74176, 74177, and 74178, attributed to the payment reduction. Some of the commenters believed that because the codes were new in CY 2011, hospitals have not had enough time to appropriately adjust their charge masters to accurately reflect the CY 2011 coding changes. One commenter urged CMS to take whatever action necessary to mitigate the payment cuts for CY 2013. Some of commenters requested that CMS delay the use of claims data and continue the use of historical data for an additional year to give more time for education and adjustment of hospital charge masters.

Response: We believe that hospitals have a process in place to adjust to the numerous coding changes that occur annually. There are hundreds of coding changes (that is, CPT, Level II Alphanumeric HCPCS, and ICD–9–CM codes) that occur every year, and hospitals make changes to their internal systems (for example, coding, charge masters, grouper, business office systems, among other) accordingly to capture these changes so that their claims are processed timely and accurately.

Because of the substantial claims data that we have for these procedures, we see no reason to delay the use of the claims data in determining the costs for

CPT codes 74176, 74177, and 74178. Specifically, we were able to use at least 1 million claims that were submitted during CY 2011 in determining the payment rates for CPT codes 74176, 74177, and 74178. Our analysis for this final rule with comment period revealed a geometric mean cost of approximately $315 for CPT code 74176 based on 333,144 single claims (out of 769,757 total claims), a geometric mean cost of approximately $477 for CPT code 74177 based on 388,506 single claims (out of 1,024,117 total claims), and a geometric mean cost of approximately $538 for CPT code 74178 based on 194,216 single claims (out of 283,435 total claims). We have no reason to believe that our claims data, as reported by hospitals, do not accurately reflect the hospital costs for CPT codes 74176, 74177 and 74178.

After consideration of the public comments received, we are finalizing our CY 2013 proposal, without modification. Specifically, for CY 2013, we are continuing to assign CPT code 74176 to APC 0331 and CPT codes 74177 and 74178 to APC 0334. In addition, we are continuing to assign these CPT codes to their existing composite APCs for CY 2013. Specifically, we are continuing to assign CPT code 74176 to composite APC 8005, and to assign CPT codes 74177 and 74178 to composite APC 8006.

Table 28 below lists the computed tomography of the abdomen and pelvis CPT codes along with their status indicators, and single and composite APC assignments for CY 2013.

TABLE 28.—APC ASSIGNMENTS FOR THE COMPUTED TOMOGRAPHY OF ABDOMEN AND PELVIS CPT CODES FOR CY 2013

CY 2013 CPT Code	CY 2013 Short Descriptor	CY 2013 SI	CY 2013 Single Code APC	CY 2013 Composite APC
74176	Ct abd & pelvis	Q3	0331	8005
74177	Ct abd & pelv w/contrast	Q3	0334	8006
74178	Ct abd & pelv 1/> regns	Q3	0334	8006

8. Respiratory Services

a. Bronchoscopy (APC 0415)

CPT code 31629 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial needle aspiration biopsy(s), trachea, main stem and/or lobar bronchus(i)) was established by the AMA's CPT Editorial Panel in 1987. CPT code 31634 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, with assessment of air leak, with administration of occlusive substance (eg, fibrin glue), if performed) was established effective January 1, 2011. CPT code 31629 has been assigned to APC 0076 (Level I Endoscopy Lower Airway) since August 2000, when the hospital OPPS was implemented, while CPT code 31634 has been assigned to APC 0076 since the code was effective on January 1, 2011.

In the CY 2013 OPPS/ASC proposed rule, we proposed to reassign both CPT codes 31629 and 31634 from APC 0076 to APC 0415 (the Level II Endoscopy Lower Airway). Consistent with CMS' policy of reviewing APC assignments annually for any 2 times rule violations and appropriateness of APC assignments based on the latest hospital outpatient claims data, we evaluated the resource cost associated with the procedures assigned to APC 0076 for the CY 2013 rulemaking update. Based on our analysis, we determined that the configuration of APC 0076 violated the 2 times rule. To eliminate the 2 times rule violation, we proposed to reassign CPT codes 31629 and 31634 from APC 0076 to APC 0415 because we believe this APC appropriately reflects these services based on their resource costs as well as clinical homogeneity.

At the August 2012 HOP Panel meeting, a presenter requested that the Panel recommend to CMS not to reassign CPT codes 31629 and 31634 to APC 0415 for CY 2013. The presenter stated that including both procedures in APC 0415 would result in a 2 times rule violation. In addition, the presenter recommended that CPT codes 31629 and 31634 be reassigned to APC 0074 (Level IV Endoscopy Upper Airway) instead of APC 0415. After discussion of the procedures and review of the hospital outpatient claims and cost report data, the Panel recommended that CPT codes 31629 and 31634 be reassigned from APC 0076 to APC 0415 for the CY 2013 OPPS update.

Comment: Some commenters disagreed with the proposal to include CPT codes 31629 and 31634 in APC 0415, and indicated that including both procedures reduces the proposed payment rate for APC 0415 by at least 23 percent. One commenter specified that adding CPT codes 31629 and 31634, which have greater volumes of lower geometric mean costs than other services assigned to APC 0415, reduces the overall payment of APC 0415. One commenter indicated that the reduction in payment would hinder patient access to the pulmonary services listed under APC 0415 and recommended alternative endoscopy lower airway APC configurations, such as establishing a new APC titled ''Level III Endoscopy Lower Airway'' for six lower endoscopy procedures, that would include both CPT codes 31629 and 31634 as well as four other lower endoscopy procedures. Specifically, the commenter suggested including 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)), 31636 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of bronchial stent(s) (includes tracheal/bronchial dilation as required), initial bronchus), 31638 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with revision of tracheal or bronchial stent inserted at previous session (includes tracheal/bronchial

dilation as required)), and CPT codes 31629 and 31634. The commenter explained that CPT codes 31626, 31631, 31636, and 31638 are different from other procedures assigned to APC 0415 because they require implanting medical devices in the patient (fiducial markers, stents), which results in extra cost. Another commenter requested that CMS reevaluate the endoscopy lower airway APCs (0076 and 0415) as more claims data become available for newer procedures, and to meet with stakeholders to discuss the future reconfiguration of APCs for endoscopy lower airway.

Response: As indicated above, we proposed to revise the APC assignments for CPT codes 31629 and 31634 after our analysis of the claims data for the CY 2013 rulemaking revealed a 2 times rule violation in APC 0076. Based on the latest hospital outpatient claims data for this final rule with comment period, we do not agree with the commenters that we should implement an alternative configuration for endoscopy lower airway APCs because the existing APCs are sufficient to reflect the costs of all of the procedures assigned to these APCs. We continue to believe that APC 0415 is the most appropriate APC assignment for CPT codes 31629 and 31634 because their resource costs are relatively similar to the procedures assigned to APC 0415. Therefore, we are accepting the Panel's recommendation and will assign both procedures to APC 0415. For the CY 2013 update, our analysis of the claims data submitted during CY 2011 and used for this final rule with comment period show a geometric mean cost of approximately $1,381 based on 2,699 single claims (out of 12,209 total claims) for CPT code 31629, and a relatively similar geometric mean cost of approximately $1,394 for CPT code 31634 based on 10 single claims (out of 16 total claims). Consistent with CMS' policy of reviewing APC assignments annually, we will again reevaluate the clinical similarity and resource use of the procedures in APC 0415 for the CY 2014 rulemaking cycle. Finally, we note that we regularly accept meetings from interested parties throughout the year, and we encourage stakeholders to continue a dialogue with us during the rulemaking cycle and throughout the year on this issue.

After consideration of the public comments we received, we are finalizing our CY 2013 proposal, without modification, to reassign CPT codes 31629 and 31634 from APC 0076 to APC 0415. The final CY 2013 geometric mean cost for APC 0415 is approximately $1,617.

b. Upper Airway Endoscopy (APC 0075)

For CY 2013, we proposed to continue to assign CPT codes 31295 (Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (eg, balloon dilation), transnasal or via canine fossa;), 31296 (Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (eg, balloon dilation)), and 31297 (Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (eg, balloon dilation)) to APC 0075 (Level V Endoscopy Upper Airway), which had a CY 2013 proposed payment rate of approximately $2,039. In addition, we proposed to reassign CPT code 31541 (Laryngoscopy, direct, operative, with excision of tumor and/or stripping of vocal cords or epiglottis; with operating microscope or telescope) from APC 0074 (Level IV Endoscopy Upper Airway) to APC 0075.

Comment: Commenters objected to the assignment of CPT codes 31295, 31296, and 31297 to APC 0075 because the commenters believed that the payment rate for APC 0075 substantially underpays providers. The commenters recommended that CMS create split APCs for sinus surgery with balloon catheter and without balloon catheter, the former of which should be deemed device-dependent to appropriately account for the cost of such procedures. The commenters also requested that CMS not finalize its proposal to reassign CPT 31541 to APC 0075 and, instead, maintain the code in APC 0074 for CY 2013.

Response: We believe that the most clinically appropriate APC assignment for CPT codes 31295, 31296, and 31297 is APC 0075, which includes other nasal and sinus endoscopy procedures. When assigning procedures to an APC, we first consider the clinical and resource characteristics of a procedure and determine the most appropriate APC assignment. 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 geometric mean cost of all of the procedures assigned to APC 0075 is approximately $4,000. Therefore, even the nonclaims 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 the geometric mean costs for procedures assigned to APC 0075. We do not agree with the commenters that new APCs should be created to differentiate between sinus surgery with balloon catheter and without balloon catheter, as APC 0075 accurately reflects a reasonable distribution of resource costs reflected in the group of clinically similar services currently assigned to the APC. We note that there is currently no 2 times rule violation in APC 0075. We do not agree with the commenters that CPT code 31541 should continue to be assigned to APC 0074, as CPT code 31541's geometric mean cost of approximately $1,962 is higher than the geometric mean cost for any service currently assigned to APC 0074 and would result in a 2 times rule violation for APC 0074 as well. We believe that the geometric mean cost and clinical characteristics of CPT code 31541 justify its assignment to APC 0075 for CY 2013.

After consideration of the public comments we received, we are finalizing our CY 2013 proposals, without modification, to continue to assign CPT codes 31295, 31296, and 31297 to APC 0075, and reassign CPT code 31541 to APC 0075, which has a final CY 2013 APC geometric mean cost of approximately $2,085.

9. Other Services

a. Payment for Molecular Pathology Services

For the January 2012 update, the AMA's CPT Editorial Panel established 101 new molecular pathology services CPT codes that were designated as either Molecular Pathology Procedures Tier 1 or Molecular Pathology Procedures Tier 2 effective January 1, 2012. Tier 1 consisted of CPT codes 81200 through 81383, while Tier 2 consisted of CPT codes 81400 through 81408. However, these new molecular pathology CPT codes are not valid for payment under Medicare for CY 2012.

Instead, molecular pathology tests for CY 2012 are billed using combinations of longstanding CPT codes that describe each of the various steps required to perform a given test. This billing method is called ''stacking'' because different ''stacks'' of codes are billed depending on the components of the furnished test. Currently, all of the stacking codes are paid under the Clinical Laboratory Fee Schedule (CLFS) and one stacking code, CPT code 83912 (Molecular diagnostics; interpretation and report), is paid on both the CLFS and the Medicare Physician Fee Schedule (MPFS). Payment for the interpretation and report of a molecular pathology test when furnished and billed by a physician is made under the MPFS using the professional component (PC, or modifier ''26'') of CPT code 83912

(83912–26). Payment for the interpretation and report of a molecular pathology test when furnished by nonphysician laboratory staff is made under the CLFS using CPT code 83912. Thus, under Medicare, molecular pathology services are paid under a fee schedule other than the OPPS.

In Addendum B of the CY 2012 OPPS/ASC final rule with comment period, we assigned the 101 molecular pathology services CPT codes to status indicator ''B'' to indicate that Medicare recognizes another more specific HCPCS code for the service, as well as to comment indicator ''NI'' to indicate that the CPT code was new for CY 2012 and that public comments would be accepted on the interim APC assignment for the new code, if applicable. We subsequently corrected the status indicator assignment for these CPT codes from ''B'' to ''E'' to indicate that they are not paid by Medicare in Addendum B of the CY 2012 OPPS/ASC final rule with comment period that was posted on the CMS Web site. In the CY 2013 OPPS/ASC proposed rule, we proposed to reassign the status indicator for the 101 molecular pathology services CPT codes from ''E'' to ''A'' for CY 2013 to indicate that the codes would be paid under a Medicare fee schedule and not under the OPPS. The public comments that we received in response to the CY 2012 OPPS/ASC final rule with comment period and the CY 2013 OPPS/ASC proposed rule are addressed below.

Comment: One commenter to the CY 2012 OPPS/ASC final rule with comment period requested that CMS consider paying separately for the molecular pathology services under the OPPS, and recommended that CMS reassign the services to status indicator ''X'' (Paid under OPPS; separate APC payment).

Several commenters who responded to the CY 2013 OPPS/ASC proposed rule requested clarification of the status indicator assignment and payment status for the molecular pathology services. One commenter indicated that CMS did not specify whether CPT codes 81200 through 81299, 81300 through 81383, and 81400 through 81408 will continue to be assigned status indicator ''E'' under the OPPS.

Another commenter pointed out that CMS did not specifically discuss the 101 molecular pathology services CPT codes in the CY 2013 OPPS/ASC proposed rule, but did propose to assign status indicator ''A'' to the new molecular pathology services CPT codes. The commenter believed that CMS is unsure as to how these services will be paid, whether they will be paid under the MPFS or under the CLFS. The commenter recommended that CMS pay for the molecular pathology services codes under the MPFS to cover the professional interpretation and work components, and under the OPPS to cover the technical component of the services when provided in a HOPD.

Response: Molecular pathology services are not paid under the OPPS. As explained above, molecular pathology services currently are billed using stacking codes that are paid under the CLFS with one stacking code, specifically, CPT code 83912, being paid under both the CLFS and the MPFS. For the CY 2013 update, the CPT ''stacking'' codes 83890 through 83914 will be deleted on December 31, 2012, and will be replaced with 115 new molecular pathology CPT codes. Specifically, this includes the 101 molecular pathology services CPT codes discussed above plus an additional 14 new Tier I Molecular Pathology Procedure CPT codes that the AMA's CPT Editorial Panel established effective January 1, 2013. In addition, CMS established one HCPCS G-code effective January 1, 2013. With the exception of the HCPCS G-code, the 115 molecular pathology CPT codes will be paid under the CLFS. Payment for the interpretation and report of a molecular pathology test when furnished and billed by a physician will be made under the MPFS using the professional component-only HCPCS code G0452 (Molecular pathology procedure; physican interpretation and report). We refer readers to the CY 2013 MPFS final rule with comment period for further information on the molecular pathology services CPT codes.

Although we did not discuss this issue in the preamble of the CY 2013 OPPS/ASC proposed rule, we proposed to assign the 101 molecular pathology services CPT codes to status indicator ''A'' for the CY 2013 update. Specifically, we assigned the 101 molecular pathology services CPT codes to status indicator ''A'' in Addendum B to the proposed rule (which is available via the Internet on the CMS Web site). We note that HCPCS codes listed in Addenda A and B are subject to comment, and responses to the comments received are addressed in the final rule with comment period.

For CY 2013, the 101 molecular pathology services CPT codes will be assigned to status indicator ''A'' because they will be paid under the CLFS. Consistent with the OPPS assignment for the 101 molecular pathology services, the 14 new CPT codes also will be assigned to status indicator ''A'' for CY 2013. Specifically, CPT codes 81201 through 81203, 81235, 81252 through 81254, 81321 through 81326, and 81479 will be assigned to status indicator ''A'' because they will be paid under the CLFS. In addition, HCPCS code G0452 will be assigned to status indicator ''B'' to indicate that the HCPCS code describes a professional component-only service that is paid under the MPFS.

In summary, after consideration of the public comments we received, we are finalizing our proposal, without modification, to assign the 101 molecular pathology services CPT codes to status indicator ''A'' for CY 2013. Consistent with the OPPS assignment for the 101 molecular pathology services, the 14 new CPT codes also will be assigned to status indicator ''A'' for CY 2013. In addition, HCPCS code G0452 will be assigned to status indicator ''B'' under the OPPS for the CY 2013 update.

b. Bone Marrow (APC 0112)

For CY 2013, we proposed to continue to assign CPT code 38240 (Bone marrow or blood-derived peripheral stem cell transplantation; allogeneic) and CPT code 38241 (Bone marrow or blood-derived peripheral stem cell transplantation; autologous) to APC 0112 (Apheresis and Stem Cell Procedures), which had a CY 2013 proposed payment rate of approximately $2,878.

Comment: One commenter requested that CMS create separate APCs for autologous and allogeneic transplants in recognition of the cost difference between the two procedures. In addition, the commenter urged CMS to develop an alternate ratesetting methodology for low volume services or services performed by a small number of providers to more accurately capture their costs.

Response: We believe that CPT codes 38240 and 38241 are both appropriately assigned to APC 0112 based on clinical homogeneity. We note that there is no 2 times rule violation in APC 0112; therefore, we do not agree with the commenter's suggestion that we need to create separate APCs for autologous and allogeneic transplants. We appreciate the commenter's interest in developing an alternate ratesetting methodology for low-volume services as we are always eager to find improved methods to more accurately capture costs of services performed in the hospital outpatient setting.

After consideration of the public comment we received, we are finalizing our CY 2013 proposal, without modification, to continue to assign CPT codes 38240 and 38241 to APC 0112,

which has a final CY 2013 APC geometric mean cost of approximately $2,972.

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, which 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 four 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 made effective for pass-through payment October 1, 2010; HCPCS codes C1830 (Powered bone marrow biopsy needle) and C1840 (Lens, intraocular (telescopic)), which we made effective for pass-through payment October 1, 2011; and HCPCS code C1886 (Catheter, extravascular tissue ablation, any modality (insertable)), which we made effective for pass-through payment January 1, 2012. In the CY 2012 OPPS/ASC final rule with comment period, we finalized the expiration of pass-through payment for HCPCS code C1749, which will expire after December 31, 2012 (76 FR 74278). Therefore, after December 31, 2012, we will package the costs of the HCPCS code C1749 device into the costs of the procedures with which the devices are reported in the hospital claims data used in OPPS ratesetting.

b. CY 2013 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 categories C1830 and C1840 were established for pass-through payments on October 1, 2011, 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 2013. Also, device pass-through category C1886 was established for pass-through payments on January 1, 2012, and will have been eligible for pass-through payments for at least 2 years but less than 3 years as of the end of CY 2013. Therefore, in the CY 2013 OPPS/ASC proposed rule (77 FR 45125), we proposed a pass-through payment expiration date for device categories C1830, C1840, and C1886 of December 31, 2013. Under our proposal, beginning January 1, 2014, device categories C1830, C1840, and C1886 will no longer be eligible for pass-through payments, and their respective device costs would be packaged into the costs of the procedures with which the devices are reported in the claims data.

Comment: One commenter expressed concern that under the CMS proposal to expire device HCPCS code C1886 from pass-through payment, CMS will have difficulty in establishing a payment rate that will reflect all costs associated with bronchial thermoplasty, the procedure with which the HCPCS code C1886 device is used. The commenter indicated that the two bronchial thermoplasty codes, CPT code 0276T (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe) and CPT code 0277T (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes) are subject to noncoverage policies for all Category III CPT codes for all but two MACs, resulting in few Medicare claims for CY 2012, the year for which CPT codes 0276T and 0277T are reported for bronchial thermoplasty, and which will be used for CY 2014 ratesetting. The commenter estimated that there are nine Medicare claims for bronchial thermoplasty in CY 2011, available for CY 2013 ratesetting, which were billed with HCPCS codes C9730 and C9731. The commenter requested that CMS delay the expiration of pass-through status for HCPCS code C1886 because of limited data available for CY 2014 ratesetting, and because two Category 1 CPT codes related to bronchial thermoplasty are expected to become effective January 1, 2013, which would result in these procedures being removed from the MAC local coverage determinations for noncovered services.

Response: We created HCPCS code C1886 as a new device category effective January 1, 2012. As such, there are no claims for HCPCS code C1886 in our CY 2011 claims data. However, although we have no claims data for CY 2011, we have over 300 units of HCPCS code C1886 reported in the first 8 months of CY 2012, with robust cost data. Therefore, we believe that we will have sufficient CY 2012 claims on which to base payment rates for the bronchial thermoplasty procedures with which HCPCS code C1886 is billed.

After consideration of the public comment we received, we are finalizing our proposal to expire from pass-through payment HCPCS C1886 on December 31, 2013, and to package its costs with the costs of the procedures with which it is billed.

We did not receive any public comments regarding our proposals to expire pass-through payment eligibility for device categories C1830 and C1840 and to package their respective costs into the costs of the procedures with which the devices are reported. Therefore, we are finalizing our proposals to expire from pass-through payment these device categories, and to package their costs with the costs of the procedures with which they are billed.

We also received a number of comments related to packaging the costs of HCPCS code C1749 into the costs of the procedures with which the HCPCS code C1749 device are reported, a policy we finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74278). We are discussing these public comments in this section instead of the section on packaging because of their relationship to device pass-through payment.

Comment: A few commenters asserted that packaging payment for the HCPCS code C1749 device (retrograde colonoscope or Third Eye Retroscope) into the costs of colonoscopy procedure codes, with which it is billed, after the period of pass-through payment ends on December 31, 2012, will not provide adequate payment for use of the device.

One commenter based this assertion on a study of CY 2011 Medicare claims data (which the commenter summarized in its comment letter) for 7 diagnostic colonoscopy procedures found in APC

0143 (Lower GI endoscopy) performed with HCPCS code C1749, finding that the weighted geometric mean costs of procedures in which HCPCS code C1749 was used is approximately $969; the cost of the same 7 colonoscopy procedures without HCPCS code C1749 is approximately $437, showing a cost difference of approximately $532, which it attributed to the cost of the HCPCS code C1749 device. At the same time, the commenter pointed out that it identified 688 claims for these 7 colonoscopy procedure codes that included units of HCPCS code C1749, while there were 1,067,828 claims for the same 7 procedure codes that did not include HCPCS code C1749 on the claim, or only 0.064 percent of the total claims for these 7 codes that included HCPCS code C1749. Therefore, the commenter claimed that the proposed rates for existing colonoscopy procedures do not fairly reflect the costs of HCPCS code C1749. The commenter further asserted that the proposed APC 0143 payment rate of $691.58 would not pay hospitals adequately for the cost of a procedure using the HCPCS code C1749 device. The commenter claimed that the payment shortfall would be even greater in the ASC setting, where the proposed payment rate for colonoscopies is $389.60. The commenter requested that CMS create a G-code (entitled ''colonoscopy, flexible, proximal to splenic flexure; with continuous retrograde examination'') to be billed along with existing colonoscopy procedure codes when using the HCPCS code C1749 device; assign the new G-code and its costs to a unique device dependent APC under the OPPS and a device-intensive APC under the ASC payment system; and require that HCPCS code C1749 be billed with the new G-code.

Some commenters suggested that CMS continue to pay for HCPCS code C1749 separately, based on OPPS claims data, from the APC payment for the procedure under a unique device-dependent APC in the OPPS and a device-intensive APC for ASC payment because the HCPCS code C1749 device represents the primary cost of this procedure. Another commenter requested that CMS extend the pass-through payment for HCPCS code C1749 through CY 2013 to help further data collection for the device regarding its clinical role and to ensure access to the device for endoscopists' use.

A number of commenters, including those who were patients or relatives of patients, emphasized the importance of being examined by the Third Eye Retroscope, the device upon which HCPCS code C1749 is based, because it provides dramatically improved detection rates of pre-cancerous adenomas, and urged CMS to improve payment for the HCPCS code C1749 procedure. Several commenters claimed that the proposal did not provide a code or payment to report use of the HCPCS code C1749 device.

Response: HCPCS code C1749 was created for device pass-through payment of the retrograde colonoscope effective October 1, 2010. Under the statute, hospitals are paid for devices eligible for pass-through payment, which is payment for the device in addition to the usual APC payment rate, for at least 2 but not more than 3 years from the date we establish pass-through payment. We finalized the expiration of pass-through payment eligibility for HCPCS code C1749 on December 31, 2012, and, consistent with our normal ratesetting methodology for expired device pass-through payment, we finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74278) our policy to package the costs of the HCPCS code C1749 device with the procedures with which it is billed, effective January 1, 2013 (76 FR 74278). For CY 2013, there are 692 units of HCPCS code C1749 reported in our CY 2011 OPPS claims data, with a geometric mean cost of approximately $536. For CY 2013, these costs would be packaged into the procedures with which HCPCS code C1749 are billed. CY 2011 was the first complete year that HCPCS code C1749 was effective, and we assume that utilization of this new device will grow over time.

We do not agree with the commenter that using the HCPCS code C1749 retrograde colonoscope during a colonoscopy is a separate procedure, and therefore would require a G-code to describe a separate procedure. We believe that the retrograde colonoscopic portion of the procedure entails a small incremental amount of colonoscopy procedure time, as it is primarily used during withdrawal of the colonoscope, and there are few additional resource costs (such as procedure room time, equipment costs) other than the HCPCS code C1749 device itself, according to the commenter in its study of the 7 colonoscopy procedure codes. Therefore, the retrograde portion of the procedure is not a separate procedure on which to base a new G-code. Therefore, we will package costs for HCPCS code C1749 with the colonoscopic procedures with which they are billed according to our standard policy. Because we are declining to create a G-code to describe the retrograde colonoscopic portion of colonoscopy procedures, there is no need to create a new, dedicated device-dependent APC, as requested by the commenter.

We also do not agree with the commenter's alternate suggestion that separate payment is needed for HCPCS code C1749 at this time. HCPCS code C1749 is currently under separate payment under the pass-through provision, and once pass-through status expires, device costs are packaged into the payment for the procedure.

Regarding the commenter's request that we extend the eligibility for pass-through payment of HCPCS code C1749 through CY 2013, based on the statutory limits at section 1833(t)(6)(B)(iii) of the Act and related payment policies not permitting partial year rate changes, we are not able to further extend pass-through payment for HCPCS code C1749. Moreover, we will be able to track the HCPCS code C1886 device utilization in CY 2013 even without the pass-through payment eligibility because HCPCS code C1749 will still be required to be reported with the procedures with which it is billed.

The commenters who believe that HCPCS codes for pass-through devices become inactive when pass-through status for a device expires are incorrect. Under our longstanding policy, once the period of device pass-through payment is complete, we package the costs of the devices with the procedures with which they are billed. In the case of HCPCS code C1749, as stated previously, it is our proposal to package the device costs with the colonoscopy procedures with which the retrograde colonoscope is billed, effective January 1, 2013, to maintain HCPCS code C1749 for the device, and to require hospitals to include HCPCS code C1749 and its costs on the claims for the procedures with which it is billed. This will provide assurance that the costs of HCPCS code C1749 will be represented in our claims data and accounted for in the relevant APC payment rates.

After consideration of the public comments we received, we are finalizing our proposals concerning the expiration for pass-through payment eligibility for device category codes C1830, C1840, and C1886 as of December 31, 2013, and to package the device costs with the respective procedures with which these devices are billed. Furthermore, we are maintaining our previous decision to package the costs of HCPCS code C1749 with the procedures with which it is billed, as of January 1, 2013.

2. Provisions for Reducing Transitional Pass-through Payments To Offset Costs Packaged Into APC Groups

a. Background

Section 1833(t)(6)(D)(ii) of the Act sets the amount of additional pass-through payment for an eligible device as the amount by which the hospital's charges for a device, adjusted to cost (cost of device) exceeds the portion of the otherwise applicable Medicare outpatient department fee schedule amount (APC payment amount) associated with the device. 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) for purposes of estimating the portion of the otherwise applicable APC payment amount associated with the device. For eligible device categories, we deduct 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, from the charges adjusted to cost for the device, as provided by section 1833(t)(6)(D)(ii) of the Act, to determine the eligible device's pass-through payment amount. 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 currently have published a list of all procedural APCs with the CY 2012 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/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. 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).

Beginning in CY 2010, we include packaged costs related to implantable biologicals in the device offset calculations in accordance with our policy that the pass-through evaluation process and 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 (74 FR 60476).

b. CY 2013 Policy

In the CY 2013 OPPS/ASC proposed rule (77 FR 45125), we proposed to continue, for CY 2013, our established methodology to estimate the portion of each APC payment rate that could reasonably be attributed to (that is, reflect) 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. We proposed to continue our policy, for CY 2013, 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 2013, 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 2013 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.

In addition, we proposed to update, on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html* the list of all procedural APCs with the final CY 2013 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 2013 device pass-through payment applications and by CMS in reviewing those applications.

Comment: One commenter recommended that all biologicals, including implantable biologicals that are approved by the FDA under biological license applications (BLAs), be treated as drugs, rather than as devices, for pass-through payment purposes for CY 2013. The commenter claimed that when Congress enacted the current payment system for SCODs that previously had pass-through status, it intended for biologicals approved under BLAs to be paid under the specific statutory provisions for drugs. The commenter argued that it is only logical, then, that Congress would have intended for these BLA-approved therapies to be paid as pass-through drugs as well. The commenter requested that, if CMS continues to evaluate implantable biologicals under the pass-through device criteria, CMS clarify its policy that the device pass-through criteria apply only to biologicals if they are solely surgically implanted according to their FDA approved indications. The commenter stated that the current regulation at 42 CFR 419.64(a)(4) is unclear how we would evaluate pass-through eligibility of a biological that has both surgically implanted and nonimplantable indications. The commenter stated that the explanation CMS provided in the CY 2012 OPPS/ASC final rule with comment period, that ''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 indications in which the

biological is not surgically implanted or inserted'' (76 FR 74280), is unclear and inconsistent with what CMS has stated previously in policy and billing instructions. The commenter recommended that CMS revise the regulation text so that if refers to ''a biological that is not always surgically implanted into the body.''

Response: As stated in previous OPPS/ASC final rules 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 category of FDA approval (74 FR 60476; 75 FR 71924; 76 FR 74279 through 74280). We do not believe it is necessary to make our OPPS payment policies regarding implantable biologicals dependent on categories of FDA approval, the intent of which is to ensure the safety and effectiveness of medical products.

We do not agree with the commenter who asserted that Congress intended biologicals approved under BLAs to be paid under the specific OPPS statutory provisions that apply to SCODs, including the pass-through provisions. Moreover, as we stated in previous 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 they also meet our criteria for payment as a device (74 FR 60476; 75 FR 71924; and 76 FR 74280). We continue to believe that implantable biologicals meet both the definitions of a device and a biological and that, for payment purposes, it is appropriate for us to consider implantable biologicals as implantable devices in all cases, and not as biologicals.

We do not agree with the commenter's assertion that the explanation offered in the CY 2012 OPPS/ASC final rule with comment period of the regulation text at 42 CFR 419.64(a)(4)(iii) which indicates that a biological for drug pass-through payment purposes must not be surgically implanted or inserted into the body, is inconsistent with our prior description of this policy, the application of this policy to date, and billing instruction to hospitals. Our policy and application process have consistently reflected that implantable biologicals are subject to the device application process since the beginning of CY 2010. For CYs 2010, 2011, and 2012, we finalized the same policy that the pass-through evaluation process and 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 as of January 1, 2010, be the device pass-through process and payment methodology only (74 FR 60476, 75 FR 71924, and 76 FR 74280, respectively). We have not established a policy in any year that stated that implantable biologicals needed to be solely surgically inserted or implanted to be subject to the device pass-through process and payment methodology. Furthermore, there is no inconsistency with our policy and billing instructions regarding pass-through devices or implantable biologicals because there are no billing instructions regarding the device pass-through application process. Rather, application instructions are found on the CMS Web site (currently at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf*). The language on the device application web site is consistent with the language in the CYs 2010, 2011, and 2012 final rules with comment period, stating that, as of January 1, 2010, implantable biologicals that are surgically inserted or implanted (through a surgical incision or natural orifice) are being evaluated for device pass-through payment under the instructions using the device pass-through process. We reiterate our explanation provided in the CY 2012 final rule with comment period (76 FR 74280) regarding the regulatory language at 42 CFR 419.64(a)(4), that 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 also are indications in which the biological is not surgically implanted or inserted. We will add similar language to our device and drug pass-through application Web sites as well.

We are finalizing the following proposals for CY 2013: to continue our established methodology to estimate the portion of each APC payment rate that could reasonably reflect the cost of an associated device eligible for pass-through payment; to continue 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; to continue our established policies for calculating and setting the device APC offset amounts for each device category eligible for pass-through payment; and 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, and, if device costs packaged into the existing APC structure are associated with the new category, to deduct the device APC offset amount from the pass-through payment for the device category.

For CY 2013, we also are finalizing our proposal and continuing our policy established in CY 2010 to include implantable biologicals in our calculation of the device APC offset amounts, and 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 2013 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.

In addition, we will update, on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html* the list of all procedural APCs with the final CY 2013 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 2013 device pass-through payment applications and by CMS in reviewing those applications.

3. Clarification of Existing Device Category Criterion

a. Background

Section 1833(t)(6)(B)(ii)(IV) of the Act directs the Secretary to establish a new device category for pass-through payment for which none of the pass-through categories in effect (or that were previously in effect) is appropriate. Commenters who responded to our various proposed rules, as well as applicants for new device categories, had expressed concern that some of our existing and previously in effect device category descriptors were overly broad, and that the device category descriptors as they are currently written may preclude some new technologies from qualifying for establishment of a new device category for pass-through payment (70 FR 68630 through 68631). As a result of these comments, we finalized a policy, effective January 1, 2006, to create an additional category for devices that meet all of the criteria required to establish a new category for

pass-through payment in instances where we believe that an existing or previously in effect category descriptor does not appropriately describe the new device. Accordingly, effective January 1, 2006, we revised § 419.66(c)(1) of the regulations to reflect this policy change. In order to determine if a new device is appropriately described by any existing or previously in effect category of devices, we apply two tests based upon our evaluation of information provided to us in the device category application. First, an applicant for a new device category must show that its device is not similar to devices (including related predicate devices) whose costs are reflected in the currently available OPPS claims data in the most recent OPPS update. Second, an applicant must demonstrate that utilization of its device provides a substantial clinical improvement for Medicare beneficiaries compared with currently available treatments, including procedures utilizing devices in any existing or previously in effect device categories. We consider a new device that meets both of these tests not to be appropriately described by any existing or previously in effect pass-through device categories (70 FR 68630 through 68631).

b. Clarification of CY 2013 Policy

In the CY 2013 OPPS/ASC proposed rule (77 FR 45126), we proposed, for CY 2013, to clarify the test that requires an applicant for a new device category to show that its device is not similar to devices (including related predicate devices) whose costs are reflected in the currently available OPPS claims data in the most recent OPPS update. We clarified that this test includes showing that a new device is not similar to predicate devices that once belonged in any existing or previously in effect pass-through device categories. Under this test, a candidate device may not be considered to be appropriately described by any existing or previously in effect pass-through device categories if the applicant adequately demonstrates that the candidate device is not similar to devices (including related predicate devices) that belong or once belonged to an existing or any previously in effect device category, and that the candidate device is not similar to devices whose costs are reflected in the OPPS claims data in the most recent OPPS update. The substantial clinical improvement criterion, which also must be satisfied in every case, as indicated in § 419.66(c)(2) of our regulations, is separate from the criterion that a candidate device not be similar to devices in any existing or previously in effect pass-through categories. We invited public comments regarding this proposed clarification.

We did not receive any public comments on our proposal to clarify the test that requires an applicant for a new device category to show that its device is not similar to devices (including related predicate devices) whose costs are reflected in the currently available OPPS claims data. Therefore, we are clarifying our existing policy as noted above.

B. Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices

1. Background

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 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 2013 OPPS/ASC proposed rule (77 FR 45126), we proposed, for CY 2013, 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. (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.)

For CY 2013, 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 2013 OPPS/ASC proposed rule (77 FR 45127) 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 2013 OPPS/ASC proposed rule (77 FR 45127), we examined the offset amounts calculated from the CY 2013 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 2012 continue to meet the criteria for CY 2013, and to determine whether

other APCs to which the policy did not apply in CY 2012 would meet the criteria for CY 2013. Based on the CY 2011 claims data available for the proposed rule, we did not propose any changes to the APCs and devices to which this policy applies.

Table 20 of the CY 2013 OPPS/ASC proposed rule (77 FR 45127) listed the proposed APCs to which the payment adjustment policy for no cost/full credit and partial credit devices would apply in CY 2013, 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 21 of the CY 2013 OPPS/ASC proposed rule (77 FR 45128) listed the proposed devices to which the payment adjustment policy for no cost/full credit and partial credit devices would apply in CY 2013. We stated in the CY 2013 proposed rule (77 FR 45127) 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 2013, consistent with the three criteria discussed earlier in this section, based on the final CY 2011 claims data available for the CY 2013 OPPS/ASC final rule with comment period. The updated lists of APCs and devices appear below in Table 29 and Table 30, respectively, of this final rule with comment period. We note that there are no changes to the lists of APCs and devices compared to the proposed rule for CY 2013.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45127), we proposed, for CY 2013, that 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 21 of the proposed rule is present on the claim, and the procedure code maps to an APC listed in Table 20 of the proposed rule. We also proposed that 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 21 of the proposed rule is present on the claim and the procedure code maps to an APC listed in Table 20 of the proposed rule. 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.

Comment: Commenters reported that there are some instances in which the hospital receives a full credit for only one component of a pacemaker or ICD replacement procedure that involves both a lead and a generator. Specifically, the commenters noted that the 2012 CPT Code Book states that when a pulse generator insertion involves the insertion or replacement of one or more lead(s), use system CPT codes 33206 (Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial), 33207 (Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); ventricular), and 33208 (Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial and ventricular) for pacemakers or CPT code 33249 (Insertion or replacement of permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber) for pacing cardioverter-defibrillators. The commenters noted that hospitals would still be required to assign an ''FB'' or ''FC'' modifier to the procedure code representing the replacement procedure, and the applicable offset would be applied to the entire APC payment, even when only one of the devices involved in the procedure was received at no cost or with full or partial credit. According to the commenters, the offset reduction may actually be much greater or much less than the credit received by the hospital, depending upon the component that was credited. The commenters requested that CMS alleviate this issue by allowing hospitals to bill individual CPT codes for each component of the replacement procedure, rather than requiring the reporting of a full system as suggested by the CPT guidance. The commenters stated that this would allow the FB or FC modifiers and the respective offsets to be applied accurately to the payment for the individual component receiving the credit, rather than being broadly applied to the APC payment for the entire replacement.

Response: We agree with the commenters that hospitals would be required to assign an ''FB'' or ''FC'' modifier to the procedure code representing the pacemaker or ICD replacement procedure as they describe, and that the applicable offset would be applied to the entire APC payment, even when just one of the devices involved in the procedure (that is, a lead or a generator) was received at no cost or with full or partial credit. However, we do not agree that this is problematic. As the commenter noted, the offset reduction may actually be much greater or much less than the credit received by the hospital, depending upon the component that was credited. As we have stated in the past (76 FR 74282), 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. However, because averaging is inherent in a prospective payment system, we do not believe this is inappropriate. Therefore, we do not agree that we should allow hospitals to bill individual CPT codes for each component of the replacement procedure, rather than requiring the reporting of a full system as suggested by the CPT guidance, as the commenters suggested.

Comment: One commenter noted that the no cost/full credit and partial credit adjustment policy applies only when expensive devices are replaced and requested clarification regarding the assignment of the ''FB/FC'' modifier to devices that providers receive at no cost or at an ''inexpensive'' cost. According to the commenter, providers lack clear guidelines to determine what is meant by ''inexpensive.'' The commenter also noted that there are inconsistencies between the ''FB/FC'' modifier list and the list of device-dependent APCs in the CY 2013 OPPS/ASC proposed rule, specifically that the FB/FC listing is not an inclusive listing of all device-dependent APCs.

Response: As we stated in the Medicare Claims Processing Manual (Pub. 100–04, Chapter 4, Section 61.3.1), when a hospital furnishes a device received without cost or with full credit from a manufacturer, the hospital must append modifier ''–FB'' to the procedure code (not the device code) that reports the service provided to furnish the device. As we stated in the Medicare Claims Processing Manual (Pub. 100–04, Chapter 4, Section 61.3.3), when a hospital receives a partial credit of 50 percent or more of the cost of a new replacement device due to warranty, recall, or field action, the hospital must append modifier ''–FC'' to the procedure code (not on the device code) that reports the service provided to replace the device. This guidance does not instruct providers to determine whether a no cost/full credit or partial credit device is ''expensive'' or ''inexpensive.'' Rather, providers should append the ''FB'' and ''FC'' modifiers to

all procedures that meet the requirements of these instructions. The I/OCE determines, on a claim by claim basis, when to apply the no cost/full credit and partial credit device adjustment policy (that is, when both a specified device code is present on the claim, and the procedure code to which the ''FB'' or ''FC'' modifier is appended maps to a specified APC, as described previously in this section).

Regarding the comment that there are inconsistencies between the ''FB/FC'' modifier list and the list of device-dependent APCs in the CY 2013 OPPS/ASC proposed rule, we believe that the commenter is referring to the fact that Table 20 in the CY 2013 OPPS/ASC proposed rule (the list of proposed APCs to which the no cost/full credit and partial credit device adjustment policy would apply (77 FR 45127)) and Table 4A (the list of proposed device-dependent APCs (77 FR 45082)) are not identical. The commenter is correct that the list of APCs to which the no cost/full credit and partial credit device adjustment policy will apply in CY 2013 in this section and the list of device-dependent APCs in section II.A.2.d.(1) of the proposed rule and this final rule with comment period are not the same. We believe this is appropriate because, as we describe earlier in this section, we use the following criteria to determine the list of APCs to which this policy will apply: (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. Not all device-dependent APCs meet these criteria, and therefore are appropriately excluded from the list of APCs to which the no cost/full credit and partial credit device adjustment policy applies.

After consideration of the public comments we received, we are finalizing our CY 2013 proposals, without modification, to continue the established no cost/full credit and partial credit adjustment policies. Table 29 below lists the APCs to which the payment adjustment policy for no cost/full credit and partial credit devices will apply in CY 2013 and displays the final adjustment percentages for both no cost/full credit and partial credit circumstances. Table 30 below lists the devices to which the no cost/full credit and partial credit device adjustment policy will apply for CY 2013, consistent with the three selection criteria discussed earlier in this section and based on the CY 2011 claims data available for this final rule with comment period.

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TABLE 29.—APCs TO WHICH THE NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WILL APPLY IN CY 2013

CY 2013 APC	CY 2013 APC Title	CY 2013 Device Offset Percentage for No Cost/ Full Credit Case	CY 2013 Device Offset Percentage for Partial Credit Case
0039	Level I Implantation of Neurostimulator Generator	87%	43%
0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes	56%	28%
0061	Level II Implantation/Revision/Replacement of Neurostimulator Electrodes	69%	34%
0089	Insertion/Replacement of Permanent Pacemaker and Electrodes	69%	35%
0090	Insertion/Replacement of Pacemaker Pulse Generator	71%	36%
0106	Insertion/Replacement of Pacemaker Leads and/or Electrodes	48%	24%
0107	Level I Implantation of Cardioverter-Defibrillators (ICDs)	84%	42%
0108	Level II Implantation of Cardioverter-Defibrillators (ICDs)	84%	42%
0227	Implantation of Drug Infusion Device	82%	41%
0259	Level VII ENT Procedures	84%	42%
0315	Level II Implantation of Neurostimulator Generator	88%	44%
0318	Implantation of Cranial Neurostimulator Pulse Generator and Electrode	89%	44%

CY 2013 APC	CY 2013 APC Title	CY 2013 Device Offset Percentage for No Cost/ Full Credit Case	CY 2013 Device Offset Percentage for Partial Credit Case
0385	Level I Prosthetic Urological Procedures	62%	31%
0386	Level II Prosthetic Urological Procedures	70%	35%
0425	Level II Arthroplasty or Implantation with Prosthesis	59%	30%
0648	Level IV Breast Surgery	50%	25%
0654	Insertion/Replacement of a permanent dual chamber pacemaker	74%	37%
0655	Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing Electrode	73%	37%
0680	Insertion of Patient Activated Event Recorders	74%	37%

TABLE 30.—DEVICES TO WHICH THE NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WILL APPLY IN CY 2013

CY 2013 Device HCPCS Code	CY 2013 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
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

CY 2013 Device HCPCS Code	CY 2013 Short Descriptor
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

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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 2013 pass-through drugs and biologicals and their designated APCs were assigned status indicator ''G'' in Addenda A and B to the proposed rule and in this final rule with comment period, which are available via the Internet on the CMS Web site.

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. However, we note that the Part B drug CAP program has been postponed since CY 2009, and such a program has not been reinstated for CY 2013.

This methodology for determining the pass-through payment amount is set forth in regulations at 42 CFR 419.64. These regulations 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/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html*.

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. For CY 2012, we estimated the OPPS pass-through payment for drugs and biologicals to be $19 million. Our OPPS pass-through payment estimate for drugs and biologicals in CY 2013 is $22 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/Medicare/Medicare-Fee-for-Service-Payment/*

HospitalOutpatientPPS/passthrough_payment.html.

2. Drugs and Biologicals With Expiring Pass-Through Status in CY 2012

In the CY 2013 OPPS/ASC proposed rule (77 FR 45128), we proposed that the pass-through status of 23 drugs and biologicals would expire on December 31, 2012, as listed in Table 22 of the proposed rule (77 FR 45129). 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, 2012. These drugs and biologicals were approved for pass-through status on or before January 1, 2011. 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 and contrast agents, 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 $80), 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+6 percent for CY 2013, as discussed further in section V.B.3. of this final rule with comment period). Section II.A.3.e. of this final rule with comment period discusses the packaging of all nonpass-through contrast agents and diagnostic radiopharmaceuticals.

Comment: Several commenters recommended that CMS continue pass-through status for new drugs, specifically diagnostic radiopharmaceuticals and contrast agents, for 3 years. The commenters asserted that providing pass-through status for 3 years would help provide a more current and accurate data set on which to base payment amounts of the procedure when the diagnostic radiopharmaceutical or contrast agent is subsequently packaged. The commenters further recommended that CMS expire pass-through status for drugs and biologicals on a quarterly as opposed to an annual basis. One commenter disagreed with a prior CMS proposal to begin the pass-through payment eligibility period on the date of first sale of the drug in the United States following FDA approval. The commenter however approved of the concurrent proposal made at that time that would require CMS to accept and expire pass-through applications for drugs and biologicals on a quarterly basis.

Response: As we stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74287), as described in section V.A. 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 but not more than 3 years, after the product's first payment as a hospital outpatient service under Medicare Part B. We continue to believe that this period of payment facilitates dissemination of these new products into clinical practice and facilitates the collection of sufficient 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-though payment for no more than 3 years as the statute requires. Further, we are confident that the period of time for which drugs, biologicals, contrast agents, and radiopharmaceuticals receive pass-through status, which is at least 2 but no more than 3 years, is adequate for CMS to collect the sufficient amount of data to make a packaging determination.

We further note that we are in full compliance with the requirements of the Act, which states that pass-through status is given for at least 2 but no 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 into an APC if it is 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 on such status. We expire pass-though status on an annual basis. Depending on when a drug is initially approved for pass-through status, the drug receives pass-through payment for at least 2 but not more than 3 years.

Comment: Commenters, including several medical societies, individual practitioners, and a manufacturer, requested that CMS appropriately pay for HCPCS code C9275 (Injection, hexaminolevulinate hydrochloride, 100 mg, per study dose). Some commenters believed that payment would be eliminated for HCPCS code C9275 and requested that CMS evaluate its statutory authority and establish appropriate payment as necessary. One commenter recommended that CMS either continue to pay separately for HCPCS code C9275 because, the commenter argued, an insufficient amount of claims data have been collected, or assign HCPCS code C9275 to a new technology APC with the accompanying blue light cystoscopy procedure until sufficient claims are gathered to determine assignment of an appropriate clinical APC category. The commenter further argued that because C9275 will always be used with the blue light cystoscopy procedure, packaging C9275 will result in zero payment for the imaging agent, since current cystoscopy APCs do not include costs of imaging agents.

The commenter stated that if CMS chooses to not provide payment for HCPCS code C9275 as a separately billable product, CMS should use its ''waiver authority'' under section 1833(t)(2)(E) of the Act to ensure that equitable payments are made under the OPPS for C9275. The commenter noted that, for CY 2013, CMS used this statutory authority to propose an

additional payment for radioisotopes derived from non-HEU sources.

Response: We proposed for CY 2013 to package the payment, for all contrast agents, that are not on pass-through status, into the payment for the associated service. We continue to believe that all nonpass-through contrast agents function effectively as supplies that are ancillary and supportive to an independent service. The product described by HCPCS code C9275 is a contrast agent that was approved for pass-through status beginning on January 1, 2011. For the CY 2013 OPPS/ASC proposed rule (77 FR 45128 through 45129), we proposed to expire pass-through status for this product because it had received at least 2 and no more than 3 years, as permitted by the Act in section 1833(t)(6). We note that because we expire pass-through status on an annual basis and not a quarterly basis, we cannot extend the pass-through status for HCPCS code C9275 for an additional number of years because it would be counter to our current policy. Therefore, we believe that our proposal to expire pass-through status for HCPCS code C9275 for CY 2013 is appropriate.

We disagree with the commenter that a sufficient amount of data was not collected for HCPCS code C9275 during its period under pass-through status. As we stated previously, we believe this pass-through period of payment facilitates dissemination for new products into clinical practice and facilitates the collection of hospital claims data, reflective of their costs for future OPPS ratesetting. 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, where the product is being used, into their chargemasters based on the utilization and costs observed in our claims data. We believe a sufficient amount of claims data has been collected in this case and we see no reason to exempt C9275 as an extraordinary case from our longstanding packaging policy to package payment for nonpass-through contrast agents.

We also do not believe that it is appropriate to extend separate payment for HCPCS code C9275 based on section 1833(t)(2)(E) of the Act. We believe that all hospitals have the opportunity to bill for and receive equitable payment for HCPCS code C9275. Hospitals can bill for an appropriate unlisted code for the cystoscopy procedure and include the costs of the product currently reported by HCPCS code C9275 in that specific claim, in order to receive payment for the procedure and the product. Therefore, we do not believe that there is an inequity that should be adjusted. Additionally, we do not believe that an additional payment amount should be made for HCPCS code C9275, for the reasons given in this final rule with comment period, to ensure equitable payments are made to hospitals. Further, extending the pass-through status for HCPCS code C9275 beyond 3 years would not be permitted under the statutory requirements of section 1833(t)(6) of the Act.

We believe that commenters have erroneously stated that payment will not be made under the OPPS or that an insufficient amount of payment will be given to the product described by HCPCS code C9275. We remind commenters that products that are packaged under the OPPS receive payment that is packaged into the payment for the associated procedure. 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. Payment for the packaged product is then included in the payment for the independent service. For HCPCS code C9275, hospitals may bill an unlisted code for the cystoscopy procedure and include the costs for HCPCS code C9275 on that claim. These costs will additionally be included in future ratesetting for these products.

We continue to 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. Therefore, we believe that HCPCS code C9275 is appropriately packaged for CY 2013 and we are finalizing our proposal to expire pass-through status for C9275 and assign this HCPCS code to a status indicator of ''N'' for CY 2013.

We note that comments pertaining to a potential future new technology APC assignment or new technology APC application for HCPCS code C9275 and the accompanying blue light cystoscopy procedure are outside the scope of this final rule with comment period.

Comment: One commenter requested that CMS review the claims used in calculating the packaging status of HCPCS code J7183 (Injection, von willebrand factor complex (human), wilate, 1 i.u. vwf:rco) and assign HCPCS code J7183 to status indicator ''K'' as pass-through status has expired, but the cost per day exceeds $80.

Response: We appreciate the commenter's diligence. HCPCS code J7183 was erroneously assigned to a status indicator of ''N'' for the CY 2013 OPPS/ASC proposed rule (77 FR 45129). The per day cost for HCPCS code J7183 for this final rule with comment period exceeds the $80 packaging threshold for CY 2013. Therefore, we are finalizing our proposal, with modification, to expire the pass-through status for HCPCS code J7183 and assign it to a status indicator of ''K'' for CY 2013.

After consideration of the public comments we received, we are finalizing our proposal, with modification as described above, to expire the pass-through status of the 23 drugs and biologicals listed in Table 31 below. We are assigning HCPCS code J7183 to status indicator ''K'' for CY 2013. Table 31 lists the drugs and biologicals for which pass-through status will expire on December 31, 2012, the status indicators, and the assigned APCs for CY 2013.

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TABLE 31.—DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH STATUS WILL EXPIRE DECEMBER 31, 2012

CY 2013 HCPCS Code	CY 2013 Long Descriptor	CY 2013 SI	CY 2013 APC
C9275	Injection, hexaminolevulinate hydrochloride, 100 mg, per study dose	N	N/A
C9367	Skin substitute, Endoform Dermal Template, per square centimeter	K	9367
J0221	Injection, alglucosidase alfa, (lumizyme), 10 mg	K	1413
J0588	Injection, incobotulinumtoxin A, 1 unit	K	9278
J0597	Injection, C-1 esterase inhibitor (human), Berinert, 10 units	K	9269
J0775	Injection, collagenase clostridium histolyticum, 0.01 mg	K	1340
J0840	Injection, crotalidae polyvalent immune fab (ovine), up to 1 gram	K	9274
J0897	Injection, denosumab, 1 mg	K	9272
J1290	Injection, ecallantide, 1 mg	K	9263
J1557	Injection, immune globulin (Gammaplex), intravenous, non-lyophilized (e.g. liquid), 500 mg	K	9270
J1741	Injection, ibuprofen, 100 mg	N	N/A
J3095	Injection, telavancin, 10 mg	K	9258
J3262	Injection, tocilizumab, 1 mg	K	9264
J3357	Injection, ustekinumab, 1 mg	K	9261
J3385	Injection, velaglucerase alfa, 100 units	K	9271
J7183	Injection, von Willebrand factor complex (human), Wilate, per 100 IU VWF: RCO	K	1352
J7335	Capsaicin 8% patch,per 10 square centimeters	K	9268
J8562	Fludarabine phosphate, oral, 10 mg	K	1339
J9043	Injection, cabazitaxel, 1 mg	K	1339
J9302	Injection, ofatumumab, 10 mg	K	9260

CY 2013 HCPCS Code	CY 2013 Long Descriptor	CY 2013 SI	CY 2013 APC
J9307	Injection, pralatrexate, 1 mg	K	9259
J9315	Injection, romidepsin, 1 mg	K	9265
Q2043	Sipuleucel-t, minimum of 50 million autologous cd54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion	K	9273

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3. Drugs, Biologicals, and Radiopharmaceuticals With New or Continuing Pass-Through Status in CY 2013

In the CY 2013 OPPS/ASC proposed rule (77 FR 45129), we proposed to continue pass-through status in CY 2013 for 21 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, 2012. These drugs and biologicals, which were approved for pass-through status between April 1, 2011 and July 1, 2012, were listed in Table 23 of the proposed rule (77 FR 45130 through 45131). The APCs and HCPCS codes for these drugs and biologicals approved for pass-through status through April 1, 2012 were assigned status indicator ''G'' in Addenda A and B of the proposed rule. Addenda A and B for the proposed rule were available via the Internet on the CMS Web site.

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 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 and we proposed to continue to provide payment for drugs and biologicals with pass-through status at a rate of ASP+6 percent in CY 2013, the amount that drugs and biologicals receive under section 1842(o) of the Act.

Thus, for CY 2013, 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 2013. We proposed that a $0.00 pass-through payment amount would be paid for most pass-through drugs and biologicals under the CY 2013 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, proposed at ASP+6 percent, is $0.

In the case of pass-through contrast agents and diagnostic radiopharmaceuticals, their pass-through payment amount would be equal to ASP+6 percent because, if not on pass-through status, payment for these products would be packaged into the associated procedure. Therefore, we proposed that 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 2013 pass-through payment amount for these policy-packaged products.

In addition, we proposed to continue to update pass-through payment rates on a quarterly basis on the CMS Web site during CY 2013 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).

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 reviewed drugs with pass-through status for CY 2013 that will change from C-codes to J-codes for CY 2013. For our CY 2013 review, we have determined that HCPCS code J1741 (Injection, ibuprofen, 100 mg) describes the product reported under HCPCS code C9279 (Injection, ibuprofen, 100 mg), HCPCS code J0485 (Injection, belatacept, 1 mg) describes the product reported under HCPCS code C9286 (Injection, belatacept, 1 mg), HCPCS code J9042 (Injection, brentuximab vedotin, 1 mg) describes the code reported under HCPCS code C9287 (Injection, brentuximab vedotin, 1 mg), HCPCS code J0716 (Injection, centruroides immune f(ab)2, up to 120 milligrams) describes the code reported under HCPCS code C9288 (Injection, centruroides (scorpion) immune f(ab)2 (equine), 1 vial), and HCPCS code J9019 (Injection, asparaginase (erwinaze), 1,000 iu) describes the code reported under HCPCS code C9289 (Injection, asparaginase Erwinia chrysanthemi, 1,000 international units (I.U.)).

In CY 2013, as is consistent with our CY 2012 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 2013, 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: 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. A few commenters 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. Another commenter requested that CMS provide an additional payment for radiopharmaceuticals that are granted pass-through status. The commenter gave an example amount of ASP+10 percent. Finally, one commenter, in response to both the proposal to continue to pay for drugs and biologicals on pass-through status and those not on pass-through status at ASP+6 percent, suggested that CMS explore alternative payment mechanisms that reward the pharmaceutical care provided by specialty trained pharmacists who ensure safe and effective medication use and provide for screening of drug interactions and contraindications.

Response: As discussed above, the statutorily mandated pass-through payment for pass-through drugs and biologicals for CY 2013 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 (ASP+6 percent for CY 2013) 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 2013, consistent with our CY 2012 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 2013, we proposed to follow the standard ASP methodology to determine its pass-through payment rate 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 2013, 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 readers may also refer to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

Finally, we note that the comment that suggested that CMS explore alternative payment mechanisms that reward the pharmaceutical care provided by specialty trained pharmacists who ensure safe and effective medication use and provide for screening of drug interactions and contraindications is outside the scope of this final rule with comment period.

Comment: One commenter stated that HCPCS code J1572 (Injection, immune globulin (flebogamma/flebogamma dif), intravenous, non-lyophilized (e.g. liquid), 500 mg) received an approval for a labeling change for the extraction process on January 20, 2012, but that this did not constitute the approval of a ''new drug.'' The commenter requested that CMS reevaluate the status indicator for HCPCS code J1572 and assign it to a status indicator of ''K'' instead of ''G'' for CY 2013, because the original FDA approval date for the product of December 15, 2003 does not meet the criteria for pass-through status.

Response: For the CY 2013 OPPS/ASC proposed rule (77 FR 45129 through 45131), we proposed to continue pass-through status for HCPCS code J1572 for the remainder of CY 2013. HCPCS code J1572 replaced HCPCS code Q4091 on January 1, 2008. The product described by HCPCS code J1572 also received FDA approval on December 15, 2003. When we reviewed the drug pass-through application for the product described by HCPCS code J1572, we concluded that the product described by HCPCS code J1572 had not previously received pass-through payment under the OPPS and had a cost that was not insignificant in relation to the OPD fee schedule amount. Therefore, we approved pass-through status for HCPCS code J1572 beginning on July 1, 2011. We believe that we appropriately assigned pass-through status to HCPCS code J1572 and we continue to believe that pass-through status should continue through CY 2013.

We disagree with the commenter that HCPCS code J1572 does not meet the criteria for pass-through status because the original FDA approval date for this product was December 15, 2003. We note that section 1833(t)(6)(A)(iv)(I) of the Act allows for pass-through payment for a device, drug, or biological as long as payment for such item was not being made as an outpatient hospital service as of December 31, 1996. Furthermore, we reiterate that the statute provides in section 1833(t)(6)(B)(iii) of the Act that pass-through status shall be in effect for a period of at least 2 but no more than 3 years of pass-through payment. Therefore, we believe continuing pass-through status for HCPCS code J1572 is appropriate.

Comment: One commenter who responded to the CY 2012 OPPS/ASC final rule with comment period requested clarification on the dosage descriptor for HCPCS code J9179 (Injection, eribulin mesylate, 0.1 mg). The commenter noted that the final rule display version referenced inconsistent dosage size.

Response: As displayed in Table 32 below, the correct dosage descriptor for HCPCS code J9179 is 0.1mg. HCPCS code J9179 will continue on pass-through status, with a status indicator of ''G,'' for CY 2013.

After consideration of the public comments we received, we are finalizing our proposal to provide payment for drugs, biologicals, diagnostic and therapeutic radiopharmaceuticals and contrast agents that are granted pass-through status based on the ASP methodology. If a diagnostic or therapeutic radiopharmaceutical receives pass-through status during CY 2013, 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 II.A.3.d. of this final rule with comment period, over the last 5 years, we implemented a policy whereby payment for all nonpass-through diagnostic radiopharmaceuticals and contrast agents is packaged into payment for the associated procedure. We proposed to continue the packaging of these items, regardless of their per day cost, in CY 2013. As stated earlier, pass-through payment is the difference between the amount authorized under section 1842(o) of the Act 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 2012, 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 2013. Similarly, we proposed that the associated copayment amount for pass-through anesthesia drugs that would otherwise be packaged if the item did not have pass-through status would be zero for CY 2013. As discussed in further detail in section II.3.c.(2) of this final rule with comment period, we are clarifying that our general policy is to package drugs used for anesthesia, and that those anesthesia drugs with pass-through status will be packaged upon the expiration of pass-through status.

The separate OPPS payment to a hospital for the pass-through diagnostic radiopharmaceutical, contrast agent, or anesthesia drug 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 were available via the Internet on the CMS Web site).

Comment: Commenters supported the CY 2013 proposal to continue to set the associated copayment amounts for pass-through diagnostic radiopharmaceuticals and contrast agents 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 2013 OPPS/ASC proposed rule (77 FR 45129 through 45130), 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 of 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 and contrast agents. We also believe that the copayment amount should be zero for anesthesia drugs that would otherwise be packaged if the item did not have pass-through status.

After consideration of the public comments received, we are finalizing our proposal, without modification, 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 2013. We are also finalizing our proposal to extend this policy to anesthesia drugs that have pass-through status, and to set a copayment amount of zero for these drugs for CY 2013.

The 26 drugs and biologicals that we are continuing on pass-through status for CY 2013 or have been granted pass-through status as of January 2013 are displayed in Table 32 below.

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TABLE 32.—DRUGS AND BIOLOGICALS WITH PASS-THROUGH STATUS IN CY 2013

CY 2012 HCPCS Code	CY 2013 HCPCS Code	CY 2013 Long Descriptor	Final CY 2013 SI	Final CY 2013 APC
A9584	A9584	Iodine I-123 ioflupane, diagnostic, per study dose, up to 5 millicuries	G	9406
C9285	C9285	Lidocaine 70 mg/tetracaine 70 mg, per patch	G	9285
C9286	J0485	Injection, belatacept, 1 mg	G	9286
C9287	J9042	Injection, brentuximab vedotin, 1 mg	G	9287
C9288	J0716	Injection, centruroides immune f(ab)2, up to 120 milligrams	G	1431
C9289	J9019	Injection, asparaginase (erwinaze), 1,000 iu	G	9289
C9290	C9290	Injection, bupivicaine liposome, 1 mg	G	9290
C9292	C9292	Injection, pertuzumab, 10 mg	G	9292
C9293	C9293	Injection, glucarpidase, 10 units	G	9293
N/A	C9294*	Injection, taliglucerase alfa, 100 units	G	9294
N/A	C9295*	Injection, carfilzomib, 1 mg	G	9295
N/A	C9296*	Injection, ziv-aflibercept, 1 mg	G	9296
C9366	Q4131	EpiFix, per square centimeter	G	9366
C9368	Q4132	Grafix core, per square centimeter	G	9368
C9369	Q4133	Grafix prime, per square centimeter	G	9369
J0131	J0131	Injection, acetaminophen, 10 mg	G	9283
J0490	J0490	Injection, belimumab, 10 mg	G	1353
J0638	J0638	Injection, canakinumab, 1mg	G	1311
J0712	J0712	Injection, ceftaroline fosamil, 10 mg	G	9282
J1572	J1572	Injection, immune globulin, (flebogamma/flebogamma dif), intravenous, non-lyophilized (e.g. liquid), 500 mg	G	0947
J2507	J2507	Injection, pegloticase, 1 mg	G	9281
J7180	J7180	Injection, factor xiii (antihemophilic	G	1416

CY 2012 HCPCS Code	CY 2013 HCPCS Code	CY 2013 Long Descriptor	Final CY 2013 SI	Final CY 2013 APC
		factor, human), 1 i.u		
J9179	J9179	Injection, eribulin mesylate, 0.1 mg	G	1426
J9228	J9228	Injection, ipilimumab, 10 mg	G	9284
Q2046	J0178	Injection, aflibercept, 1 mg	G	1420
Q4124	Q4124	Oasis Ultra Tri-Layer matrix, per square centimeter	G	9365

*HCPCS codes C9294, C9295, and C9296 are effective January 1, 2013.

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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 2013, in the CY 2013 OPPS/ASC proposed rule (77 FR 45131), we proposed to continue to package payment for all nonpass-through diagnostic radiopharmaceuticals and contrast agents, as discussed in section II.A.3.e. of the proposed rule and 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 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 2013. 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 diagnostic 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 following: 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/Medicare/Coding/OutpatientCodeEdit/index.html*.

For CY 2013 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 24 of the proposed rule (77 FR 45132) 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.

We did not receive any public comments on this proposal. Therefore, we are finalizing our policy, 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 2013 and future years. In addition, we will continue to reduce the payment amount for procedures in the APCs listed in Table 33 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 2012, we finalized a policy to apply the diagnostic radiopharmaceutical offset policy to payment for pass-through diagnostic radiopharmaceuticals, as described above. For CY 2013, we proposed to continue to apply the diagnostic radiopharmaceutical offset policy to payment for pass-through diagnostic radiopharmaceuticals.

Comment: Commenters recommended that CMS continue to apply radiopharmaceutical edits for nuclear medicine procedures using radiopharmaceuticals as long as diagnostic radiopharmaceuticals are packaged. The commenters noted that the proposed rule was silent on whether CMS will continue this policy for CY 2013 and they requested that CMS confirm in the final rule that it will continue to apply the radiopharmaceutical edits and use only claims with a radiopharmaceutical code in determining nuclear medicine APC rates.

Response: Beginning in CY 2008, we implemented nuclear medicine procedure-to-radiolabeled product claims processing edits in the I/OCE that required a diagnostic radiopharmaceutical to be present on the same claim as a nuclear medicine procedure for payment under the OPPS to be made. These edits ensure that hospitals submit correctly coded claims that report the HCPCS codes for the products and their charges that are necessary for performance of nuclear medicine procedures. Although we do not discuss our policy regarding nuclear medicine-to-radiolabeled product claims processing edits in this final rule with comment period, we will continue to annually update and implement this list in accordance with our original finalized policy. We refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60384 through 60390) for a detailed discussion of the nuclear medicine procedure-to-radiolabeled product edits and the evolution of our edit policy. In addition, specific instructions for the nuclear medicine procedure-to-radiolabeled product claims processing edits are contained within the I/OCE CMS specifications on the CMS Web site at *http://www.cms.gov/OutpatientCodeEdit/02OCEQtrReleaseSpecs.asp#TopOfPage*.

Comment: A few commenters recommended that CMS publish preliminary offset amounts for diagnostic radiopharmaceuticals and contrast agents with the proposed rule to allow for meaningful assessment of and public comment on the data.

Response: The exact data used to calculate all of the proposed and final payment rates, including the associated offset amounts, for the CY 2013 OPPS are available for purchase under a CMS data use agreement through the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HhospitalOutpatientPPS/index.html*. 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 do not post the offset amounts by APC until publication of the final rule with comment period because we assign services to APCs based on our estimate of their full resource cost, including, but not limited to, packaged diagnostic radiopharmaceuticals and contrast agents. The offset amount is the portion of each APC payment rate that could reasonably be attributed to the cost of predecessor diagnostic radiopharmaceuticals and contrast agents when considering a new diagnostic radiopharmaceutical and contrast agent for pass-through payment and has no bearing on APC assignment.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue to apply the diagnostic radiopharmaceutical offset policy to payment for pass-through diagnostic radiopharmaceuticals, as described in the CY 2013 OPPS/ASC proposed rule (77 FR 45131).

Table 33 below displays the APCs to which nuclear medicine procedures will be assigned in CY 2013 and for which we expect that an APC offset could be applicable in the case of diagnostic radiopharmaceuticals with pass-through status.

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TABLE 33.—APCs TO WHICH NUCLEAR MEDICINE PROCEDURES WILL BE ASSIGNED FOR CY 2013

CY 2013 APC	CY 2013 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.

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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 and the otherwise applicable OPD fee schedule amount. There currently are no contrast agents with pass-through status under the OPPS. 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.

Although there are no contrast agents with pass-through status, we believe that a payment offset is necessary in the event that a new contrast agent is approved for pass-through status during CY 2013, in order to provide an appropriate transitional pass-through payment for them 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 2013 OPPS/ASC proposed rule (77 FR 45132), we proposed for CY 2013 to deduct from the payment for new pass-through contrast agents that are approved for pass-through status as a drug or biological during CY 2013, 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 2013, as we did in CY 2012, 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 2013 to recognize that when a contrast agent with pass-through status is billed with any procedural APC listed in Table 25 of the proposed rule (77 FR 45132 through 45133), 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.

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/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html* 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.

We proposed to identify procedural APCs for which we expect a contrast offset could be applicable in the case of a pass-through contrast agent as any procedural APC with a ''policy-packaged'' drug amount greater than $20 that is not a nuclear medicine APC identified in Table 33 above, and these APCs are displayed in Table 34 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 (70 FR 60483 through 60484). For CY 2013, we proposed to continue to recognize that when a contrast agent with pass-through status is billed with any procedural APC listed in Table 25 of the proposed rule (77 FR 45132 through 45133), 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.

Comment: One commenter urged CMS to publish the proposed offset amount for contrast agents in the proposed rule to allow interested stakeholders the opportunity to review the data and comment on the amount of the offset.

Response: As we stated previously, the exact data used to calculate all of the proposed and final payment rates, including the associated offset amounts, for the CY 2013 OPPS are available for purchase under a CMS data use agreement through the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. 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 do not post 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 contrast agents. The offset amount is the portion of each APC payment rate that could reasonably be attributed to the cost of a predecessor contrast agent when considering a new diagnostic radiopharmaceutical and contrast agent for pass-through payment and has no bearing on APC assignment.

After consideration of the public comments we received, we are finalizing our proposal for CY 2013 without modification.

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TABLE 34.—APCs TO WHICH A CONTRAST AGENT OFFSET MAY BE APPLICABLE FOR CY 2013

CY 2013 APC	CY 2013 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.
0152	Level I Percutaneous Abdominal and Biliary Procedures.
0177	Level I Echocardiogram With Contrast.
0178	Level II Echocardiogram With Contrast.
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.

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B. OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status

1. Background

Under the CY 2012 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.

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; for CY 2011, we set the packaging threshold at $70; and for CY 2012, we set the packaging threshold at $75.

Following the CY 2007 methodology, for the CY 2013 OPPS/ASC proposed rule (77 FR 45133), 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 2013 and rounded the resulting dollar amount ($81.59) to the nearest $5 increment, which yielded a figure of $80. 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 2013; 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 2013 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 2013 OPPS/ASC proposed rule (77 FR 45134), to determine the proposed CY 2013 packaging status for all nonpass-through drugs and biologicals that are not policy packaged, 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 2011 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2011 claims processed before January 1, 2012 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 2013, 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 2013, 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+6 percent (which is the payment rate we proposed for separately payable drugs and nonimplantable biologicals for CY 2013, as discussed in more detail in section V.B.3.b. of this final rule with comment period) to calculate the CY 2013 proposed rule per day costs. We used the manufacturer submitted ASP data from the fourth quarter of CY 2011 (data that were used for payment purposes in the physician's office setting, effective April 1, 2012) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2013 we proposed to use payment rates based on the ASP data from the fourth quarter of CY 2011 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to the proposed rule (which was available via the Internet on the CMS Web site) because these were the most recent data available for use at the time of development of the proposed rule. These data were also the bases for drug payments in the physician's office setting, effective April 1, 2012. 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 2011 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 identify 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 2011 HCPCS codes that were reported to the CY 2012 HCPCS codes that we displayed in Addendum B of the proposed rule (which was available via the Internet on the CMS Web site) for payment in CY 2013.

Comment: The majority of commenters objected to the proposed increase in the OPPS packaging threshold to $80 for CY 2013. The

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 $75 for CY 2013. 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 argued for parity across the payment systems and they 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 hospital update factor for the year, reflective of all statutory adjustments. One commenter believed that these dollar figures are arbitrary and recommended that CMS tie the threshold for separate payment to the annual market basket rather than randomly assigning thresholds for separate payment for these products.

One commenter noted that increasing the packaging threshold could have the unintended impact of undermining conversion to LEU sources of diagnostic radiopharmaceuticals if CMS adopts a proposal to unbundle diagnostic radiopharmaceuticals from the APC rate under the policy packaging rule without also waiving the dollar threshold for radiopharmaceuticals produced from LEU sources.

Response: As discussed in detail in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66758 through 66767), 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), the CY 2011 OPPS/ASC final rule with comment period (75 FR 71940 through 71943), and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74300 through 74301), 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 (which 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 relative value of each component. Under the MPFS, separate payment is made for each service provided in the physician's office; when individual drugs are administered to beneficiaries 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 for these drugs, 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 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 drug packaging threshold for the CY 2013 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 updating the packaging threshold of $50 for the CY 2005 OPPS 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 2013 or to eliminate or to freeze the packaging threshold at $75.

We disagree with the commenters who suggested that CMS should limit increases in the outpatient drug packaging threshold amount to the hospital update factor for the year, reflective of all statutory adjustments or the market basket update. 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 strongly disagree with the commenter who suggested that our methodology for updating the packaging threshold is arbitrary and recommended that CMS tie the threshold for separate payment to the annual market basket rather than randomly assigning thresholds for separate payment for these products. As we have stated above, 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 manufacturer, we believe that the PPI for Prescription Drugs is an appropriate price index to use to update the packaging threshold for CY 2007 and subsequent years. Therefore, we believe that our continued methodology of updating the

CY 2005 $50 packaging threshold for inflation based on the PPI for Prescription Drugs is not arbitrary in nature nor does it have the effect of randomly assigning a payment threshold for drugs. Our methodology continues to be an accurate way to apply an annual inflation adjustment factor that is consistent with the practices of many health care payment policy areas, and many other areas of government policy, that acknowledge real costs by using an inflation adjustment factor instead of a static dollar value.

Finally, we disagree with commenters that increasing the packaging threshold could have the unintended impact of undermining conversion to LEU sources. As we discuss in section II.A.3.e. of this final rule with comment period, we are finalizing our proposals for CY 2013 to continue to package payment for all nonpass-through diagnostic radiopharmaceuticals. Therefore, diagnostic radiopharmaceuticals will not be subject to the packaging threshold and will instead be packaged regardless of their per day cost. Additionally, as we discuss in section III.A.C.3., removing the diagnostic radiopharmaceutical so that this cost is passed through directly to Medicare is not consistent with the fundamental concept of packaging under the OPPS. Moreover, the diagnostic radiopharmaceutical is never separately billed, being a supply in the diagnostic procedure it supports, so the true cost cannot be captured by single service claims. Most significantly from the standpoint of payment for non-HEU sources, however, a separate payment for the diagnostic radiopharmaceutical does not unbundle the cost of the isotope from the much larger cost of the drug component, nor does it differentiate between HEU and non-HEU sources, so it does not create a differential payment to further the CMS goals of payment equity or the Administration's goal of promoting non-HEU conversion.

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 anticancer treatment regiment to treat nausea. One commenter believed that CMS packaged all 5–HT3 antiemetic drugs (HCPCS codes J1260 (Injection, dolasetron mesylate, 10 mg), J1626 (Injection, granisetron hydrochloride, 100 mcg), J2405 (Injection, ondansetron hydrochloride, per 1 mg), J2469 (Injection, palonosetron hcl, 25 mcg), Q0166 (Granisetron hydrochloride, 1 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 24 hour dosage regimen), Q0180 (Dolasetron mesylate, 100 mg, oral, FDA-approved prescription antiemetic, for use as a complete therapeutic substitute for an iv anti-emetic at the time of chemotherapy treatment, not to exceed a 24 hour dosage regimen)). The commenter opposed the packaging of these drugs.

Response: We continue to believe that use of these antiemetics is an integral part of an anticancer 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, allows us to continue our policy of not specifically exempting these products from the OPPS drug packaging threshold.

Additionally, we clarify that we did not propose to assign a packaged payment status indicator to all 5–HT3 antiemetic codes in the CY 2013 OPPS/ASC proposed rule. HCPCS code J2469 (Injection, palonosetron hcl, 25 mcg) had a per day cost above the proposed $80 packaging threshold and was assigned a separately payable status indicator of ''K'' for the proposed rule. HCPCS code J2469 has a CY 2013 estimated per day cost, from the CY 2011 claims data, above the CY 2013 drug packaging threshold and therefore will receive separate payment in CY 2013.

Comment: One commenter recommended that CMS not package any drugs used in anticancer regimens.

Response: We disagree with the commenter for the reasons mentioned above. We believe that packaging certain items, including items used in anticancer 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 anticancer regimen or in outpatient treatment of other significant disease 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 anticancer 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 not providing any exceptions to the standard drug packaging methodology for any class of drugs, including anticancer therapies, for CY 2013.

Since publication of the CY 2013 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 2013 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 2013. We then rounded the resulting updated dollar amount ($81.91) to the nearest $5 increment, which yielded a figure of $80. Therefore, after consideration for the public comments we received, and consistent with our methodology for establishing the packaging threshold using the most recent PPI forecast data, we are adopting a CY 2013 packaging threshold of $80. 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 OPPS/ASC 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 2013 OPPS/ASC final rule with comment period, we proposed to use ASP data from the first quarter of CY 2012, 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, 2012, along with updated hospital claims data from CY

2011. We note that we also proposed to use these data for budget neutrality estimates and impact analyses for this CY 2013 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 2012. 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, 2012. These physician's office payment rates will then be updated in the January 2013 OPPS update, based on the most recent ASP data to be used for physician's office and OPPS payment as of January 1, 2013. For items that do not currently have an ASP-based payment rate, we proposed to recalculate their mean unit cost from all of the CY 2011 claims data and updated cost report information available for this CY 2013 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 2013 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 cost fluctuates relative to the proposed CY 2013 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2012. Specifically, for CY 2013, consistent with our historical practice, we proposed to apply the following policies to these HCPCS codes for drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals whose relationship to the proposed $80 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 2012 and that were proposed for separate payment in CY 2013, and that then have per day costs equal to or less than $80, based on the updated ASPs and hospital claims data used for this CY 2013 final rule with comment period, would continue to receive separate payment in CY 2013.
- HCPCS codes for drugs and nonimplantable biologicals that were packaged in CY 2012 and that are proposed for separate payment in CY 2013, and that then have per day costs equal to or less than $80, based on the updated ASPs and hospital claims data used for this CY 2013 final rule with comment period, would remain packaged in CY 2013.
- HCPCS codes for drugs and nonimplantable biologicals for which we proposed packaged payment in CY 2013 but then have per day costs greater than $80, based on the updated ASPs and hospital claims data used for this CY 2013 final rule with comment period, would receive separate payment in CY 2013.

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 cost fluctuates relative to the CY 2013 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2012. Therefore, we are finalizing our proposal, without modification, for CY 2013.

We note that HCPCS codes J2700 (Injection, oxacillin sodium, up to 250 mg) and J9218 (Leuprolide acetate, per 1 mg) were paid separately for CY 2012 and were proposed for separate payment in the CY 2013 OPPS/ASC proposed rule and had final per day costs of less than the $80 drug packaging threshold, based on updated ASPs and the CY 2011 hospital claims data available for this CY 2013 final rule with comment period. Therefore, HCPCS codes J2700 and J9218 will continue to be paid separately in CY 2013 according to the established methodology set forth above.

In addition, we proposed to package HCPCS codes J0365 (Injection, aprotonin, 10,000 kiu), J1460 (Injection, gamma globulin, intramuscular, 1 cc), J1560 (Injection, gamma globulin, intramuscular, over 10 cc), J7183 (Injection, von willebrand factor complex (human), wilate, 1 i.u. vwf:rco), and Q4105 (Integra dermal regeneration template (drt), per square centimeter) for CY 2013. Using updated ASPs and the CY 2011 hospital claims data available for this final rule with comment period, HCPCS codes J0365, J1460, J1560, J7183, and Q4105 now have per day costs greater than $80. In accordance with our established policy for such cases, for CY 2013 we will pay for HCPCS codes J0365, J1460, J1560, J7183, and Q4105 separately.

Finally, because we did not have claims data for HCPCS codes J1452 (Injection, fomivirsen sodium, intraocular, 1.65 mg) and J1835 (Injection, itraconazole, 50 mg) in the CY 2013 OPPS/ASC proposed rule, we had proposed a status indicator of ''E'' for these products in CY 2013. However, since publication of the proposed rule, we have received claims data and the per day cost for these products are more than the $80 CY 2013 packaged threshold. These products will be paid separately and will be assigned a status indicator of ''K'' for CY 2013.

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 2013, 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 2013 OPPS/ASC proposed rule (77 FR 45135), 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 2013.

For CY 2013, 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 2011 claims data and our pricing information at ASP+6 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. The following drugs did not have pricing information available for the ASP methodology for this CY 2013 OPPS/ASC final rule and, as is our current policy for determining the packaging status of other drugs, we used the mean unit cost available from the fourth quarter CY 2011 claims data to make the packaging determinations for these drugs: HCPCS codes J3472 (Injection, hyaluronidase, ovine, preservative free, per 1000 usp units), 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), 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), 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), 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), 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), and 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).

For all other drugs and biologicals that have HCPCS codes describing different dosages, we then multiplied the weighted average ASP+6 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).

We did not receive any public comments on this proposal. Therefore, we are finalizing our CY 2013 proposal, without modification. The packaging status of each drug and biological HCPCS code to which this methodology would apply is displayed in Table 35 below.

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TABLE 35.—HCPCS CODES TO WHICH THE CY 2013 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY APPLIES

CY 2013 HCPCS Code	CY 2013 Long Descriptor	CY 2013 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	N
J1560	Injection, gamma globulin, intramuscular over 10 cc	N
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N
J1644	Injection, heparin sodium, per 1000 units	N
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
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

CY 2013 HCPCS Code	CY 2013 Long Descriptor	CY 2013 SI
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
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	N

CY 2013 HCPCS Code	CY 2013 Long Descriptor	CY 2013 SI
	chemotherapy treatment, not to exceed a 48-hour dosage regimen	
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

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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'' 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,'' known as SCODs. 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 section 1842(o) and section 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.

It has been our longstanding policy to apply the same treatment to all separately payable drugs and biologicals, which include SCODs, and drugs and biologicals that are not SCODs. Therefore, we apply the payment methodology in section 1833(t)(14)(A)(iii)(I) of the Act to SCODs, as required by statute, but we also apply it to separately payable drugs and biologicals that are not SCODs, which is a policy choice rather than a statutory requirement. In the CY 2013 OPPS/ASC proposed rule, we proposed to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals. Although we did not distinguish SCODs in that discussion, we note that we are required to apply section 1833(t)(14)(A)(iii)(II) of the Act to SCODs, but we are choosing to apply it to other separately payable drugs and biologicals, consistent with our history of using the same payment methodology for all separately payable drugs and biologicals.

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. 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 proposal 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 prior year's rule.

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 the CMS 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 CMS 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, which 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 our rationale described in the CY 2010 OPPS/ASC proposed rule (74 FR 35326 through 35333), we stated that we believed that approximately $150 million of the estimated $395 million total in pharmacy overhead cost, specifically between one-third and one-half of that cost, included in our claims data for coded packaged drugs and biologicals with reported ASP data should be attributed to separately payable drugs and biologicals and 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 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.

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 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), based on our standard drug payment methodology, should, at least for CY 2010, be attributed to separately payable drugs and biologicals.

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). 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 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 for their pharmacy overhead costs. Based on this redistribution, we proposed a CY 2010 payment rate for separately payable drugs and biologicals of ASP+4 percent.

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 (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 stated that 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 drugs and biologicals captured by these uncoded packaged drug costs (74 FR 60511 through 60513). In addition, as in prior years, we 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). 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, including an analysis of uncoded packaged drug and biological cost and our evaluation of the services with which uncoded packaged drug cost appears in the claims data. We conducted this analysis in an effort to assess how much uncoded drugs resemble coded packaged drugs (75 FR 71966). We stated that, in light of this information, we were not confident that the drugs captured by uncoded drug cost are the same drugs captured by coded packaged drug cost, and therefore, we did not believe we could assume that they are the same drugs, with comparable overhead and handling costs. Without being able to calculate the ASP for these uncoded packaged drugs and biologicals and without being able to gauge the magnitude of overhead complexity associated with these drugs and biologicals, we did not believe that we should have assumed that the same amount of proportional overhead should be redistributed between coded and uncoded packaged drugs, and therefore, we redistributed $50 million from uncoded packaged drugs and $150 million from coded packaged drugs (75 FR 71966). We reiterated our commitment to continue to refine our drug pricing methodology and noted that we would continue to pursue the most appropriate methodology for establishing payment for drugs and biologicals under the OPPS and continue to evaluate the appropriateness of this methodology when we establish each year's payment for drugs and biologicals under the OPPS (75 FR 71967).

For CY 2012, we continued our overhead adjustment methodology of redistributing ⅓ to ½ of allocated overhead for coded packaged drugs or $150 million plus an additional $50 million in allocated overhead for uncoded packaged drugs. Additionally, we finalized a policy to update these amounts by the PPI for pharmaceuticals and redistributed $161 million in allocated overhead from coded packaged drugs and $54 million from uncoded packaged drugs. We further finalized a policy to hold the redistributed proportion of packaged drugs constant between the proposed and the final rule, which increased the final redistribution amount in the CY 2012 final rule to $240.3 million ($169 million from coded packaged drugs and $71.3 million from uncoded packaged drugs). This approach resulted in a final payment rate of ASP+4 percent for separately payable drugs.

b. CY 2013 Payment Policy

In reexamining our current drug payment methodology for the CY 2013 OPPS/ASC proposed rule, we reviewed our past efforts to determine an appropriate payment methodology for drugs and biologicals, as described above. Since the inception of the OPPS, we have remained committed to establishing a drug payment methodology that is predictable, accurate, and appropriate. Pharmacy stakeholders and the hospital community have also, throughout the years, continually emphasized the importance of both predictable and accurate payment rates for drugs, noting that a payment methodology that emphasizes predictability and accuracy leads to appropriate payment rates that reflect the cost of drugs and biologicals (including overhead) in HOPDs. Pertinent stakeholders also have noted that predictable and accurate payment rates minimize the effect of anomalies in the claims data that may incorrectly influence the future payment for services. We understand that, with predictable payment rates, hospitals are better able to plan for the future.

As discussed above, since CY 2006, we have attempted to establish a drug payment methodology that reflects hospitals' acquisition costs for drugs and biologicals while taking into account relevant pharmacy overhead and related handling expenses. We have attempted to collect more data on hospital overhead charges for drugs and biologicals by making several proposals that would require hospitals to change the way they report the cost and charges for drugs. None of these proposals were adopted due to significant stakeholder concern, including that hospitals stated that it would be administratively burdensome to report hospital overhead charges. We established a payment policy for separately payable drugs and biologicals, authorized by section 1833(t)(14)(A)(iii)(I) of the Act, based on an ASP+X amount that is 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). As we previously stated, we refer to this methodology as our standard drug payment methodology.

In CY 2010, taking into consideration comments made by the pharmacy stakeholders and acknowledging the limitations of the reported data due to charge compression and hospitals' reporting practices, we added an ''overhead adjustment'' (an internal adjustment of the data) by redistributing cost from coded and uncoded packaged drugs and biologicals to separately payable drugs in order to provide more appropriate payments for drugs and biologicals in the HOPD. We continued this overhead adjustment methodology through CY 2012, and further refined our overhead adjustment methodology by finalizing a policy to update the redistribution amount for inflation and keep the redistribution ratio constant between the proposed rule and the final rule.

Application of the standard drug payment methodology, with the overhead adjustment, has always yielded a finalized payment rate in the range of ASP+4 percent to ASP+6 percent for nonpass-through separately payable drugs. We believe that the historic ASP+4 to ASP+6 percentage range is an appropriate payment rate for separately payable drugs and biologicals administered within the HOPD, including acquisition and pharmacy overhead and related expenses. However, because of continuing uncertainty about the full cost of pharmacy overhead and acquisition cost, based in large part on the limitations of the submitted hospital charge and claims data for drugs, we are concerned that the continued use of our current standard drug payment methodology (including the overhead adjustment) still may not appropriately account for average acquisition and pharmacy overhead cost and, therefore, may result in payment rates that are not as predictable, accurate, or appropriate as they could be.

Section 1833(t)(14)(A)(iii)(II) of the Act requires an alternative methodology for determining payment rates for SCODs wherein, if hospital acquisition cost data are not available, payment shall be equal (subject to any adjustment for overhead costs) 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. Considering stakeholder and provider feedback, continued limitations of the hospital claims and cost data on drugs and biologicals, and Panel recommendations, in the CY 2013 OPPS/ASC proposed rule (77 FR 45140), we proposed for CY 2013 to pay for separately payable drugs and biologicals at ASP+6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act, hereinafter referred to as the statutory default.

As noted above, section 1833(t)(14)(A)(iii)(II) of the Act authorizes the Secretary to calculate and adjust, as necessary, the average price for a drug in the year established under section 1842(o), 1847A, or 1847B of the Act, as the case may be, in determining payment for SCODs. Pursuant to sections 1842(o) and 1847A of the Act, physician Part B drugs are paid at ASP+6 percent. We believe that proposing the statutory default of ASP+6 percent is appropriate at this time as it yields increased predictability in payment for separately payable drugs and biologicals under the OPPS. We believe that ASP+6 percent is an appropriate payment amount because it is consistent with payment amounts yielded by our drug payment methodologies over the past 7 years. We proposed that the ASP+6 percent payment amount for separately payable drugs and biologicals requires no further adjustment, and represents the combined acquisition and pharmacy overhead payment for drugs and biologicals for CY 2013.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45140), we proposed that payments for separately payable drugs and biologicals are included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act, and that the budget neutral weight scaler is not applied in determining payments for these separately paid drugs and biologicals.

Comment: Commenters strongly supported CMS' proposal to pay for separately payable drugs and biologicals based on the statutory default rate of ASP+6 percent. The commenters stated that ASP+6 percent is administratively simple, improves stability of drug and biological payments, and better covers the costs of drug acquisition and pharmacy overhead than the payment rates CMS has finalized in previous years. The commenters noted that, by contrast, the current payment methodology involves complex calculations and an annual overhead adjustment in which costs are redistributed from packaged drugs to separately payable drugs. Another commenter supported CMS' proposal to pay for separately payable drugs and biologicals because it believed that this change in the payment methodology will prevent the inappropriate shifting of overhead costs from contrast agents. One commenter also expressed support for the proposal and noted the importance of finalizing the proposal, as more hospitals seek to access preferred drug pricing under the 340B program.

One commenter noted that the implementation of the survey of hospital drug costs required by section 1833(t)(14)(D)(iii), instead of the proposed statutory default rate of ASP+6 percent, would impose a costly administrative burden on both hospitals and CMS without demonstrating an equivalent benefit compared to the use of the average sales price that is based on the certified sales price of the drugs and biologicals. Other commenters supported CMS' proposal to pay for drugs and biologicals at ASP+6 percent because neither the GAO nor CMS have conducted the periodic surveys required by the statute since CY 2005 on average acquisition costs. They argued that, in the absence of current survey data on average acquisition costs, the statute requires that payment be set at the statutory default rate of ASP+6 percent and that an additional adjustment for overhead be made.

Several commenters agreed with CMS and noted that this proposal allowed for stable and predictable payment rates for separately paid drugs and biologicals while removing the need to address charge compression and other issues. One commenter noted, in particular, that the proposal eliminates the issues related to the inclusion of 340B sales in the rate calculation. The commenter further recommended that CMS continue its policy of paying 340B and non-340B hospitals at the same rate for separately paid drugs and biologicals. Other commenters noted that payment for the acquisition and overhead costs of drugs and biologicals at ASP+6 percent will help to protect patients' access to care in the most clinically appropriate setting. The commenters also argued that this payment rate would create parity with the physician office setting.

Finally, many of the comments supported CMS' goal to establish a payment methodology that accurately and predictably estimates acquisition and overhead costs for separately paid drugs and biologicals.

Response: We appreciate the commenters' support. For several years, we have attempted to identify a methodology for paying for the average acquisition cost and pharmacy overhead costs for SCODs in a manner that is both appropriate and that is not burdensome

to hospitals. After several years of refining a payment methodology, which has included the standard payment methodology and the overhead adjustment methodology, we determined in the CY 2013 OPPS/ASC proposed rule (77 FR 45140) that, because of continuing uncertainty about the full cost of pharmacy overhead and acquisition cost, based in large part on the limitations of the submitted hospital charge and claims data for drugs, the continued use of our current standard drug payment methodology (including the overhead adjustment) still may not appropriately account for average acquisition and pharmacy overhead cost and therefore may result in payment rates that are not as predictable, accurate, or appropriate as they could be. Therefore, we proposed to pay for separately payable drugs and biologicals at the statutory default rate of ASP+6 percent, as is consistent with section 1833(t)(14)(iii)(II) of the Act which requires an alternative methodology for determining payment rates for SCODs wherein, if hospital acquisition cost data are not available, payment shall be equal (subject to any adjustment for overhead costs) to the 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.

In the past, commenters, pertinent stakeholders, and the HOP Panel (previously known as the APC Panel) have strongly advocated for the use of the statutory default payment rate of ASP+6 percent. As we stated in the proposed rule, we believe that our proposal is consistent with these previous comments and we agree with the commenters that proposing a payment rate of ASP+6 percent based on the statutory default for separately payable drugs and biologicals is appropriate at this time. We agree with commenters that the statutory default obviates both the need to utilize complex calculations for acquisition and overhead costs and the requirement to collect data from hospital surveys, which would prove to be burdensome to both hospitals and to CMS. Additionally, we agree with commenters that the statutory default payment rate of ASP+6 percent eliminates the 340B program concerns many commenters have expressed in the past. Therefore, we believe that the statutory default payment rate of ASP+6 percent is appropriate for CY 2013.

Comment: Several commenters supported CMS' proposal of ASP+6 percent but stated their concerns that this level of payment is not sufficient to cover both drug acquisition and pharmacy overhead cost. The commenters stated that they considered this an improvement over the rate used in previous years and that this payment rate should be the minimum level of payment, or the payment floor, necessary to cover acquisition costs alone. Therefore, the commenters recommended that CMS finalize ASP+6 percent as the payment rate for acquisition costs alone and provide an additional, separate payment for hospital pharmacy overhead costs. One commenter also expressed concern whether ASP+6 percent is sufficient to cover both acquisition and handling. However, the commenter stated that the ASP+6 percent proposed payment rate is preferable to CMS continuing to attempt to determine what level of redistribution from packaged drugs to separately payable drugs should occur on an annual basis. One commenter reaffirmed the notion that ASP+6 percent should be the minimum level of payment that should be provided to cover hospitals' drug acquisition costs but the commenter recommended that CMS reconsider ASP+6 percent to be the minimum payment level to cover drug acquisition costs in both the physician's office and the hospital outpatient setting. The commenter argued that this would create payment parity and also enable the creation of a supplemental system to make a separate and additional ASP plus percentage amount to hospitals to cover their significant overhead costs.

One commenter supported CMS' proposal and stated that if CMS should finalize its policy to pay for separately payable drugs and biologicals at ASP+6 percent, CMS should not pay for pharmacy overhead, which is permitted but not required by section 1833(t)(14)(E)(iii) of the Act, in addition to the ASP+6 percent payment because payment at ASP+6 percent already includes payment for pharmacy overhead equal to 5 percent of ASP (the difference between ASP+6 percent and the ASP+1 percent that the OIG found to be the average acquisition cost of hospital drugs and biologicals in a study conducted by the OIG in 2010) (*https://oig.hhs.gov/oei/reports/oei-03-09-00420.pdf*). Moreover, the commenter further noted that payment for separately payable drugs and biologicals under section 1842(o) of the Act at 106 percent of ASP includes payment for the services of the pharmacy from which the physician purchases the drugs and biologicals. Therefore, the commenter further noted, if CMS pays hospitals ASP+6 percent for separately paid drugs and biologicals, it is also paying for the associated pharmacy overhead and should pay nothing more.

Response: We disagree with the commenters who stated that ASP+6 percent should be the payment for the acquisition cost alone and that separate payment for overhead should be made. We note that while the statute states that payment for SCODs under section 1833(t)(14)(A)(iii)(II) of the Act equals the payment rates established in the physician's office, subject to any adjustment for overhead costs, the statute does not mandate that such an adjustment for overhead be made. We believe that the payment rate of ASP+6 percent includes a sufficient amount for overhead costs for separately payable drugs and biologicals and we see no further evidence that any additional adjustment for overhead is required. As we stated in the proposed rule, we believe that the historic ASP+4 to ASP+6 percentage range is an appropriate payment rate for separately payable drugs and biologicals administered within the HOPD, including acquisition and pharmacy overhead and related expenses, and we have not seen any evidence to indicate that these rates have limited beneficiary access to drugs, insufficiently paid for acquisition and overhead costs for drugs administered in the HOPD, or caused a migration of care from the hospital outpatient setting to the physician's office. To the contrary, we continue to see increases in the utilization of drugs and biologicals administered in the outpatient department in our claims data, even at payment rates of ASP+4 or 5 percent. Therefore, we believe that ASP+6 percent is an appropriate payment rate for separately payable drugs and biologicals.

Additionally, we agree with the commenter who cited the OIG study conducted in 2010, which used first quarter 2009 Medicare payment amounts compared to first quarter 2009 hospital acquisition costs for 33 separately payable drugs. The OIG concluded that, in the aggregate, Medicare payments were 1 percent higher than acquisition costs amounts for the responding non-340B hospitals for the selected separately payable drugs. This study supports our position that the ASP+6 percentage amount proposed for CY 2013 sufficiently pays for overhead and acquisition costs for drugs and requires no further adjustment.

We continue to believe that ASP+6 percent based on the statutory default is appropriate for hospitals for CY 2013 and that this percentage amount

includes payment for acquisition and overhead cost. Furthermore, many hospitals and major hospital associations supported our proposed ASP+6 percent for CY 2013 and made no request for additional payment for overhead costs in their comments to the CY 2013 OPPS/ASC proposed rule. Therefore, we believe that a payment rate of ASP+6 percent is appropriate for CY 2013.

Comment: A few commenters supported CMS' proposal, but recommended that CMS examine ways to compensate hospitals for the unique, higher overhead and handling costs associated with therapeutic radiopharmaceuticals.

Response: As we stated above, we continue to believe that ASP+6 percent based on the statutory default is appropriate for hospitals for CY 2013 and that this percentage amount includes payment for acquisition and overhead cost. We see no evidence that an additional overhead adjustment is required for separately payable drugs, biologicals and therapeutic radiopharmaceuticals for CY 2013.

Comment: One commenter remained concerned that the comparison of ASP to cost is not an ''apple to apples'' comparison because the cost data incorporate data from hospitals that receive 340B program discounts from drugs they purchase. The commenter further stated that the ASP calculation excludes 340B program sales, which underestimates the aggregate costs of drugs for most hospitals and the ASP-based rate that CMS produces by comparing aggregate costs to ASP is too low. The commenter asked that CMS review its cost calculation to ASP to ensure that 340B program drugs are not artificially reducing the CMS calculation.

Response: For CY 2013, we proposed to pay for separately payable drugs and biologicals at ASP+6 percent based on the statutory default established in section 1833(t)(14)(A)(iii)(II) of the Act. While we understand that commenters were previously concerned about the impact of 340B hospital data on our previous standard and overhead adjustment methodology calculations, we did not in fact propose to continue these methodologies for CY 2013.

Comment: One commenter supported CMS' proposal to increase the payment rate for SCODs to ASP+6 percent for CY 2013. However, the commenter believed that the law requires that SCOD payment rates, other than the ASP+6 percent default rate, must be set on a drug by drug basis, as mandated by section 1833(t)(14)(A)(iii)(I) of the Act. Therefore, the commenter recommended that CMS perform an individualized, drug by drug determination for the payment rate for each SCOD.

Response: Section 1833(t)(14)(A)(iii)(I) 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, subject to any adjustment of overhead costs. 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), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary. Previously under the standard methodology and the overhead adjustment methodology, we established ASP as a proxy for the average acquisition cost. However, we did not propose to use the authority given under section 1833(t)(14)(A)(iii)(I) of the Act to pay for SCODs for CY 2013. For CY 2013, we instead proposed to pay for separately payable drugs and biologicals based on the statutory authority established in section 1833(t)(14)(A)(iii)(II) of the Act.

Comment: One commenter recommended that CMS design a payment strategy that would maintain one formula for health care prescribers, but develop a multi-tiered reimbursement strategy that would encourage the use of generic drugs over their branded counterparts, using ASP+6 percent as an appropriate base for the most expensive drugs and providing additional reimbursement for multi-source generic drugs. Another commenter recommended that CMS adopt a new policy of assigning each ''branded prescription drug'' a unique HCPCS code, so that Part B utilization of these drugs can be accurately determined.

Response: We made no such proposal to develop a multi-tiered payment strategy that would encourage the use of generic drugs over their branded counterparts, using ASP+6 percent as an appropriate base for the most expensive drugs and providing additional payment for multi-source generic drugs. The commenters' recommendation to assign a unique HCPCS code for each ''branded prescription drug'' is outside the scope of this final rule with comment period.

Comment: One commenter asked that, for CY 2014, CMS consider paying for influenza and PPV vaccines at 106 percent of ASP.

Response: This comment is outside the scope of the CY 2013 OPPS/ASC final rule. However, we plan to address this issue in an upcoming rulemaking cycle.

Comment: One commenter supported CMS' proposal to pay for separately payable drugs at ASP+6 percent, but the commenter urged CMS to consider the effect of its coding practices on brand manufacturers' annual fee payment under section 9008 of the Patient Protection and Affordable Care Act (ACA) and asked that CMS support the exclusion of wholesaler prompt pay discounts from the ASP calculations of separately payable drugs.

Response: Comments about individual ASP calculations for drugs and biologicals, or the inclusion or exclusion of prompt pay discounts in these calculations, are outside the scope of this final rule with comment period.

At its February 2012 Panel meeting, the Panel made four recommendations on drugs and biologicals paid under the OPPS. First, the Panel recommended that CMS require hospitals to bill all drugs that are described by Healthcare Common Procedure Coding System (HCPCS) codes under revenue code 0636. While we agree that drugs and biologicals may be reported under revenue code 0636, we believe that drugs and biologicals may also be appropriately reported in revenue code categories other than revenue code 0636, including but not limited to, revenue codes 025x and 062x. As we stated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71966), we recognize that hospitals may carry the costs of drugs and biologicals in multiple cost centers and that it may not be appropriate to report the cost of all drugs and biologicals in one specified revenue code. Additionally, we generally require hospitals to follow National Uniform Billing Committee (NUBC) guidance for the choice of an appropriate revenue code that is also appropriate for the hospital's internal accounting processes. Therefore, we are not accepting the Panel's recommendation to require hospitals to bill all drugs that are described by HCPCS codes under revenue code 0636. 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. 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 may improve payment accuracy for

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, when specific HCPCS codes are available for those drugs and biologicals.

Comment: Some 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. One commenter recommended that CMS not require hospitals to report the HCPCS code for each drug and biological in revenue code 0636 because to do so would impose an unreasonable burden on hospitals without a commensurate benefit to the accuracy of Medicare payment for drugs and biologicals under the OPPS if CMS finalizes its proposal to pay separately paid drugs at ASP+6 percent. Moreover, the commenter continued, in the case of packaged drugs and biologicals, the charges that are reported with revenue codes but without HCPCS codes are reduced to costs by application of the CCR for the cost center that applies to the revenue code under which the charges are reported and are packaged into the cost of the service. The commenter further stated that, therefore, to require that all drugs and biologicals be reported under any specific revenue code would require hospitals to revise their cost accounting systems to accommodate such a change because the revenue code in which charges are reported must correspond to the cost center in which the costs are reported on the cost report for the cost report to be completed correctly and for the cost of packaged drugs and biologicals to be calculated correctly.

Response: We do not accept the commenter's recommendation that CMS require drugs and biologicals to be reported under revenue code 0636. We do agree with the commenter who recommended that CMS not require hospitals to report the HCPCS code for each drug and biological in revenue code 0636 because doing so would impose an unreasonable burden on hospitals. Further, we agree that charges that are reported with revenue codes but without HCPCS codes are reduced to costs by application of the CCR for the cost center that applies to the revenue code under which the charges are reported and are packaged into the cost of the service. As we stated in the CY 2013 OPPS/ASC proposed rule, we believe that drugs and biologicals may also be appropriately reported in revenue code categories other than revenue code 0636, including, but not limited to, revenue codes 025x and 062x. As we stated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71966), we recognize that hospitals may carry the costs of drugs and biologicals in multiple cost centers and that it may not be appropriate to report the cost of all drugs and biologicals in one specified revenue code. Additionally, we generally require hospitals to follow National Uniform Billing Committee (NUBC) guidance for the choice of an appropriate revenue code that is also appropriate for the hospital's internal accounting processes. Therefore, we are not accepting the Panel's recommendation to require hospitals to bill all drugs that are described by HCPCS codes under revenue code 0636.

However, we are reiterating once again in this CY 2013 OPPS/ASC final rule with comment period that the OPPS ratesetting as a whole, not just for drugs and biologicals, 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. Therefore, we continue to encourage hospitals to report a charge for each service they furnish, either by billing the HCPCS code and a charge for that service if separate reporting is consistent with CPT and CMS instructions or by reporting the charge for the packaged service with an appropriate revenue code but without a HCPCS code, when specific HCPCS codes are unavailable.

Second, the Panel recommended that CMS exclude data from hospitals that participate in the 340B program from its ratesetting calculations for drugs. Under the proposed statutory default payment rate of ASP+6 percent, hospitals' 340B status does not affect the drug payment rate.

Third, the Panel recommended that CMS freeze the packaging threshold at $75 until the drug payment issue is more equitably addressed. The OPPS is based on the concept of payment for groups of services that share clinical and resource characteristics. We believe 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, we are not accepting the Panel's recommendation to freeze the packaging threshold at $75 until the drug payment issue is more equitably addressed. Instead, as discussed in section V.B.2. of the proposed rule and this final rule with comment period, we proposed and are finalizing an OPPS drug packaging threshold for CY 2013 of $80. However, we do believe that we have addressed the drug payment issue by proposing to pay for separately paid drugs and biologicals at ASP+6 percent for CY 2013 based upon the statutory default.

Finally, the Panel recommended that CMS pay hospitals for separately payable drugs at a rate of ASP+6 percent. This Panel recommendation is consistent with our CY 2013 proposed payment rate based upon the statutory default under section 1833(t)(14)(A)(iii)(II) of the Act, which authorizes us to pay for drugs and biologicals under the OPPS at ASP+6 percent, when hospital acquisition cost data are not available.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to pay for separately payable drugs and biologicals at ASP+6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act, hereinafter referred to as the statutory default. The ASP+6 percent payment amount for separately payable drugs and biologicals requires no further adjustment and represents the combined acquisition and pharmacy overhead payment for drugs and biologicals for CY 2013. As we stated in the proposed rule (77 FR 45140), our goals continue to be to develop a methodology that accurately and predictably estimates acquisition and overhead costs for separately payable drugs and biologicals in order to pay for them appropriately. If a better payment methodology is developed in the future then the proposed policy to pay ASP+6 percent according to the statutory default would be an interim step in the development of this payment policy. We recognize the challenges in doing so given the current data sources and the object of maintaining the smallest administrative burden possible.

In addition, we are finalizing our proposal which states that payment for separately payable drugs and biologicals be included in the budget neutrality adjustments, under the requirements of section 1833(t)(9)(B) of the Act, and that the budget neutral weight scaler is not applied in determining payment of these separately paid drugs and biologicals.

We note that separately payable drug and biological payment rates listed in Addenda A and B to this final rule with comment period, which illustrate the final CY 2013 payment of ASP+6 percent for separately payable nonpass-

through drugs and biologicals and ASP+6 percent for pass-through drugs and biologicals, reflect either ASP information that is the basis for calculating payment rates for drugs and biologicals in the physician's office setting effective October 1, 2012, or WAC, AWP or mean unit cost from 2011 claims data and updated cost report information available for this final rule with comment period. In general, these published payment rates are not reflective of actual January 2013 payment rates. This is because payment rates for drugs and biologicals with ASP information for January 2013 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of 2012 (July 1, 2012 through September 30, 2012) are used to set the payment rates that are released for the quarter beginning in January 2013 near the end of December 2012. In addition, payment rates for drugs and biologicals in Addenda A and B to this final rule with comment period for which there was no ASP information available for October 2012 are based on mean unit cost in the available CY 2011 claims data. If ASP information becomes available for payment for the quarter beginning in January 2013, we will price payment for these drugs and biologicals based on their newly available ASP information. Finally, there may be drugs and biologicals that have ASP information available for this final rule with comment period (reflecting October 2012 ASP data) that do not have ASP information available for the quarter beginning in January 2013. These drugs and biologicals will then be paid based on mean unit cost data derived from CY 2011 hospital claims. Therefore, the payment rates listed in Addenda A and B to this final rule with comment period are not for January 2013 payment purposes and are only illustrative of the CY 2013 OPPS payment methodology using the most recently available information at the time of issuance of this final rule with comment period.

4. Payment Policy for Therapeutic Radiopharmaceuticals

Beginning in CY 2010 and continuing for CY 2012, we established a policy to pay for separately paid therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals. We allow 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. If ASP information is unavailable for a therapeutic radiopharmaceutical, then we base therapeutic radiopharmaceutical payment on mean unit cost data derived from hospital claims. 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 2013. Therefore, in the CY 2013 OPPS/ASC proposed rule (77 FR 45141), we proposed for CY 2013 to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent, based on the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. We proposed to continue to set payment rates for therapeutic radiopharmaceuticals 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 2011 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. For a complete history of the OPPS payment policy for therapeutic radiopharmaceuticals, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65811), the CY 2006 OPPS final rule with comment period (70 FR 68655), and the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524).

Comment: Commenters supported CMS' proposal to pay for separately payable therapeutic radiopharmaceuticals under the statutory default payment rate of ASP+6 percent, if ASP data is submitted to CMS. The commenters also supported CMS' proposal to continue to set payment rates for therapeutic radiopharmaceuticals based on ASP information, if available, for a ''patient ready'' dose. One commenter recommended that CMS use its discretion and continue to pay on the basis of hospital specific reasonable cost-finding where ASP information is not available.

Response: We appreciate the commenters' support. We continue to believe that providing payment for therapeutic radiopharmaceuticals based on ASP or mean unit cost if ASP information is not available would provide appropriate payment for these products. 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 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 (the usual process relies on alternative data sources 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 are not available. We have stated previously, in the CY 2008 OPPS/ASC final rule with comment period, that we continue to believe that payment on a claims-specific basis is not consistent with the payment of times and services on a prospective basis under the OPPS and may lead to extremely high or low payment to hospitals for radiopharmaceuticals, even when those products would be expected to have relatively predictable and consistent acquisition and holding costs across individual clinical cases and hospitals. For CY 2013, Medicare pays for only a few outpatient services at reasonable cost. These services include, but are not limited to, corneal tissue acquisition and influenza vaccines, and are paid at reasonable cost in part because the input costs for future years are highly 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, therapeutic radiopharmaceutical payment based on mean unit cost is an appropriate proxy for hospitals' acquisition and handling data.

Comment: One commenter 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 commenter recommended that payment for all of the BEXXAR® drug components be paid as a SCOD.

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 (as noted in 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. Payment for unlabeled tositumomab is included in the payment for the administration procedure (described by HCPCS code G3001). Therefore, we do not agree with the commenter's recommendation that we should assign a separate HCPCS code to unlabeled tositumomab, which is a packaged supply.

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 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 2013, therapeutic radiopharmaceuticals will be paid based on the statutory default payment rate of ASP+6 percent. The final CY 2013 payment rates for nonpass-through separately payable therapeutic radiopharmaceuticals are included in Addenda A and B to the proposed rule (which is available via the Internet on the CMS Web site).

5. Payment for Blood Clotting Factors

For CY 2012, 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 2012, we provided payment for blood clotting factors under the OPPS at ASP+4 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 2012 updated furnishing fee is $0.181 per unit.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45141), we proposed to pay for blood clotting factors at ASP+6 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 policy to pay for a furnishing fee for blood clotting factors under the OPPS is consistent with the methodology applied in the physician office and inpatient hospital setting, and first articulated in the CY 2006 OPPS final rule with comment period (70 FR 68661) and 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 were 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 proposed to 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/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html.*

Comment: 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. These commenters also supported CMS' proposal to pay for separately payable drugs at ASP+6 percent based on the statutory default, for CY 2013.

Response: We appreciate the commenters' support. We continue to believe that applying the furnishing fee for blood clotting factors is appropriate for CY 2013. 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. Additionally, for the reasons discussed in section V.B.3. of this final rule with comment period, we agree with the commenters that ASP+6 percent based on the statutory default is an appropriate payment rate for CY 2013.

After consideration of the public comments we received, we are finalizing our 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 payment of an updated furnishing fee. We will announce the actual figure of the percent change in the applicable CPI and the updated furnishing fee calculation based on that figure through the applicable program instructions and posting on the CMS Web site.

6. 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) did 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 and the CY 2012 OPPS/ASC final rule with comment period at ASP+4 percent (76 FR 74330 through 74332).

In the CY 2013 OPPS/ASC proposed rule (77 FR 45142), we proposed to provide payment for new CY 2013 drugs (excluding contrast agents and diagnostic radiopharmaceuticals), nonimplantable biologicals, and therapeutic radiopharmaceuticals, at ASP+6 percent, consistent with the proposed CY 2013 payment methodology for other separately payable nonpass-through drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals to pay at ASP+6 percent based on the statutory default. We believe 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.

We also proposed to continue to package payment for all new nonpass-through diagnostic radiopharmaceuticals and contrast agents with HCPCS codes but without claims data (those new CY 2013 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 and contrast agents, as discussed in more detail in section II.A.3.g. of this final rule with comment period.

In accordance with the OPPS ASP methodology, in the absence of ASP data, for CY 2013, 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 and are not diagnostic radiopharmaceuticals and contrast agents. 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 2013 at ASP+6 percent) for items that have not been granted pass-through status. This proposed policy, which utilizes the ASP methodology that requires us to use WAC data when ASP data are unavailable and 95 percent of AWP when WAC and ASP data are unavailable, for new nonpass-through drugs and biologicals with an ASP, is consistent with prior years' policies for these items, and 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.

Similarly, we proposed to continue 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, for CY 2013 we proposed to announce any changes to the payment amounts for new drugs and biologicals in this CY 2013 OPPS/ASC final rule with comment period and also on a quarterly basis on the CMS Web site during CY 2013 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 2013 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 2013 OPPS/ASC final rule with comment period (which is 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 2013 OPPS/ASC final rule with comment period.

There are several nonpass-through drugs and biologicals that were payable in CY 2011 and/or CY 2012 for which we did not have CY 2011 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 2013, 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+6 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 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. Therefore, for the reasons described in our proposed rule, we are finalizing our CY 2013 proposal, with modification, to use the estimated number of units per day included in Table 37 below to determine estimated per day costs for the corresponding drugs and biologicals for CY 2013. For those drugs and biologicals without CY 2011 claims data that we determine to be separately payable in CY 2013, payment will be made at ASP+6 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 proposed estimated units per day and status indicators for these items were displayed in Table 27 of the proposed rule (77 FR 45143).

In the CY 2013 OPPS/ASC proposed rule (77 FR 45143), 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 2013. We proposed to pay separately for items with an estimated per day cost greater than $80 (with the exception of diagnostic radiopharmaceuticals and contrast agents, which we proposed to continue to package regardless of cost as discussed in more detail in section II.A.3.d. of this final rule with comment period) in CY 2013. We proposed that the CY 2013 payment for separately payable items without CY 2011 claims data would be ASP+6 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 note that if the WAC is also unavailable, we would make payment at 95 percent of the most recent AWP available.

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+6 percent under the statutory default. 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 responding to the CY 2013 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 agent with HCPCS codes but without OPPS claims data. We summarize these comments and provide our response in section II.A.3.e. of this final rule with comment period. We are finalizing our CY 2013 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 2012 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+6 percent for CY 2013, consistent with the final CY 2013 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 2013. 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 become 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 2013, we also proposed to continue our CY 2012 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 responding to the CY 2013 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 2013, as discussed in section V.B.3.c. of this final rule with comment period.

We are finalizing our CY 2013 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 are 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 2013 that do not have pass-through status.

Consistent with other ASP-based payments, for CY 2013, we proposed to announce any changes to the payment amounts for new drugs and biologicals in the CY 2013 OPPS/ASC final rule with comment period and also on a quarterly basis on the CMS Web site during CY 2013 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 2013 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 2013 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 2013 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 2013 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.

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TABLE 36.—DRUGS AND BIOLOGICALS WITHOUT CY 2011 CLAIMS DATA

CY 2013 HCPCS Code	CY 2013 Long Descriptor	Estimated Average Number of Units Per Day	CY 2013 SI	CY 2013 APC
C9367	Skin substitute, Endoform Dermal Template, per square centimeter	55	K	9367
J0630	Injection, calcitonin salmon, up to 400 units	1.5	K	1433
J2793	Injection, Rilonacept	320	K	1291
J7196	Injection, antithrombin recombinant, 50 IU	268	K	1332
J8562	Fludarabine phosphate, oral, 10 mg	1	K	1339
J9065	Injection, cladribine, per 1 mg	10	K	0858
J9151	Injection, daunorubicin citrate, liposomal formulation, 10 mg	5	K	0821
J0205	Injection, alglucerase, per 10 units	420	K	0900
J2724	Injection, protein c concentrate, intravenous, human, 10 iu	1540	K	1139
Q0515	Injection, sermorelin acetate, 1 microgram	70	K	3050
J2513	Injection, pentastarch, 10% solution, 100 ml	4	N	N/A
J3355	Injection, urofollitropin, 75 IU	2	K	1741
90581	Anthrax vaccine, for subcutaneous or intramuscular use	1	K	1422
J2265	Injection, minocycline hydrochloride, 1 mg	300	K	1423
J8650	Nabilone, oral, 1 mg	4	K	1424

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Finally, there were 19 drugs and biologicals, shown in Table 28 of the proposed rule (77 FR 45144), that were payable in CY 2011, but for which we lacked CY 2011 claims data and any other pricing information for the ASP methodology for the CY 2013 OPPS/ASC proposed rule. In CY 2009, for similar items without CY 2007 claims data and without pricing information for the ASP methodology, we 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 became 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. We continued this policy for CY 2011 and CY 2012 (75 FR 71973 and 76 FR 74334).

For CY 2013, we proposed to continue to assign status indicator ''E'' to drugs and biologicals that lack CY 2011 claims data and pricing information for the ASP methodology. All drugs and biologicals without CY 2011 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 2013 were displayed in Table 28 of the proposed rule (77 FR 45144). If pricing information becomes available, we proposed to assign the products status indicator ''K'' and pay for them separately for the remainder of CY 2013.

Comment: Several commenters disagreed with CMS' proposal to assign a status indicator ''E'' to HCPCS code Q4102 (Talymed, per square centimeter) for CY 2013. The commenters requested a status indicator of ''K'' to more closely align the product with others on the market, such as the products represented by HCPCS code Q4101 and Q4102. The commenters indicated that a status indicator of ''E'' would make it impossible for the necessary claims data and pricing to be collected.

The manufacturers of the product that is described by HCPCS code Q4101 assured CMS that they will be submitting ASP data shortly and anticipate that CMS will replace the

status indicator ''E'' with the status indicator ''K'' upon submission of this data.

Response: For this final rule with comment period, we have not received ASP pricing information in order to assign a status indicator of ''K'' to HCPCS code Q4101. Therefore, according to our longstanding policy, we will continue to assign HCPCS code Q4101 to a status indicator of ''E.'' If pricing information becomes available, we will assign HCPCS code Q4101 a status indicator ''K'' and pay for it separately for the remainder of CY 2013. We cannot assign a payable status indicator to products that have no available payment information.

Comment: One commenter who responded to the CY 2012 OPPS/ASC final rule with comment period expressed concern that the assignment of status indicator ''E'' to HCPCS code Q4128 was a technical error that should have been changed to status indicator ''K'' effective January 1, 2012.

Response: For the CY 2012 OPPS/ASC final rule with comment period, HCPCS code Q4128 (Flexhd or allopatch hd, per square centimeter) was not erroneously assigned a status indicator of ''E'' because we did not have ASP pricing information available to us at the time of the publication of the final rule. However, during CY 2012, we received pricing information for HCPCS code Q4128 and assigned status indicator ''K'' to this code. For CY 2013, this HCPCS code continues to have a status indicator of ''K'' and the price is published in Addendum B of this final rule with comment period.

After the proposed rule was published, we were able to use updated CY 2011 claims data and ASP pricing information for HCPCS code J1452 (Injection, fomivirsen sodium, intraocular, 1.65 mg), HCPCS code J1835 (Injection, itraconazole, 50 mg), and HCPCS code J9212 (Injection, interferon alfacon-1, recombinant, 1 microgram). Therefore, we are assigning HCPCS code J1452, HCPCS code J1835, and HCPCS code J9212 a status indicator of ''K'' for CY 2013. The revised status indicators for these HCPCS codes are included in Addendum B to this CY 2013 OPPS/ASC final rule with comment period (which is available via the Internet on the CMS Web site).

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 Q4134 (Hmatrix, per square centimeter), Q4135 (Mediskin, per square centimeter), and Q4136 (Ez-derm, per square centimeter) as lacking CY 2011 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 2013 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 Q4134, Q4135, and Q4136.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to assign status indicator ''E'' to these drugs and biologicals. As was our policy in CY 2012, if pricing information becomes available for these products in CY 2013, we will assign the products status indicator ''K'' and pay for them separately for the remainder of CY 2013.

All drugs and biologicals without CY 2011 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 2013 are displayed in Table 37 below.

TABLE 37.—DRUGS AND BIOLOGICALS WITHOUT CY 2011 CLAIMS DATA AND WITHOUT PRICING INFORMATION FOR THE ASP METHODOLOGY

CY 2013 HCPCS Code	CY 2013 Long Descriptor	CY 2013 SI
90296	Diphtheria antitoxin, equine, any route	E
90393	Vaccina immune globulin, human, for intramuscular use	E
J3305	Injection, trimetrexate glucuronate, per 25 mg	E
90706	Rubella virus vaccine, live, for subcutaneous use	E
90725	Cholera vaccine for injectable use	E
90727	Plague vaccine, for intramuscular use	E
J0190	Injection, biperiden lactate, per 5 mg	E
J2670	Injection, tolazonline hcl, up to 25 mg	E
J2940	Injection, somatrem, 1 mg	E
J3305	Injection, trimetrexate glucuronate, per 25 mg	E
J3320	Injection, spectinomycin dihydrochloride, up to 2 gm	E
J9165	Injection, diethylstilbestrol diphosphate, 250 mg	E
Q4117	Hyalomatrix, per square centimeter	E
Q4120	Matristem Burn matrix, per square centimeter	E
Q4126	Memoderm, per square centimeter	E
Q4127	Talymed, per square centimeter	E
Q4134	Hmatrix, per square centimeter	E
Q4135	Mediskin, per square centimeter	E
Q4136	Ez-derm, per square centimeter	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 not to exceed 2.0 percent of total program payments estimated to be made for all covered services under the OPPS furnished for that year.

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 estimate the pass-through spending to determine whether payments exceed the applicable percentage and the appropriate pro rata reduction to the conversion factor for the projected level of pass-through spending in the following year to ensure that total estimated pass-through spending for the prospective payment year is budget neutral, as required by section 1833(t)(6)(E) of the Act.

For devices, developing an estimate of pass-through spending in CY 2013 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 2013. 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 of items consists of items that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2012 or beginning in CY 2013. The sum of the CY 2013 pass-through estimates for these two groups of device categories equals the total CY 2013 pass-through spending estimate for device categories with pass-through status. We base the device pass-through estimated payments for each device category on the amount of payment as established in section 1833(t)(6)(D)(ii) of the Act, and as outlined in previous rules, including the CY 2012 OPPS/ASC final rule with comment period (76 FR 74335 through 74336). We note that, 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), is the device pass-through process and payment methodology (74 FR 60476). As has been our past practice (76 FR 74335), we

include an estimate of any implantable biologicals eligible for pass-through payment in our estimate of pass-through spending for devices.

For drugs and nonimplantable 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. We note that the Part B drug CAP program has been postponed since CY 2009, and such a program was not proposed to be reinstated for CY 2013. Because we will pay for most nonpass-through separately payable drugs and nonimplantable biologicals under the CY 2013 OPPS at ASP+6 percent, as we discussed in section V.B.3. of this final rule with comment period, which represents the otherwise applicable fee schedule amount associated with most pass-through drugs and nonimplantable biologicals, and because we will pay for CY 2013 pass-through drugs and nonimplantable biologicals at ASP+6 percent, as we discussed in section V.A. of this final rule with comment period, our estimate of drug and nonimplantable biological pass-through payment for CY 2013 for this group of items is zero, as discussed below. Furthermore, payment for certain drugs, specifically diagnostic radiopharmaceuticals and contrast agents, 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 2013 will be paid at ASP+6 percent like other pass-through drugs and nonimplantable biologicals. Therefore, our estimate of pass-through payment for all diagnostic radiopharmaceuticals and contrast agents with pass-through status approved prior to CY 2013 is not zero. In section V.A.4. of this final rule with comment period, we discuss our 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 are associated with the drug receiving pass-through payment, we are offsetting the amount of pass-through payment for diagnostic radiopharmaceuticals or contrast agents. For these drugs, the APC offset amount is the portion of the APC payment for the specific procedure performed with the pass-through 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 reduce our estimate of pass-through payment for these drugs by this amount.

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 for CY 2012 and that will continue to be eligible for pass-through payment in CY 2013. 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 2012 or beginning in CY 2013. The sum of the CY 2013 pass-through estimates for these two groups of drugs and nonimplantable biologicals equals the total CY 2013 pass-through spending estimate for drugs and nonimplantable biologicals with pass-through status.

B. Estimate of Pass-Through Spending

In the CY 2013 OPPS/ASC proposed rule (77 FR 45145), we proposed to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2013, consistent with section 1833(t)(6)(E)(ii)(II) of the Act, and our OPPS policy from CY 2004 through CY 2012 (76 FR 74336).

For the first group of devices for pass-through payment estimation purposes, there currently are three device categories eligible for pass-through payment for CY 2013: C1830 (Powered bone marrow biopsy needle); C1840 (Lens, intraocular (telescopic)); and C1886 (Catheter, extravascular tissue ablation, any modality (insertable). In the proposed rule, we estimated that CY 2013 pass-through expenditures related to these three eligible device categories would be approximately $42 million. In estimating our CY 2013 pass-through spending for device categories in the second group, we include: Device categories that we knew at the time of the development of the proposed rule will be newly eligible for pass-through payment in CY 2013 (of which there are none); additional device categories that we estimate could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2013; and contingent projections for new device categories established in the second through fourth quarters of CY 2013. 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 2013 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 2013 (spending for the first group of device categories ($42 million) plus spending for the second group of device categories ($10 million)) would be $52 million.

We did not receive any public comments regarding our proposed pass-through spending estimate for devices. Therefore, for CY 2013, we are continuing to use our established methodology for estimating pass-through spending for device categories. For this final rule with comment period, using our established methodology and updated data and information, we estimate CY 2013 pass-through spending for the first group of device categories to be $42, and the CY 2013 pass-through spending for the second group of device categories to be $10 million. The total estimated pass-through spending for device categories for CY 2013 (spending for the first group of device categories ($42 million) plus spending for the second group of device categories ($10 million)) is $52 million.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45146), to estimate CY 2013 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 2013, 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 2013 OPPS utilization of the products.

For the known drugs and nonimplantable biologicals (excluding diagnostic radiopharmaceuticals and contrast agents) that will be continuing on pass-through status in CY 2013, in the proposed rule (77 FR 45145), we estimated the pass-through payment amount as the difference between ASP+6 percent and the payment rate for nonpass-through drugs and nonimplantable biologicals that will be separately paid at ASP+6 percent, which is zero for this group of drugs. Because payment for a diagnostic radiopharmaceutical or contrast agent is packaged if the product was not paid separately due to its pass-through status, we proposed to include in the CY 2013 pass-through estimate the difference between payment for the drug or 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 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 are associated with the drug receiving pass-through payment. In the proposed rule, using the proposed methodology described above, we calculated a CY 2013 proposed spending estimate for this first group of drugs and nonimplantable biologicals of approximately $13 million.

We did not receive any public comments on our proposed methodology for calculating the spending estimate for the first group of drugs and nonimplantable biologicals. Therefore, for this final rule with comment period, we are finalizing our proposed methodology. Using our established methodology and updated data and information, we calculated a final CY 2013 spending estimate for the first group of drugs and nonimplantable biologicals of approximately $15 million.

In the proposed rule (77 FR 45146), to estimate CY 2013 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 are newly eligible for pass-through payment in CY 2013, additional drugs and nonimplantable biologicals that we estimate could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2013, 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 2013), 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 2013 pass-through payment estimate. We also proposed to consider the most recent OPPS experience in approving new pass-through drugs and nonimplantable biologicals. Using our proposed methodology for estimating CY 2013 pass-through payments for this second group of drugs, we calculated a proposed spending estimate for this second group of drugs and nonimplantable biologicals of approximately $19 million.

We did not receive any public comments on our proposed methodology for estimating CY 2013 pass-through payments for this second group of drugs and nonimplantable biologicals. Therefore, for this final rule with comment period, are finalizing our proposed methodology. Using that methodology and updated data and information, we calculated a final CY 2013 spending estimate for this second group of drugs and implantable biologicals of approximately $7 million.

As discussed in section V.A. of this final rule with comment period, radiopharmaceuticals are considered drugs for pass-through purposes. Therefore, we include radiopharmaceuticals in our CY 2013 pass-through spending estimate for drugs and nonimplantable biologicals. Our CY 2013 estimate for total pass-through spending for drugs and nonimplantable biologicals (spending for the first group of drugs and nonimplantable biologicals ($15 million) plus spending for the second group of drugs and nonimplantable biologicals ($7 million)) equals $22 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 2013 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2013 will be approximately $74 million (approximately $52 million for device categories and approximately $22 million for drugs and nonimplantable biologicals), which represents 0.15 percent of total projected OPPS payments for CY 2013. We estimate that pass-through spending in CY 2013 will not amount to 2.0 percent of total projected OPPS CY 2013 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, including trauma team activation. As we proposed in the CY 2013 OPPS/ASC proposed rule (77 FR 45146 through 45148), for CY 2013, we are continuing to recognize these CPT and HCPCS codes describing clinic visits, Type A and Type B emergency department visits, and critical care services, which are listed below in Table 38, for CY 2013. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74338 through 74346) for a full discussion of our longstanding policy on OPPS payment for hospital outpatient visits.

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TABLE 38.—HCPCS CODES USED TO REPORT CLINIC AND EMERGENCY DEPARTMENT VISITS AND CRITICAL CARE SERVICES

CY 2013 HCPCS Code	CY 2013 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

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At its August 27–28, 2012 meeting, the HOP Panel recommended that CMS move HCPCS code G0379 (Direct admission of patient for hospital observation care) to APC 0608 (Level 5 Hospital Clinic Visits). We are accepting this recommendation, as discussed below in this section.

B. Policies for Hospital Outpatient Visits

We proposed in the CY 2013 OPPS/ASC proposed rule (77 FR 45147 through 45148), for CY 2013, to continue our longstanding policies related to hospital outpatient visits, which includes clinic visits, emergency department visits, and critical care services. Specifically, we proposed to continue to recognize the definitions of a new patient and an established patient, which are based on whether the patient has been registered as an inpatient or outpatient of the hospital within the 3 years prior to a visit. We also proposed to continue to apply our policy of calculating costs for clinic visits under the OPPS using historical hospital claims data through five levels of clinic visit APCs (APCs 0604 through 0608). In addition, we proposed to continue to recognize Type A emergency departments and Type B emergency departments for payment purposes under the OPPS, and to pay for Type A emergency department visits based on their costs through the five levels of Type A emergency department APCs (APCs 0609 and 0613 through 0616) and to pay for Type B emergency department visits based on their costs through the five levels of Type B emergency department APCs (APCs 0626 through 0630). 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 APC assignments and payment rates for these hospital outpatient visits. Finally, we proposed to continue to instruct 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. We note that our continued expectation is that hospitals' internal guidelines will comport with the principles listed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66805). We encourage hospitals with specific questions related to the creation of internal guidelines to contact their servicing fiscal intermediary or MAC. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74338 through 74346) for a full historical discussion of these longstanding policies. We note recent reports in the public media of billing inaccuracies in hospital outpatient clinic visits, and remind hospitals that we are committed to vigorously enforcing our payment policies and will pursue appropriate action against any potentially fraudulent activities we identify.

We also proposed to continue the methodology established in the CY 2011 OPPS/ASC final rule with comment period for calculating a payment rate for critical care services that includes packaged payment of ancillary services. 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 was 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 believed it was 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 was 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 would 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 these services 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 are 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.

Because the CY 2012 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 final rule with comment period (76 FR 74343 through 74344), we continued 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 claims data, into which the cost of the ancillary services is intrinsically packaged for CY 2012. We also continued 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.

As we discussed in the CY 2013 OPPS/ASC proposed rule (77 FR 45148), the CY 2011 hospital claims data on which the CY 2013 payment rates are based reflect the first year of claims billed under the revised CPT guidance to allow the reporting of all the ancillary services and their associated charges separately when they are provided in conjunction with critical care. Because our policy to establish relative payment weights based on geometric mean cost data for CY 2013 represents a change from our historical practice to base payment rates on median costs, and because we now have hospital claims data for the first time reflecting the revised coding guidance for critical care, we reviewed the CY 2011 hospital claims data available for the proposed rule and determined that the data show increases in both the mean and median line item costs as well as the mean and median line item charges for CPT code 99291, when compared to CY 2010 hospital claims data. Specifically, the mean and median line item costs increased 13 percent and 16 percent, respectively, and the mean and median line item charges increased 11 percent and 14 percent, respectively. Additionally, when compared to CY 2010 hospital claims data, CY 2011 hospital claims data showed no substantial change in the ancillary services that are present on the same claims as critical care services, and also showed continued low volumes of many ancillary services. We stated in the proposed rule that, had the majority of hospitals changed their billing practices to separately report and charge for the ancillary services formerly included in the definition of critical care CPT codes 99291 and 99292, we would have expected to see a decrease in the costs and charges for these CPT codes, and a significant increase in ancillary services reported on the same claims. We indicated that the lack of a substantial change in the services reported on critical care claims, along with the increases in the line item costs and charges for critical care services, strongly suggests that many hospitals did not change their billing practices for CPT code 99291 following the revision to the CPT coding guidance effective January 1, 2011.

In light of not having claims data to support a significant change in hospital billing practices, we stated in the proposed rule that we continue to believe that it is inappropriate to pay separately in CY 2013 for the ancillary services that hospitals may now report in addition to critical care services. Therefore, for CY 2013, we proposed, to continue our CY 2011 and CY 2012 policy to recognize the existing CPT codes for critical care services and establish a payment rate based on historical claims data. We also 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. We stated that we will continue to monitor the hospital claims data for CPT code 99291 in order to determine whether revisions to this policy are warranted based on changes in hospitals' billing practices.

Comment: One commenter indicated that because hospitals have used internal, hospital-defined guidelines for over 10 years, CMS should not move to standard national guidelines. In the absence of national guidelines for visit reporting, some commenters urged CMS to support a request to the AMA's CPT Editorial Panel to create unique CPT codes for hospital reporting of emergency department and clinic visits.

Response: We agree with the commenter that we should not move to national guidelines for visits in CY 2013. As we have in the past (76 FR 74345 through 74346), 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. As we have also stated in the past (76 FR 74346), 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.

Comment: One commenter recommended that CMS reassign HCPCS code G0379 to APC 0608 (Level 5 Hospital Clinic 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 mean cost and clinical characteristics to CPT code 99205 (Office or other outpatient visit for the evaluation and management of a new patient (Level 5)). The commenter pointed out that the

mean cost for HCPCS code G0379 is more similar to the mean cost for APC 0608 than it is to the mean cost for APC 0604. The commenter argued that the resources associated with HCPCS code G0379 resemble those expended for high-level clinic visits more than resources for low-level clinic visits, and noted that CMS' claims logic for composite APC 8002 (Level I Extended Assessment and Management) treats HCPCS code G0379 similarly to high-level clinic visit CPT codes 99205 and 99215 (Office or other outpatient visit for the evaluation and management of an established patient (Level 5)).

Response: We agree with the rationale set forth by the commenter and with the Panel, which recommended CMS reassign HCPCS code G0379 from APC 0604 to APC 0608. Therefore, we are reassigning HCPCS code G0379 to APC 0608 for CY 2013.

Comment: Commenters 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.

Response: 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 mean cost calculation for critical care.

Comment: One commenter argued that the ancillary services associated with critical care do not meet CMS' criteria for packaging. The commenter suggested that, rather than packaging the ancillary services associated with critical care, CMS use CY 2008 cost data for CPT code 99291 updated with an overall inflation factor to recalculate the cost of critical care exclusive of bundled ancillary services.

Response: As we discussed above in this section and in the CY 2013 OPPS/ASC proposed rule (76 45147 through 45148), the policy to package ancillary services associated with critical care was implemented in CY 2011 and resulted from a change in CPT guidance effective January 1, 2011. We packaged the ancillary services because the costs of those ancillary services were already intrinsically included in the cost calculated for critical care; to pay for the ancillary services separately result in overpayment. Because the claims data for critical care for CY 2011 do not reflect that hospitals have changed their billing practices in response to the revised CPT guidance effective January 1, 2011—that is, they have not adjusted their charging practices to reflect that the ancillary services are no longer included in the definition of critical care—we continue to believe that the costs of the ancillary services continue to be reflected in the hospitals' charges for critical care, and that to pay separately for the ancillary services would be inappropriate. We also do not agree with the commenter that we should use claims data from CY 2008 to calculate costs for critical care. We remind the commenter that the OPPS is a system of averages, in which the costs of services, calculated from the most recent year's claims data, are weighted relative to the other services in the system, for that given year. To utilize a payment rate derived from claims outside of the most recent claims data, despite any update by the overall inflation factor, would be inconsistent with the standard methodology of the OPPS, and would not allow for that service to be appropriately valued relative to the other services in the OPPS.

After consideration of the public comments we received, we are finalizing our CY 2013 proposals related hospital outpatient visits, with one modification. As described above, we are reassigning HCPCS code G0379 to APC 0608 for CY 2013.

C. Transitional Care Management

In the CY 2013 MPFS proposed rule (77 FR 44774 through 44780), we discussed a multiple year strategy exploring the best means to encourage the provision of primary care and care coordination services to Medicare beneficiaries. As part of the strategy discussed in that proposed rule, we proposed to address the non-face-to-face work involved in hospital or SNF discharge care coordination by creating a HCPCS G-code for care management involving the transition of a beneficiary from care furnished by a treating physician during a hospital stay (inpatient, outpatient observation services, or outpatient partial hospitalization), SNF stay, or CMHC partial hospitalization program to care furnished by the beneficiary's physician or qualified nonphysician practitioner in the community. As discussed in the CY 2013 MPFS proposed rule, care management involving the transition of a beneficiary from care furnished by a treating physician during a hospital or a SNF stay to the beneficiary's primary physician or qualified nonphysician practitioner in the community could avoid adverse events such as readmissions or subsequent illnesses, improve beneficiary outcomes, and avoid a financial burden on the health care system. Successful efforts to improve hospital discharge care coordination and care transitions could improve the quality of care while simultaneously decreasing costs.

The proposed HCPCS G-code included in the CY 2013 MPFS proposed rule, GXXX1, specifically describes post-discharge transitional care management services, which include all non-face-to-face services related to the transitional care management, furnished by the community physician or nonphysician practitioner within 30 calendar days following the date of discharge from an inpatient acute care hospital, psychiatric hospital, LTCH, SNF, and IRF; discharge from hospital outpatient observation or partial hospitalization services; or discharge from a PHP at a CMHC, to the community-based care. The post-discharge transitional care management services include non-face-to-face care management services provided by clinical staff member(s) or office-based case manager(s) under the supervision of the community physician or qualified nonphysician practitioner.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45148 through 45159), we stated that while we do not pay for physician or nonpractitioner professional services under the OPPS (42 CFR 419.22), we recognize that certain elements of the transitional care coordination services described by proposed HCPCS code GXXX1 could be provided to a hospital outpatient as an ancillary or supportive service in conjunction with a primary diagnostic or therapeutic service that would be payable under the OPPS, such as a clinic visit. We stated that, as described in section II.A.3. of the proposed rule, we package payment for services that are typically ancillary and supportive to a primary service. While we do not make separate payment for such services, their costs are included in the costs of other services furnished by the hospital to the beneficiary on the same day. We indicated in the CY 2013 OPPS/ASC proposed rule that, because transitional care management services

described by HCPCS code GXXX1 may be ancillary and supportive to a primary service provided to a hospital outpatient, we proposed to assign HCPCS code GXXX1 a status indicator of ''N'' (Items and Services Packaged into APC Rates), signifying that its payment would be packaged (77 FR 45159).

Comment: The majority of commenters supported the proposed development of a HCPCS G-code to identify the non-face-to-face work involved in hospital or SNF discharge care coordination. Some commenters supported establishing a HCPCS G-code as a short-term solution to capture the non-face-to-face services, but suggested that in the long term, CMS consider generating new CPT codes specific to the post-discharge transitional care management that would also capture face-to-face components of transitional care. Some commenters also stated that the requirements for billing the post-discharge transitional care services (regardless of whether they are identified with the new HCPCS G-code or a CPT code) should not be arduous or complex. A few commenters expressed concern that the proposed HCPCS G-code for transitional care management would be duplicative of discharge day management services described by other CPT codes. Some commenters requested that CMS establish a separate APC for the proposed HCPCS G-code with a status indicator of ''S'' or ''X'' for transitional care management services or assign the HCPCS G-code to APC 0605 (Level 2 Hospital Clinic Visits).

Response: For the reasons outlined in the CY 2013 MPFS final rule with comment period, we are adopting the following CPT transitional care management codes in place of the proposed HCPCS G-code: CPT code 99495 (Transitional care management services w/moderate medical decision complexity; Face to face visit within 14 days) and CPT code 99496 (Transitional care management services w/high medical decision complexity; Face to face visit within 7 days). We agree with the commenters that the requirements for billing the post-discharge transitional care management services should not be arduous or complex, and we refer readers to the CY 2013 MPFS final rule with comment period for a full discussion of the billing requirements for CPT codes 99495 and 99496. We also refer readers to the CY 2013 MPFS final rule with comment period for a full discussion of why we do not believe that recognition of the transitional care management services described by CPT codes 99495 and 99496 is duplicative of services described by other CPT codes.

The CPT transitional care management code 99495 includes the following required elements:

- Communication (direct contact, telephone, electronic) with the patient and/or caregiver within 2 business days of discharge;
- Medical decision-making of at least moderate complexity during the service period; and
- Face-to-face visit, within 14 calendar days of discharge.

CPT code 99496 includes the following required elements:

- Communication (direct contact, telephone, electronic) with the patient and/or caregiver within 2 business days of discharge;
- Medical decision-making of high complexity during the service period; and
- Face-to-face visit, within 7 calendar days of discharge.

As we describe in the CY 2013 MPFS final rule with comment period, the services described by CPT codes 99495 and 99496 are for an established patient whose medical and/or psychosocial problems require moderate or high complexity medical decision-making during transitions in care from an inpatient hospital setting (including acute hospital, rehabilitation hospital, long-term acute care hospital), partial hospital, observation status in a hospital, or SNF/nursing facility, to the patient's community setting (home, domiciliary, rest home, or assisted living). Transitional care management commences upon the date of discharge and continues for the next 29 days.

Transitional care management is comprised of one face-to-face visit within the specified timeframes, in combination with non-face-to-face services that may be performed by the physician or other qualified health care professional and/or licensed clinical staff under his or her direction. Because the transitional care management services described by CPT codes 99495 and 99496 involve at least one face-to-face visit, (unlike the proposed HCPCS G-code), we believe that CPT codes 99495 and 99496 represent a primary, independent service that should be separately payable under the OPPS. We are assigning CPT code 99495 to APC 0605 (Level 2 Hospital Clinic Visit) and CPT code 99496 to APC 0606 (Level 3 Hospital Clinic Visit) on an interim basis for CY 2013. As with all new CPT codes, these interim assignments are open to public comment for a period of 60 days following the publication of this final rule with comment period.

As we discuss in the CY 2013 MPFS final rule with comment period, we are adopting these new transitional care management codes to provide a separate reporting mechanism to the community physician for these services in the context of the broader CMS multi-year strategy to recognize and support primary care and care management. We wish to emphasize again that the policies we are finalizing in this final rule with comment period may be short-term payment strategies that may be modified and/or revised over time to be consistent with broader primary care and care management initiatives. We refer readers to the CY 2013 MPFS final rule with comment period for a full discussion of post-discharge transitional care management services in particular and, more broadly, the multiple year strategy exploring the best means to encourage primary care and care coordination services.

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. Section 1861(ff)(1) of the Act defines partial hospitalization services as ''the items and services described in paragraph (2) prescribed by a physician and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which plan sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan.'' Section 1861(ff)(2) of the Act describes the items and services included in partial hospitalization services. Section 1861(ff)(3)(A) of the Act specifies that a partial hospitalization program (PHP) is a program furnished by a hospital to its outpatients or by a community mental health center (CMHC) (as defined in subparagraph (B)), and ''which is a distinct and organized intensive ambulatory treatment service offering less than 24-hour-daily care other than in an individual's home or in an inpatient or residential setting.'' Section 1861(ff)(3)(B) of the Act defines community mental health center.

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 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 Medicare Part B services furnished to hospital outpatients designated by the Secretary, which include partial hospitalization services (65 FR 18444 through 18445).

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, we have 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 July 1, 2000 (65 FR 18452 through 18455). Under this methodology, the median per diem costs have been used to calculate the relative payment weights for PHP APCs.

From CY 2003 through CY 2006, the median per diem costs for CMHCs fluctuated significantly from year to year, while the median per diem costs 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 cost by computing a separate per diem cost for each day rather than for each bill. We refer readers to a complete discussion of these refinements in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 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.B. 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 submitted for days when fewer than 3 units of therapeutic services are provided (73 FR 68694).

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.3. 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 APC 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 (74 FR 60556 through 60559).

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 a PHP 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 in section X.C. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71990).

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71994), we also 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). In the CY 2011 OPPS/ASC proposed rule, we proposed that CMHC APC medians would be based only on CMHC data and hospital-based PHP APC medians 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 the final rule with comment period (75 FR 71991), for CY 2011, using CY 2009 claims data, CMHC costs had significantly decreased again. We attributed the decrease to the lower cost structure of CMHCs compared to hospital-based PHP providers, 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 also were concerned that paying hospital-based PHPs at a lower rate than their cost structure reflects could lead to hospital-based PHP closures and possible access problems for Medicare beneficiaries, given that hospital-based PHPs offer the widest access to PHP services because they are located across the country. Creating the four payment rates (two for CMHCs and two for hospital-based PHPs) based on each provider's data 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 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 CMHCs 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 per diem costs were calculated by taking 50 percent of the difference between the CY 2010 final hospital-based PHP 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 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.

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 payment 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). We refer readers to the court case, *Paladin Cmty. Mental Health Ctr. v. Sebelius,* No. 10–949, 2011 WL 3102049 (W.D.Tex. 2011), *aff'd,* No. 11–50682, 2012 WL 2161137 (5th Cir. June 15, 2012) (*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 payment 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.'' On July 25, 2011, the District Court dismissed the plaintiffs' complaint and application for preliminary injunction for lack of subject-matter jurisdiction, which the plaintiffs appealed to the United States Court of Appeals for the Fifth Circuit. On June 15, 2012, the Court of Appeals affirmed the District Court's dismissal for lack of subject-matter jurisdiction and found that the Secretary's payment rate determinations for PHP services are not a facial violation of a clear statutory mandate. (*Paladin* at *6).

For CY 2012, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74348 through 74352), we determined the relative payment weights for PHP services provided by CMHCs based on data derived solely from CMHCs and the relative payment weights for hospital-based PHP services based exclusively on hospital data. The statute is reasonably interpreted to allow the relative payment weights for the OPPS payment rates for PHP services provided by CMHCs to be based solely on CMHC data and relative payment weights for hospital-based PHP services to be based exclusively on hospital 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), we developed the APCs, as set forth in 42 CFR 419.31 of the regulations (65 FR 18446 and 18447; 63 FR 47559 through 47562 and 47567 through 47569). As discussed above, 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 both hospital-based and CMHC-based settings, only on the basis of 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. For CY 2009, we established new APCs for PHP services based exclusively on hospital data. Specifically, 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 PHP services provided by CMHCs in CY 2011 were ''based on'' hospital data, no less than the relative payment weights for the two APCs for hospital-based PHP services.

Although we used hospital data to establish the relative payment weights for APCs 0033, 0172, 0173, 0175, and 0176 for PHP services, we believe that we have the authority to discontinue the use of hospital data in determining the OPPS relative payment weights for PHP services provided by CMHCs. 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 provided by CMHCs based on ''new cost data, and other relevant information and factors.''

B. PHP APC Update for CY 2013

In the CY 2013 OPPS/ASC proposed rule (77 FR 45094 through 45098 and 45151), we proposed to develop the relative payment weights that underpin the OPPS using geometric means rather than the current median-based methodology. We stated that this

proposal to base the relative payment weights on geometric means would also apply to the per diem costs used to determine the relative payment weights for the four PHP APCs (77 FR 45151). We stated that, for PHP APCs, as with all other OPPS APCs, the proposal to base the relative payment weights on geometric means rather than medians would not affect the general process to establish appropriate claims for modeling. We stated that, as with the current median-based methodology, the PHP APC per diem payment rates would continue to be calculated by computing a separate per diem cost for each day of PHP service. When there are multiple days of PHP services entered on a claim, a unique cost would continue to be computed for each day of care. However, a geometric mean would be used to calculate the per diem costs rather than a median. We stated that the process would still be repeated separately for CMHCs and hospital-based PHPs using that provider's claims data for the two categories of days with 3 services and days with 4 or more services. We stated that the four PHP APC per diem costs would continue to be included in the scaling of all APCs under the OPPS to the mid-level office visit (APC 0606). For a detailed discussion of the CY 2013 OPPS weight scaler, we refer readers to section II.A.4. of this final rule with comment period.

In the CY 2013 OPPS/ASC proposed rule, for CY 2013, using CY 2011 claims data, we computed proposed CMHC PHP APC geometric mean per diem costs for Level I (3 services per day) and Level II (4 or more services per day) services using only CY 2011 CMHC claims data, and hospital-based PHP APC geometric mean per diem costs for Level I and Level II services using only CY 2011 hospital-based PHP claims data. These proposed geometric mean per diem costs were shown in Table 30 of the CY 2013 OPPS/ASC proposed rule (77 FR 45151) and are reprinted below.

REPRINTED TABLE 30.--PROPOSED CY 2013 GEOMETRIC MEAN PER DIEM COSTS FOR CMHC AND HOSPITAL-BASED PHP SERVICES, BASED ON CY 2011 CLAIMS DATA

APC	Group Title	Proposed Geometric Mean Per Diem Costs
0172	Level I Partial Hospitalization (3 services) for CMHCs	$87.76
0173	Level II Partial Hospitalization (4 or more services) for CMHCs	111.89
0175	Level I Partial Hospitalization (3 services) for hospital-based PHPs	182.66
0176	Level II Partial Hospitalization (4 or more services) for hospital-based PHPs	232.74

Under the CY 2013 proposal to base the OPPS relative payment weights on geometric mean costs, the proposed geometric mean per diem costs for CMHCs would continue to be substantially lower than the proposed geometric mean per diem costs for hospital-based PHPs for the same units of service. For CY 2013, the proposed geometric mean per diem costs for days with 3 services (Level I) were approximately $88 for CMHCs and approximately $183 for hospital-based PHPs. The proposed geometric mean per diem costs for days with 4 or more services (Level II) were approximately $112 for CMHCs and approximately $233 for hospital-based PHPs. We stated that this analysis indicated that there continue to be fundamental differences between the cost structures of CMHCs and hospital-based PHPs.

The CY 2013 proposed geometric mean per diem costs for CMHCs calculated under the proposed CY 2013 methodology using CY 2011 claims data also have decreased compared to the CY 2012 final median per diem costs for CMHCs established in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74352), with per diem costs for Level I services decreasing from approximately $98 to approximately $88, and costs for Level II services decreasing from approximately $114 to approximately $112. In contrast, the CY 2013 proposed geometric mean per diem costs for hospital-based PHPs calculated under the proposed CY 2013 methodology using CY 2011 claims data have increased compared to the CY 2012 final median per diem costs for hospital-based PHPs, with per diem costs for Level I services increasing from approximately $161 to approximately $183, and per diem costs for Level II services increasing from approximately $191 to approximately $233.

To provide a comparison in the CY 2013 OPPS/ASC proposed rule, we also calculated PHP median per diem costs for CY 2013 using CY 2011 claims data (77 FR 45151 through 45152). We computed median per diem costs for each provider type using that provider's claims data for Level I services and for Level II services. These comparative median per diem costs were shown in Table 31 of the CY 2013 OPPS/ASC proposed rule (77 FR 45152) and are reprinted and discussed below.

REPRINTED TABLE 31.--COMPARATIVE PHP MEDIAN PER DIEM COSTS FOR CMHC AND HOSPITAL-BASED PHP SERVICES, BASED ON CY 2011 CLAIMS DATA AS SET FORTH IN THE CY 2013 OPPS/ASC PROPOSED RULE		
APC	**Group Title**	**Comparative Median Per Diem Costs**
0172	Level I Partial Hospitalization (3 services) for CMHCs	$87.52
0173	Level II Partial Hospitalization (4 or more services) for CMHCs	121.27
0175	Level I Partial Hospitalization (3 services) for hospital-based PHPs	163.86
0176	Level II Partial Hospitalization (4 or more services) for hospital-based PHPs	224.57

The proposed geometric mean per diem costs for hospital-based PHPs for Level I and Level II services calculated under the proposed CY 2013 methodology using CY 2011 claims data would be higher than the median per diem costs calculated under the current median-based methodology, using CY 2011 claims data. For hospital-based PHPs, the per diem costs would increase from approximately $164 under the current median-based methodology to approximately $183 under the proposed geometric mean-based methodology for Level I services, and from approximately $225 to approximately $233 for Level II services.

The proposed geometric mean per diem costs for CMHCs for Level I services calculated under the proposed CY 2013 methodology using CY 2011 claims data would be approximately the same as the median per diem costs calculated under the current median-based methodology, using CY 2011 claims data. The proposed geometric mean per diem costs for CMHCs for Level II services calculated under the proposed CY 2013 methodology using CY 2011 claims data would be slightly lower than the median per diem costs calculated under the current median-based methodology, using CY 2011 claims data. For CMHCs, the per diem costs would be approximately $88 under both the current median-based methodology and the proposed geometric mean-based methodology for CMHC Level I services, and would decrease from approximately $121 under the current median-based methodology to approximately $112 under the proposed geometric mean-based methodology for CMHC Level II services.

We stated that the data analysis also shows that 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 provided. The median per diem costs for Level I services were approximately $88 for CMHCs and approximately $164 for hospital-based PHPs. The median per diem costs for Level II services were approximately $121 for CMHCs and approximately $225 for hospital-based PHPs. We stated that the significant difference in per diem costs between CMHCs and hospital-based PHPs emphasizes the distinct cost structures between the two provider types.

Finally, we stated that the data analysis indicates that CMHC median per diem costs for Level I services would have decreased from CY 2012 final median per diem costs (using CY 2010 claims data) (established in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74352)) to CY 2013 (using CY 2011 claims data) from approximately $98 to approximately $88, using only CMHC claims data. The CMHC median per diem costs for Level II services would have slightly increased from CY 2012 final median per diem costs (using CY 2010 claims data) to CY 2013 (using CY 2011 claims data) from approximately $114 to approximately $121, using only CMHC claims data. Hospital-based PHP median per diem costs for Level I and Level II services would have increased from the CY 2012 final median per diem costs (using CY 2010 claims data) to CY 2013 (using CY 2011 claims data) from approximately $161 to approximately $164 for Level I services and from approximately $191 to approximately $225 for Level II services, using only hospital claims data.

In summary, while we have historically based the OPPS payments on median costs for services in the APC groups, for CY 2013, we proposed to calculate the relative payment weights for the OPPS APCs using geometric means, including the four PHP APCs, as discussed in section II.A.2.f. of the proposed rule. We invited public comments on these proposals.

Comment: A few commenters representing CMHCs opposed the proposed conversion from the historically applied median-based methodology to the geometric mean-based methodology and the resulting CMHC payment rates. The commenters believed that the median cost approach is more stable and less sensitive to extreme observations and, therefore, a more appropriate methodology. One CMHC commenter preferred the median-based methodology because it resulted in a higher payment rate for the CMHC APC for Level II services than when calculated using a geometric mean-based methodology. The commenters recommended that CMS continue using a median-based methodology and not change to a geometric mean-based methodology for calculating the per diem costs.

Response: We acknowledge the commenters' concern about the change from the median-based methodology to the geometric mean-based methodology and its impact on CMHCs. In the CY 2013 OPPS/ASC proposed rule, we proposed to develop the OPPS relative

payment weights using geometric mean cost for all APCs that were previously calculated using median cost, including the PHP APCs (77 FR 45094 through 45098 and 45151). Under the CY 2013 proposal, OPPS payments to CMHCs for partial hospitalization also would be calculated based on geometric mean per diem costs, rather than the previous use of median per diem costs. This would help ensure that the relativity of the OPPS payment weights was properly aligned. As discussed in section II.A.2.f. of this final rule with comment period, we do not believe that paying for some services based on median costs while using geometric mean costs for other services is appropriate, equitable, or consistent with statute. Therefore, our CY 2013 proposal was to develop the OPPS relative payment weights using geometric mean costs for any services previously calculated using median costs, whether that was on a standard, per diem, or line item basis (77 FR 45097).

In the CY 2013 OPPS/ASC proposed rule, we recognized that median costs had historically served as an appropriate measure on which to establish relative payment weights. However, in our proposal to establish the CY 2013 OPPS relative payment weights using geometric mean cost, we discussed a number of reasons why we believed that changing to geometric mean cost would represent an incremental improvement as well as be appropriate. These reasons included changes CMS has made throughout the history of the OPPS with the goal of deriving more accurate information from available claims and cost report data, as well as benefits of using a metric that more accurately describes the range of costs associated with providing services.

While commenters have suggested that medians are more appropriate because they are less sensitive to outlier observations, in particular for CMHCs, we believe that including those outlier observations in developing the weights and capturing the full range of service costs will lead to more accurate relative payment weights. In addition to better incorporating those cost values that surround the median and, therefore, describing a broader range of cost patterns, basing the relative payment weights on geometric mean costs may also promote better stability in the payment system by making OPPS payments more reflective of the range of costs associated with providing services. In the short term, geometric mean-based relative payment weights would make the relative payment weights more reflective of the service costs. However, making this change also may promote more payment stability in the long term by including a broader range of observations in the relative payment weights, making them less susceptible to gaps in estimated cost near the median observation and also making changes in the relative payment weight a better function of changes in estimated service costs.

We note that using the geometric means would increase the relative payment weights for some services and decrease the relative payment weights for others. We believe those updated relative payment weights to be more reflective of the costs associated with providing those services, which is consistent with the goal of developing relative payment weights that accurately describe service costs. As described in the CY 2013 OPPS/ASC proposed rule, we have made a number of changes in the history of the OPPS to derive more information from what is available to us and ensure that the cost information we use for ratesetting is as accurate as possible. We believe that making changes consistent with those goals is preferable, rather than choosing one methodology or another simply due to the numeric payment rates that arise from any different methodology.

Thus, for the reasons discussed above, we believe that using geometric mean costs to calculate the relative payment weights for the OPPS represents an improvement to our cost estimation process and will lead to relative payment weights that are more reflective of service cost patterns. For these reasons, we disagree with the commenters' assertion that use of the median-based methodology is a preferable option. We believe that this change is appropriate and requires all OPPS services previously paid through median-based calculations (including CMHC based per diem costs) to transition together to geometric mean cost calculations to establish accurate cost relativity in the system. Therefore, we are finalizing the geometric mean-based methodology in this final rule with comment period. For a more detailed discussion of geometric mean-based relative payment weights, we refer readers to section II.A.2.f. of this final rule with comment period.

Comment: Several hospital-based PHP providers supported the conversion from a median-based methodology to a geometric mean-based methodology and the resulting hospital-based PHP per diem payments. These commenters also recommended that CMS continue to recognize the cost structure differences between hospital-based PHPs and CMHCs by calculating four separate PHP APCs based on each providers' own unique data, and stated that it was a necessary improvement to help ensure PHP access in hospital-based settings for the future. The commenters also encouraged CMS to continue to refine data analysis strategies that help bring payment accuracy as well as stability to the partial hospitalization benefit in order to allow programs that meet the needs of Medicare beneficiaries to exist.

Response: We appreciate the commenters' support of the two-tiered, four PHP APC per diem payment rates based on each providers' own unique data. We continue to believe that it is important to calculate PHP APC per diem payment rates based on the data for each type of provider in order to appropriately pay for PHP services, which will support continued access to quality services. We are constantly monitoring the OPPS in search of potential refinements that would improve the accuracy and stability of the payment system. Over the past several years, we have made changes to PHP APC per diem payment rates to more accurately align the payments with costs. These changes have included establishing separate APC per diem payment rates for CMHCs and hospital-based providers based on each providers' costs as well as a two-tiered APC per diem payment rate for both CMHC and hospital-based PHPs under which we pay one amount for days with 3 services and another amount for days with 4 or more services. As discussed in the CY 2013 OPPS/ASC proposed rule, we believe that the use of geometric mean costs rather than median costs in the ratesetting process is another improvement, because it allows the payment metric to consider a broader range of service costs among other factors (77 FR 45097). We will continue to monitor the impact of our payment policies on the PHP benefit and providers.

Comment: A few CMHC providers requested that CMS suspend implementation of the proposed PHP APC per diem payment rates for CMHCs and maintain the current CY 2012 CMHC PHP APC per diem payment rates as a means to preserve CMHCs. The commenters stated that many of the CMHCs throughout the country have already closed due to CMS' ongoing payment rate reductions. Another commenter stated that no business in the United States or anywhere else in the world can survive and continue to operate after such a decrease over 3 years. The commenter further stated that it appeared that the goal of CMS was to substantially reduce the total number of CMHCs participating in the Medicare

program and consequentially reduce payments nationwide. One commenter expressed concern that, instead of being rewarded, CMHCs are being targeted and punished for providing more cost-effective services than the hospital-based PHPs. This same commenter was ''highly offended'' by the following sentence from the CY 2012 OPPS/ASC proposed rule (77 FR 45150): ''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.'' The commenter stated that the sentence implies ''CMHCs provide less valuable services than hospital-based PHPs, hire less qualified staff, and overall perform very poorly compared to hospital based PHPs.''

Several commenters expressed concern that the proposed reductions to the CMHC PHP APC per diem payment rates could further erode the viability of the safety net system, and make it more difficult for patients to receive needed mental health care and services. One of these commenters also stated that if patients are unable to receive care in a CMHC, many will have only the emergency departments as a last resort.

Response: We understand the concerns raised by the commenters regarding CMHC APC per diem payment rate reductions. We are not targeting or trying to punish specific providers, and we are not trying to reduce the number of CMHCs participating in the Medicare program. However, we continue to believe that it is important to calculate PHP APC per diem payment rates based on the data for each type of provider in order to appropriately pay for services. CMHCs' costs have fluctuated significantly and then generally declined over the years. CMHCs' costs also have remained significantly lower than hospital-based PHPs' costs, which have been relatively stable since the inception of the OPPS. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74347), we stated that CMHCs have a lower cost structure than hospital-based PHP providers because the data showed and continue to show that CMHCs provide fewer PHP services in a day and use less costly staff than hospital-based PHPs. In other words, hospital-based providers have traditionally provided more services than CMHCs during a PHP day. Providing fewer services during a PHP day results in less overhead expense for the provider; that is, less time the provider needs to pay staff, less time the provider needs to heat the building, and less time the provider needs to light the building. Therefore, providing fewer PHP services during a day directly contributes to a lower overall cost structure. We did not intend to offend any of our providers. We also did not mean to imply that, in comparison to hospital-based PHPs, CMHCs provide inferior, less valuable or poor quality services; we were only stating the differences in these providers' cost structures based on our cost analysis.

In light of these differences in cost structures between provider types, it was inappropriate to continue to treat CMHCs and hospital-based PHP providers in the same manner. We were concerned that paying hospital-based PHPs at a lower rate than their cost structure reflects could lead to closures and possible access problems for hospital-based programs providing services to Medicare beneficiaries, given that hospital-based PHPs offer the widest access to PHP services because they are located across the country. Paying providers based on the four PHP APC per diem payment rates supports continued access to the PHP benefit, while also providing appropriate payment based on the unique cost structures of CMHCs and hospital-based PHPs. We believe that the CMHC APC per diem payment rates accurately reflect the cost data of the CMHCs.

The PHP APC per diem payment rates are directly related to the accuracy of the claims and cost reports submitted by providers. It is imperative that providers submit accurate claims and cost reports in order for the payment rates to most accurately reflect the providers' costs. The resulting PHP APC per diem payment rates reflect the cost of what providers expend to maintain such programs. So, it is unclear why this would lead to program or business closures. As we stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74350), 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, and Federal and State fraud and abuse efforts, among others. It does not directly imply that closure could be due to reduced payment rates alone, especially when these payment rates reflect the costs of PHP providers.

In response to the commenters' concerns that further reduction in the CMHC PHP APC per diem payment rates could further erode the viability of the safety net system and make it more difficult for patients to receive needed mental health services, we take such concerns seriously. Currently, we monitor facility closings and openings to make sure that access issues do not exist, and we will continue to do so in the future. We also remain steadfast in our concern regarding access to care for all beneficiaries, while also providing appropriate payments for such care. A PHP is not the only program in which a Medicare beneficiary is able to receive needed mental health care. Although not equivalent to a PHP, Medicare provides payment for outpatient mental health services in addition to PHP services. Many beneficiaries in need of mental health treatment receive other outpatient services generally from hospital programs which are available nationwide, and no evidence suggests that there is an increase in adverse outcomes due to lack of access to care. Other forms of access to mental health services remain available. We continue to believe that it is important to calculate PHP APC per diem payment rates based on the data of each type of provider in order to appropriately pay for PHP services, which will support continued access to quality services.

Commenters also requested that we suspend implementation of the proposed CY 2013 PHP APC per diem payment rates for CMHCs, and that we pay based on the CY 2012 per diem payment rates to preserve CMHCs. As discussed above, we cannot establish payment rates that do not accurately reflect the current cost data. We believe that having separate payment rates for CMHCs and hospital-based providers based on each providers' costs as well as a two-tiered APC per diem payment rate for both CMHC and hospital-based PHPs under which we pay one amount for days with 3 services and another amount for days with 4 or more services along with using geometric means to more accurately reflect the costs associated with providing OPPS services supports the PHP benefit and pays providers appropriately for the services that they provide. For these reasons, we are not suspending implementation of the CY 2013 PHP APC per diem payment rates for CMHCs.

Comment: One commenter stated that the database of claim payments used in calculating the new payment rates includes at least two providers indicted for fraud, and recommended that these claims be removed.

Response: We strive to ensure that the claims we use for modeling the OPPS payment rates contain accurate cost information on services. In addition, we note that providers with questionable data are subject to further investigation. We request that the commenter provide us with more details regarding those providers.

Comment: One commenter suggested that, instead of calculating the PHP APC

per diem payment rates using claims data, CMS should use the quality of the provided services to base payments, including record reviews, denials due to lack of medical necessity or inadequate documentation, site visits, interviews with patients, and most importantly patient outcomes. Another commenter recommended that CMS establish quality and outcome criteria to judge performance that would influence future ratesetting, and provide rewards to individual providers for outstanding quality and outcomes.

Response: Sections 1833(t)(2) and 1833(t)(9) of the Act set forth the requirements for establishing and adjusting the OPPS payment rates, including the PHP payment rates. The existing policies and procedures implementing these statutory provisions do not consider quality measures when setting base payment rates. However, we note that section 1833(t)(17) of the Act implements an outpatient quality reporting program for subsection (d) hospitals that applies a payment reduction for hospitals that fail to meet the program requirements.

Comment: One commenter requested that CMS establish a ratesetting task force to review the CMS ratesetting methodology and CMHCs' and hospital-based PHPs' costs as a means to identify fair and adequate payment rates for both. Another commenter requested an open discussion with CMS and associations whose members are PHP providers.

Response: We maintain positive working relationships with various industry leaders representing both CMHCs and hospital-based PHP providers with whom we have consistently met over the years to discuss industry concerns and ideas. These relationships have provided significant and valued input regarding PHP ratesetting. We also hold Hospital Outpatient Open Door Forum calls monthly, in which all individuals are welcome to participate and/or submit questions regarding specific issues, including questions related to PHPs.

Furthermore, we initiate rulemaking annually, through which we receive public comments on proposals set forth in a proposed rule and respond to those comments in a final rule. All individuals are provided an opportunity to comment, and we give consideration to each comment that we receive.

Given the relationships that we have established with various industry leaders and the various means for us to receive comments and recommendations, we believe that we receive adequate input regarding ratesetting and take that input into consideration when establishing the payment rates. We continue to welcome any input and information that the industry is willing to provide.

Comment: A few commenters addressed issues related to the costs used to calculate the PHP APC per diem payment rates. One commenter expressed concern that CMS' ratesetting methodology does not take into consideration the array of services that are delivered in PHPs, such as assisting with appointments regarding social security and Medicare; housing searches; primary healthcare; eye and dental services; working with families; obtaining prescription medications; and accessing transportation, food banks and food stamps.

Two commenters expressed concern that CMHCs must retain the same level of licensed staff as hospital-based PHPs, yet the discrepancy between the proposed CMHC and hospital-based PHP per diem payment rates is now significant. The commenters stated that because all PHPs must hire psychiatrists, licensed clinicians, licensed supervisors, and bachelor-level case managers, it is difficult to understand why and how CMS calculated such different payment rates for essentially the same services.

Lastly, one commenter further questioned why a licensed therapist in a community-based treatment setting can be paid $110.27 for a 45 to 50 minute individual counseling session, while a CMHC is expected to deliver up to 6 hours of care per day including treatment, food, transportation, among others, for $111.89 per day (for 4 or more services).

Response: Section 1861(ff) of the Act and 42 CFR 410.43 describe the items and services included in partial hospitalization services. As set forth in these sections, partial hospitalization services generally consist of a variety of group, individual, and family psychotherapy sessions, supplemented with occupational therapy, the services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients, drugs and biologicals furnished for therapeutic purposes that cannot be self-administered, diagnostic services, education and training, and certain activity therapies designed to stabilize an acute episode of mental illness. The PHP APC per diem payment rate is the bundled payment for these partial hospitalization services. Physician services that meet the requirements of § 415.102(a) for payment on a fee schedule basis, physician assistant services, nurse practitioner and clinical nurse specialist services, and qualified psychologist services are separately covered (as are services furnished to skilled nursing facility residents as defined in § 411.15(p)) and are not paid as partial hospitalization services (§ 410.43(b)). Further, section 1861(ff)(2)(I) of the Act explicitly excludes meals and transportation from the items and services included in partial hospitalization services.

Regarding the concern about the discrepancy between the proposed CMHC and hospital-based PHP per diem payment rates, as discussed above, we believe that it is important to calculate PHP APC per diem payment rates based on the data for each type of provider in order to appropriately pay for services. We base the PHP APC per diem payment rates on claims and cost reports submitted by providers. The resulting PHP APC per diem payment rates reflect the cost of what providers expend to maintain such programs.

In response to the commenter who questioned why the payment to a CMHC for a full day of mental health treatment is about the same as the amount a therapist is paid for one individual counseling session, we believe the commenter is comparing the professional fee the therapist is paid under the MPFS for providing a therapy service ($110.27, according to the commenter) to the proposed Level II APC per diem payment rate to a CMHC under the OPPS for CY 2013 ($111.89). We believe that this is not an appropriate comparison because these payments are for completely different services. It is important to note that CMHCs receive the per diem amount per person per day. Thus, assuming the PHP has 10 patients, the facility is receiving over $1,000 for the day. That amount, which is intended to cover the facility's per diem cost for a day of PHP, includes the cost of staff who are not authorized to bill Medicare Part B as discussed above. Again, we base the PHP APC per diem payment rates on claims and cost reports submitted by providers. Thus, resulting PHP APC per diem payment rates reflect the cost of what providers expend to maintain such programs.

In summary, after consideration of the public comments we received, we are finalizing our CY 2013 proposal, without modification, to update the four PHP APC per diem payment rates based on geometric mean cost levels calculated using the most recent claims data for each provider type. The updated PHP APCs geometric mean per diem costs for PHP services that we are finalizing for CY 2013 are shown in Tables 39 and 40 below. We will continue our efforts to explore payment

reforms that will support quality and result in greater payment accuracy and reduction of fraud and abuse within the partial hospitalization program.

TABLE 39.--CY 2013 GEOMETRIC MEAN PER DIEM COSTS FOR CMHC PHP SERVICES

APC	Group Title	Mean Per Diem Costs
0172	Level I Partial Hospitalization (3 services) for CMHCs	$87.39
0173	Level II Partial Hospitalization (4 or more services) for CMHCs	$112.82

TABLE 40.--CY 2013 GEOMETRIC MEAN PER DIEM COSTS FOR HOSPITAL-BASED PHP SERVICES

APC	Group Title	Mean Per Diem Costs
0175	Level I Partial Hospitalization (3 services) for hospital-based PHPs	$185.90
0176	Level II Partial Hospitalization (4 or more services) for hospital-based PHPs	$234.81

C. Coding Changes

CPT codes are established by the AMA and the Level II HCPCS codes are established by the CMS HCPCS Workgroup. CPT and Level II HCPCS codes are used to report procedures, services, and items and supplies under the hospital OPPS. These codes are updated and changed throughout the year.

Subsequent to the publication of the CY 2013 OPPS/ASC proposed rule, the AMA's CPT Editorial Panel deleted 28 psychiatric CPT codes, including those related to PHP services, and replaced them with 12 new CPT codes, effective January 1, 2013. For a detailed explanation of the OPPS treatment of new, deleted or revised CPT and Level II HCPCS codes we refer readers to section III.A. of this final rule with comment period. As a result of the AMA's CPT coding changes to the psychiatric CPT codes, we are making corresponding changes to the PHP code set that is used for billing and documenting PHP services. Specifically, we are making the following changes:

- The initial E/M codes are being separated based on whether the service was completed by a physician (CPT code 90792 (Initial evaluation with medical services done by a physician)), or a nonphysician (CPT code 90791 (Initial evaluation done by a non-physician)). Currently, for PHPs, E/M services are billed under: CPT codes 90801 (Psychiatric diagnostic interview examination) and 90802 (Interactive psychiatric diagnostic interview). Effective January 1, 2013, CPT codes 90801 and 90802 will be deleted and the E/M services will be billed using the following CPT codes: CPT code 90791 (Psychiatric diagnostic evaluation (no medical services) when completed by a non-physician) and CPT code 90792 (Psychiatric diagnostic evaluation (with medical services) when completed by a physician).
- The psychotherapy codes will no longer be for a range of time, but for a specific period of time. The following CPT codes that are currently used to bill for and document PHP individual psychotherapies will be deleted in CY 2013: CPT code 90816 (Psytx hosp 20–30 min); CPT code 90817 (Psytx hosp 20–30 min w/e&m); CPT code 90818 (Psytx hosp 45–50 min); CPT code 90819 (Psytx hosp 45–50 min w/e&m); CPT code 90821 (Psytx hosp 75–80 min); CPT code 90822 (Psytx hosp 75–80 min w/e&m); CPT code 90823 (Intac psytx hosp 20–30 min); CPT code 90824 (Intac psytx hsp 20–30 w/e&m); CPT code 90826 (Intac psytx hosp 45–50 min); CPT code 90827 (Intac psytx hsp 45–50 w/e&m); CPT code 90828 (Intac psytx hosp 75–80 min); and CPT code 90829 (Intac psytx hsp 75–80 w/e&m). These codes will be replaced with the following new psychotherapy CPT codes: CPT codes 90832 (Psychotherapy, 30 minutes); CPT codes 90834 (Psychotherapy, 45 minutes); and CPT codes 90837 (Psychotherapy, 60 minutes). If the time spent for psychotherapy is more than half the time of the code, then that code can be used to bill for PHP services. For example, if the time spent for psychotherapy is 16 minutes up to 37 minutes, CPT code 90832 (Psychotherapy, 30 minutes) would be used. For psychotherapy lasting 38 to 52 minutes, CPT code 90834 (Psychotherapy, 45 minutes) would be used, and for psychotherapy lasting 53 minutes or more, CPT code 90837 (Psychotherapy, 60 minutes) would be used. When psychotherapy is provided during the same encounter as an E/M service, there will be timed add-on CPT codes for psychotherapy that are to be used by psychiatrists to indicate that psychotherapy was provided during the same encounter as an E/M service. When E/M services are completed with

psychotherapy, the following CPT codes may be used effective January 1, 2013: Appropriate E/M code (not selected on basis of time) and CPT code +90833 (30-minute psychotherapy add-on code); Appropriate E/M code (not selected on basis of time) and CPT code +90836 (45-minute psychotherapy add-on code); and Appropriate E/M code (not selected on basis of time) and CPT code +90838 (60-minute psychotherapy add-on code). The following table provides a list of the PHP-related individual psychotherapy CPT codes that will be deleted December 31, 2012.

BILLING CODE 4120–01–P

TABLE 41.—INDIVIDUAL PSYCHOTHERAPY CPT CODES THAT WILL BE DELETED DECEMBER 31, 2012

CY 2012 CPT Code	Long Descriptor
90816	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 20 to 30 minutes face-to-face with the patient
90817	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 20 to 30 minutes face-to-face with the patient; with medical evaluation and management services
90818	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 45 to 50 minutes face-to-face with the patient
90819	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 45 to 50 minutes face-to-face with the patient; with medical evaluation and management services
90821	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 75 to 80 minutes face-to-face with the patient
90822	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 75 to 80 minutes face-to-face with the patient; with medical evaluation and management services
90823	Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 20 to 30 minutes face-to-face with the patient
90824	Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 20 to 30 minutes face-to-face with the patient; with medical evaluation and management services
90826	Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 45 to 50 minutes face-to-face with the patient

CY 2012 CPT Code	Long Descriptor
90827	Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 45 to 50 minutes face-to-face with the patient; with medical evaluation and management services
90828	Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 75 to 80 minutes face-to-face with the patient
90829	Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 75 to 80 minutes face-to-face with the patient; with medical evaluation and management services

• Instead of separate codes for interactive psychotherapy, there is now an add-on CPT code for interactive complexity, which may be used when the patient encounter is more complex because of the need to involve people other than the patient (CPT code +90785). This add-on CPT code can be used with initial evaluation codes, with the psychotherapy codes, with the nonfamily group psychotherapy code, and with the E/M codes when they are used in conjunction with psychotherapy services. The CPT manual includes specific guidelines as to what constitutes interactive complexity that should be understood before this add-on CPT code is used. Documentation must clearly indicate exactly what the complexity was.

Beginning on January 1, 2013, interactive psychotherapy should be billed using the psychiatric evaluation codes, the psychotherapy and psychotherapy add-on CPT codes, and the group (nonfamily) psychotherapy CPT code +90785 (Interactive psychotherapy).

Relevant coding requirements must be followed. We recommend learning how to accurately bill for and document these new codes. More information may be found on the CPT/AMA Web site: *http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt.page.*

All other PHP CPT and HCPCS codes will remain unchanged and active for billing and documentation of PHP services. We refer readers to the table below that highlights which PHP CPT/HCPCS codes are changing and which PHP CPT/HCPCS codes will remain unchanged and active for billing and documentation of services.

The following Table 42 provides a crosswalk between the CPT/HCPCS code options in CY 2012 and the CPT/HCPCS code options that are effective on January 1, 2013.

TABLE 42.—CROSSWALK OF DELETED AND NEW PHP CPT AND HCPCS BILLABLE CODES FOR 2013

CURRENT CPT/HCPCS CODE	NEW CPT/HCPCS CODE
90801 (Psychiatric diagnostic interview)	90791 (psychiatric diagnostic evaluation (no medical services) 90792 (psychiatric diagnostic evaluation with medical services)
90802 (Intac psychiatric diagnostic interview)	90791 or 90792, with +90785 (interactive complexity add-on code)
90816 (Psytx hosp 20-30 min)	90832 psychotherapy, 30 min. (with patient and/or family)
90817 (Psytx hosp 20-30 min w/e&m)	Appropriate inpatient E/M code (not selected on basis of time), and +90833, 30-minute psychotherapy add-on code (with patient and/or family)
90818 (Psytx hosp 45-50 min)	90834 psychotherapy, 45 min. (with patient and/or family)
90819 (Psytx hosp 45-50 min w/e&m)	Appropriate inpatient E/M code (not selected on basis of time), and +90836, 45-minute psychotherapy add-on code (with patient and/or family)
90821 (Psytx hosp 75-80 min)	90837 psychotherapy, 60 min. (with patient and/or family)
90822 (Psytx hosp 75-80 min w/e&m)	Appropriate inpatient E/M code (not selected on basis of time), and +90838, 60-minute psychotherapy add-on code (with patient and/or family)
90823 (Intac psytx hosp 20-30 min)	90832, psychotherapy, 30 min. +90785, interactive complexity add-on code (with patient and/or family)
90824 (Intac psytx hsp 20-30 w/e&m)	Appropriate inpatient E/M code (not selected on basis of time), and +90833, 30-minute psychotherapy add-on code, and +90785, interactive complexity add-on code (with patient and/or family)

CURRENT CPT/HCPCS CODE	NEW CPT/HCPCS CODE
90826 (Intac psytx hosp 45-50 min)	90834, psychotherapy, 45 min. +90785, interactive complexity add-on code (with patient and/or family)
90827 (Intac psytx hsp 45-50 w/e&m)	Appropriate inpatient E/M code (not selected on basis of time), and +90836, 45-minute psychotherapy add-on code, and +90785, interactive complexity add-on code (with patient and/or family)
90828 (Intac psytx hosp 75-80 min)	90837, psychotherapy, 60 min. +90785, interactive complexity add-on code (with patient and/or family)
90829 (Intac psytx hsp 75-80 w/e&m)	Appropriate inpatient E/M code (not selected on basis of time), and +90838, 60-minute psychotherapy add-on code, and +90785, interactive complexity add-on code (with patient and/or family)
90845 (Psychoanalysis)	Retained/No changes
90846 (Family psytx w/o patient)	Retained/No changes
90847 (Family psytx w/patient)	Retained/No changes
90865 (Narcosynthesis)	Retained/No changes
90880 (Hypnotherapy)	Retained/No changes
96101 (Psycho testing by psych/phys)	Retained/No changes
96102 (Psycho testing by technician)	Retained/No changes
96103 (Psycho testing admin by comp)	Retained/No changes
96116 (Neurobehavioral status exam)	Retained/No changes
96118 (Neuropsych tst by psych/phys)	Retained/No changes
96119 (Neuropsych testing by tec)	Retained/No changes
96120 (Neuropsych tst admin w/comp)	Retained/No changes
G0129 (Partial hosp prog service)	Retained/No changes
G0176 (OPPS/PHP;activity therapy)	Retained/No changes
G0177 (OPPS/PHP; train & educ serv)	Retained/No changes
G0410 (Grp psych partial hosp 45-50)	Retained/No changes
G0411 (Inter active grp psych parti)	Retained/No changes

The following Table 43 shows all of the billable PHP revenue and CPT/HCPCS codes effective on January 1, 2013. This table is also located in the Medicare Claims Processing Manual, Pub. 100–04, Chapter 4, Section 260.1, which is available on the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf.*

TABLE 43.—PARTIAL HOSPITALIZATION BILLABLE CODES

Revenue Codes	Description	CPT/HCPCS Codes
043X	Occupational Therapy	G0129
0900	Behavioral Health Treatment/Services	90791 or 90792
0904	Activity Therapy	G0176
0914	Individual Psychotherapy	90785, 90832, 90833, 90834, 90836, 90837, 90838, 90845, 90865, or 90880
0915	Group Therapy	G0410 or G0411
0916	Family Psychotherapy	90846 or 90847
0918	Psychiatric Testing	96101, 96102, 96103, 96116, 96118, 96119, or 96120
0942	Education/Training	G0177

D. 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 charges for PHP services provided 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. Therefore, we designated a portion of the estimated OPPS outlier target amount specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS each year, excluding outlier payments. 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.

We proposed in the CY 2013 OPPS/ASC proposed rule (77 FR 45153) to continue our policy of identifying 1.0 percent of the aggregate total payments under the OPPS for outlier payments for CY 2013. We proposed that a portion of that 1.0 percent, an amount equal to 0.12 percent of outlier payments (or 0.0012 percent of total OPPS payments) would be allocated to CMHCs for PHP outlier payments. In section II.G. of the CY 2013 OPPS/ASC proposed rule, for the hospital outpatient outlier payment policy, we proposed to set a dollar threshold in addition to an APC multiplier threshold (77 FR 45110 through 45111). 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 2013 at 3.40 times the APC payment amount and the CY 2013 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 rate for APC 0173, the outlier payment will be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 0173 payment rate. We invited public comments on these proposals.

We did not receive any public comments regarding our proposed outlier policy. Therefore, we are finalizing our CY 2013 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 2013, as proposed, we are setting the outlier threshold at 3.40 multiplied by the APC payment amount and the CY 2013 outlier percentage applicable to costs in excess of the threshold at 50 percent.

IX. Procedures That Would Be Paid Only as Inpatient Procedures

A. Background

We refer readers to the CY 2012 final rule with comment period (76 FR 74352 through 74353) for a full historical discussion of our longstanding policies on how we identify procedures that are typically provided only in an inpatient setting (referred to as the inpatient list) and, therefore, will not be paid by Medicare under the OPPS; and on the criteria that we use to review the inpatient list each year to determine whether or not any procedures should be removed from the list.

B. Changes to the Inpatient List

In the CY 2013 OPPS/ASAC proposed rule (77 FR 45153), for CY 2013, we proposed to use the same methodology (described in the November 15, 2004 final rule with comment period (69 FR 65835)) of reviewing the current list of procedures on the inpatient list to

identify any procedures that are being performed a significant amount of the time on an outpatient basis, and appropriately may be removed from the list. The established criteria upon which we make such a determination are as follows:

1. Most outpatient departments are equipped to provide the services to the Medicare population.
2. The simplest procedure described by the code may be performed in most outpatient departments.
3. The procedure is related to codes that we have already removed from the inpatient list.
4. A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis.
5. 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.

Using this methodology, we identified two procedures that potentially could be removed from the inpatient list for CY 2013: CPT code 22856 (Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical); and CPT code 27447 (Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty)). We then reviewed the clinical characteristics and related evidence for these two potential procedures for possible removal from the inpatient list and found them to be appropriate candidates for removal from the inpatient list. For CY 2013, we proposed to remove the procedures described by CPT codes 22856 and 27447 from the inpatient list because we believe that the procedures may be appropriately provided as hospital outpatient procedures for some Medicare beneficiaries, based upon the evaluation criteria mentioned above and should thus be paid under the OPPS.

The two procedures that we proposed to remove from the inpatient list for CY 2013 and their CPT codes, long descriptors, proposed APC assignments, and proposed status indictors were displayed in Table 34 of the proposed rule.

Comment: A few commenters supported CMS' proposal to remove CPT code 27447 (Total knee arthroplasty) from the list of inpatient procedures, and asserted that this procedure may be appropriately provided on an outpatient basis for some Medicare beneficiaries, given thorough preoperative screening by medical teams with significant experience and expertise involving knee replacement procedures. The commenters referenced a study presented at the American Academy of Orthopedic Surgeons 2009 annual meeting, which noted recent advances in total knee replacement procedures, including improved perioperative anesthesia, and expedited rehabilitation protocols, as well as significant enhancements to the postoperative process, such as improvements in pain management, early mobilization, careful monitoring, and that early preventive intervention for the most common medical complications have decreased the average length of hospital stays to the point that total knee arthroplasty can now be performed on an outpatient basis in certain cases. The commenters noted significant success involving same day discharge for patients who met the screening criteria and whose experienced medical teams were able to perform the procedure early enough in the day for the patients to achieve postoperative goals, allowing home discharge by the end of the day. The commenters remarked that the benefits of providing total knee arthroplasty on an outpatient basis will lead to significant enhancements in patient well-being and cost savings to the Medicare program, including shorter hospital stays resulting in fewer medical complications, improved results, and enhanced patient satisfaction.

A few commenters urged CMS to group total knee arthroplasty into a new APC with unicompartmental knee replacement or to group these two procedures with other clinically similar orthopedic implant procedures from APC 0425 to create a more clinically homogenous APC for resource-intensive arthroplasty, if CMS finalized its proposal to remove total knee arthroplasty from the inpatient list. One commenter requested CMS to assign CPT code 27447 a status indicator of ''S.''

The majority of commenters asked that CMS retract its proposal to remove CPT code 27447 from the inpatient list. Commenters argued that CPT code 27447 is not being performed in numerous hospitals on an outpatient basis and noted that the published average length of stay for this procedure is over 3 days, with a recommended best practice target of 3 days when no complications exist. Commenters stated that removing CPT code 27447 from the inpatient list will create a dangerous situation for Medicare beneficiaries, who are older and more medically complex patients, as there are serious potential adverse effects, including inadequate pain management, unsafe ambulation, and risk for falls. Commenters also noted that patients undergoing total knee replacement often have several comorbidities and increased risks, such as death, loss of a limb, nerve damage resulting from neurovascular injury, myocardial infarction (MI), pulmonary embolism (PE), deep vein thrombosis (DVT), and infection and loss of mobility, as well as anaphylaxis, obstructive sleep apnea, and aspiration of stomach contents into the lungs. Several commenters stated that many patients will require some type of sub acute rehabilitation, which could include a SNF, and if these patients are not admitted, they will not meet their qualifying 3-day inpatient stay and will not be eligible for SNF care, which likely will lead to poor outcomes postoperatively. Some commenters stated that Medicare patients require greater than 24 hours of inpatient hospital care following total knee replacement procedures for clinical reasons, including anesthesia recovery, physical therapy, blood loss monitoring, and pain control, which often includes intravenous pain medications for 24 to 48 hours following the procedure, and the outpatient setting cannot handle the high acuity for the extended postoperative care that this type of patient requires. Other commenters stated that they do not believe that the clinical characteristics of CPT code 27447 justify its selection as an appropriate candidate for removal from the inpatient list.

Commenters pointed out that, while Medicare's definition of outpatient surgery specified that it includes the care provided during the normal recovery period, which is defined as less than 24 hours, the length of stay for total knee arthroplasty patients is markedly longer than 24 hours for outpatient surgery recovery. In addition, the commenters noted that, according to the Medicare Claims Processing Manual, Chapter 4, section 180.7, '' 'Inpatient only' services are generally, but not always, surgical services that require inpatient care because of the nature of the procedure, the typical underlying physical condition of patients who require the service, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged.'' Several commenters cited the lack of any evidence-based publications supporting outpatient total knee arthroplasty in

patients over the age of 65 and asserted that patients having total knee replacement surgery as outpatients were significantly more likely to die or need readmission within 90 days, compared with inpatients remaining in the hospital for 3 to 4 days, according to a study presented at the February 2012 American Association of Orthopedic Surgery meeting. Commenters also noted, according to the same study, the rates of subsequent revision surgery were nearly doubled in patients having 1-day hospital stays compared with the 3- to- 4-day standard.

Commenters further noted that performing total knee arthroplasty in the outpatient setting may impact the types of rehabilitation services available to patients upon completion of the surgery, and may make justifying the medical necessity of inpatient rehabilitation more difficult. Furthermore, commenters expressed concern that commercial carriers will change total knee arthroplasty to an outpatient procedure, thereby making it more difficult to get such a procedure authorized.

Commenters also stated that all hospitals do not have the robotics available for less invasive surgical technique and only a few centers across the country are routinely doing knee replacement as outpatients, and even those hospitals are doing them on specific patient types. One commenter remarked that, while outpatient joint replacements are possible in hospitals in major cities with large resources and an educated skilled support staff, it would be dangerous to the patient to perform outpatient total knee arthroplasties in small rural communities, as there are limited nurses, therapists, and other support staff in many communities across the country.

Some commenters expressed concern about the effects of CMS' proposed removal of CPT 27447 on participants in the CMS Innovation Center's (CMMI's) Bundled Payments for Care Improvement (BPCI) initiative.

Response: We appreciate all of the public comments we received on the removal of CPT code 27447 from the inpatient list. In light of all of these public comments, for CY 2013, we have decided not to remove CPT code 27447 from the inpatient list as we proposed. Based on the public comments, we have concerns regarding whether this procedure may be appropriately provided as a hospital outpatient procedure for some Medicare beneficiaries based upon the evaluation criteria above.

Comment: The majority of commenters supported CMS' proposal to provide payment for CPT code 22856 in the hospital outpatient setting, but recommended assigning CPT code 22856, as well as CPT codes 22551 and 22554, to APC 0052 (Level IV Musculoskeletal Procedures Except Hand and Foot), APC 0425 (Level II Arthroplasty or Implantation of Prosthesis), or a newly created APCs in order to appropriately compensate hospitals for their costs associated with this procedure. One commenter believed that CPT code 22856, for patient safety reasons, should remain on the inpatient list.

Response: We appreciate commenters' support of our proposal to provide payment for CPT code 22856 in the hospital outpatient setting. We believe that this procedure may be appropriately provided as a hospital outpatient procedure for some Medicare beneficiaries based upon the evaluation criteria above. However, we do not agree with the commenters' recommendation to assign CPT code 22856, as well as CPT codes 22551 and 22554, to APC 0052, 0425, or a newly created APC. We believe that CPT code 22856, as well as CPT codes 22551 and 22554, are appropriately placed in APC 0208.

Comment: Several commenters requested that CMS remove 39 additional CPT codes from the CY 2012 inpatient 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.

Response: We reevaluated data on the 39 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 44 below. As a result of the reevaluation, we remain convinced that these procedures can be safely performed only in the inpatient setting.

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TABLE 44.—ADDITIONAL PROCEDURES REQUESTED BY COMMENTERS TO BE REMOVED FROM THE INPATIENT ONLY LIST FOR CY 2013

HCPCS Code	Long Descriptor	CY 2013 Status Indicator
0075T	Transcatheter placement of extracranial vertebral or intrathoracic carotid artery stent(s), including radiologic supervision and interpretation, percutaneous; initial vessel	C
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), requiring general anesthesia	C
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
20937	Autograft for spine surgery only (including harvesting the graft); morselized (through separate skin or fascial incision) (list separately in addition to code for primary procedure)	C
20938	Autograft for spine surgery only (including harvesting the graft); structural, bicortical or tricortical (through separate skin or fascial incision) (list separately in addition to code for primary procedure)	C
21141	Reconstruction midface, LeFort I; single piece, segment movement in any direction, without bone graft	C
21196	Reconstruction of mandibular rami & body with sag split & int fix	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
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).	C
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar.	C
22585	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); each additional interspace (List separately in addition to code for primary procedure	C
22845	Anterior instrumentation; 2 to 3 vertebral segments (list separately in addition to code for primary procedure)	C

HCPCS Code	Long Descriptor	CY 2013 Status Indicator
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar	C
22840	Posterior nonsegmental instrumentation (eg, Harrington rod technique, pedicle fixation across 1 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)	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 post op hemorrhage, thrombosis or infection; neck	C
37182	TIPS procedure	C
37617	Ligation, major artery; abdomen	C
38562	Limited lymphadenectomy for staging (separate procedure); pelvic and para-aortic	C
43840	Gastrorrhaphy, suture of perforated duodenal or gastric ulcer, wound, or injury	C
44300	Open jejunostomy following a diagnostic laparoscopy	C
44314	Revision of ileostomy; complicated (reconstruction indepth) (separate procedure)	C
44345	Revision of colostomy; complicated (reconstruction indepth) (separate procedure)	C
44346	Revision of colostomy; with repair of paracolostomy hernia (separate procedure)	C
44602	Suture of small intestine accidental laceration	C
49010	Exploration, retroperitoneal area with or without biopsy(s) (separate procedure)	C
49255	Omentectomy, epiploectomy, resection of omentum	C
51840	Anterior vesicourethropexy , or urethropexy (eg, Marshall-Marchetti-Krantz, Burch); simple	C
54411	Removal and replacement of a multi-component inflatable penile prosthesis through an infected field at the same operative session	C
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	C
56630	Vulvectomy, radical, partial;	C
61624	Transcatheter permanent occlusion or embolization, percutaneous, any method; central nervous system	C

HCPCS Code	Long Descriptor	CY 2013 Status Indicator
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
63267	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; lumbar	C
63710	Dural graft, spinal	C

BILLING CODE 4120–01–C

Comment: Some commenters requested that CMS add CPT codes 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), and 44213 (Laparoscopy, surgical, mobilization (take-down) of splenic flexure performed in conjunction with partial colectomy (List separately in addition to primary procedure)) to the inpatient list.

Response: We note that CPT codes 44206, 44207, 44208, and 44213 have been payable in the outpatient setting for a number of years without significant concern raised by the public. Therefore, we find no reason to reassign CPT codes 44206, 44207, 44208, and 44213 to the inpatient list at this time.

Comment: A number of commenters requested that the inpatient list be eliminated in its entirety, and if the inpatient list cannot be eliminated in its entirety, an appeals process be developed. Commenters also requested that the inpatient list be reviewed clinically. In addition, commenters expressed concern about the way Recovery Audit Contractors (RACs) target procedures removed from the inpatient list and encouraged CMS to provide a period to allow hospitals to make the appropriate adjustments without being at risk of an audit. The commenters urged CMS to provide, in both regulatory language and transmittals, that procedures with APC payment rates can be performed, covered, and paid by Medicare on an inpatient basis when medical necessity is documented and the physician has ordered inpatient status.

Response: We appreciate these comments and thoughtful suggestions. We continue to believe that the inpatient list is a valuable tool for ensuring that the OPPS only pays for services that can safely and appropriately be performed in the hospital outpatient setting, and we will not eliminate the inpatient only list at this time. We do not plan to adopt a specific appeals process for claims related to inpatient procedures performed in the HOPD in light of the added administrative burden, and the existing processes established for a beneficiary or a provider to appeal a specific claim remain in effect. We are committed to clinically reviewing the inpatient list timely to reflect changes in medical practice, and we plan to continue our current practice of reviewing procedures for removal from the inpatient list through the formal notice-and-comment rulemaking process. The inpatient list is made available to the public through the OPPS/ASC final rule with comment period at least 60 days prior to its effective date of January 1 of the upcoming year. We believe that the 60 days between the release of the OPPS/ASC final rule with comment period and the effective date of January 1 of the upcoming year provide sufficient time for hospitals to make the appropriate adjustments to reflect the upcoming year's inpatient list. As we have stated in Section 180.7 of Chapter 4 of the Medicare Claims Processing Manual, procedures removed from the inpatient list may be appropriately furnished in either the inpatient or outpatient settings and such procedures continue to be payable when furnished in the inpatient setting.

Comment: One commenter who responded to the CY 2012 OPPS/ASC final rule with comment period supported CMS' decision to assign a status indicator of ''C'' to Category III codes 0293T (Insertion of left atrial hemodynamic monitor; complete system, includes implanted communication module and pressure sensor lead in left atrium including transseptal access, radiological supervision and interpretation, and associated injection procedures, when performed) and 0294T (Insertion of left atrial hemodynamic monitor; pressure sensor lead at time of insertion of pacing cardioverter-defibrillator pulse generator including radiological supervision and interpretation and associated injection procedures, when performed (list separately in addition to primary procedure)).

Response: We appreciate the commenter's support.

At its August 27–28, 2012 meeting, the Panel recommended that CMS remove HCPCS code 22856 from the list of inpatient procedures. We are accepting this recommendation.

After consideration of the public comments we received, we are modifying our proposal and only removing CPT code 22856 from the CY 2013 inpatient list. CPT code 27447 will remain on the inpatient list for CY 2013.

The procedure that we are removing from the inpatient list for CY 2013 and its CPT code, long descriptor, APC assignment, and status indictor are displayed in Table 45 below.

TABLE 45.—PROCEDURE REMOVED FROM THE INPATIENT ONLY LIST AND ITS APC ASSIGNMENTS FOR CY 2013

HCPCS Code	Long Descriptor	CY 2013 APC Assignment	CY 2013 Status Indicator
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical	0208	T

The complete list of codes to be paid by Medicare in CY 2013 only as inpatient procedures is included as Addendum E to this final rule with comment period (which is available via the Internet on the CMS Web site).

X. Policies for the Supervision of Outpatient Services in Hospitals and CAHs

A. Conditions of Payment for Physical Therapy, Speech-Language Pathology, and Occupational Therapy Services in Hospitals and CAHs

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74360 through 74371), we clarified that hospital outpatient therapeutic services and supplies, including those 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 42 CFR 410.27 when they are paid under the OPPS or paid to CAHs under section 1834(g) of the Act. We issued this clarification in response to inquiries regarding the application of these conditions of payment to radiation therapy services that are described under section 1861(s)(4) of the Act when these services are furnished to hospital outpatients.

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74369), in our response to public comments on the CY 2012 OPPS/ASC proposed rule, we indicated that the supervision and other requirements of § 410.27 do not apply to professional services or to services that are paid under other fee schedules such as the Clinical Laboratory Fee Schedule (CLFS). After the publication of the CY 2012 OPPS/ASC final rule with comment period, we continued to receive questions about the applicability of the regulations to physical therapy (PT), speech-language pathology (SLP), and occupational therapy (OT) services furnished in CAHs. Several stakeholders expressed concern that the rules could be applied differently in CAHs than in OPPS hospitals. The stakeholders were concerned that OPPS hospitals, which are paid for outpatient therapy services at the applicable amount based on the Medicare Physician Fee Schedule (MPFS), would not be subject to the regulations, but that CAHs, which are paid for outpatient therapy services on a reasonable cost basis, would be subject to them.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45154), we clarified that it was not our intent in the CY 2012 OPPS/ASC final rule with comment period to establish different requirements for CAHs and for OPPS hospitals for the same services. We clarified that the limited set of PT/SLP/OT services that are paid under the OPPS are subject to the supervision requirements in § 410.27, whether they are furnished in OPPS hospitals or CAHs. The PT/SLP/OT services that are not paid under the OPPS and are paid instead at the applicable amount based on the MPFS are not subject to the supervision requirements in § 410.27, whether they are furnished in OPPS hospitals or in CAHs.

Comment: Commenters expressed appreciation and support for the clarification in the proposed rule. One commenter requested that CMS rescind the requirement of direct supervision for all PT/SLP/OT services, regardless of whether they are furnished as therapy services and paid at the applicable amount under the MPFS or are furnished as nontherapy services and paid under the OPPS.

Response: Stakeholders may direct requests for changes in the minimum required level of supervision for therapeutic services, including therapy or other services that are hospital outpatient services, to the independent review process that we established for considering such requests in the CY 2012 OPPS/ASC final rule with comment period. The instructions for submitting a request are discussed in the CY 2012 final rule with comment period and are available on the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html*.

In this final rule with comment period, we are clarifying that the supervision and other requirements of the regulation at § 410.27 apply to facility services that are paid to hospitals under the OPPS and to these same services when they are furnished in CAHs and paid on a reasonable cost basis. In OPPS hospitals, the requirements of § 410.27 do not apply to professional services that are separately billed under the MPFS or to PT, SLP, and OT services that are billed by the hospital as therapy services and are paid at the applicable amount based on the MPFS. The requirements of § 410.27 also do not apply to these same professional and PT, SLP, and OT services when they are furnished in CAHs.

In OPPS hospitals, a small subset of ''sometimes therapy'' PT, SLP, and OT services are paid under the OPPS when they are not furnished as therapy, meaning not under a certified therapy plan of care. Because the supervision and other conditions of payment under § 410.27 apply to this subset of ''sometimes therapy'' services when they are furnished in OPPS hospitals as nontherapy services (because they are paid under the OPPS and not based on the MPFS), those conditions of payment also apply to this subset of ''sometimes therapy'' services when they are furnished as nontherapy in CAHs. When OPPS hospitals and CAHs furnish these services as therapy services (under a therapy plan of care by a qualified therapist), the conditions of payment under § 410.27 do not apply because

OPPS hospitals are paid for these services based on the MPFS and not under the OPPS. As we did in the CY 2013 OPPS/ASC proposed rule, we are providing a list of the ''sometimes therapy'' services that may be paid under the OPPS in Table 46 below.

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TABLE 46.--"SOMETIMES THERAPY" SERVICES THAT ARE PAID UNDER THE OPPS WHEN NOT FURNISHED AS THERAPY SERVICES

HCPCS Code	Descriptor
97597	Debridement (eg, high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (eg, fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; first 20 sq cm or less
97598	Debridement (eg, high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (eg, fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; each additional 20 sq cm, or part thereof (list separately in addition to code for primary procedure)
97602	Removal of devitalized tissue from wound(s), non-selective debridement, without anesthesia (eg, wet-to-moist dressings, enzymatic, abrasion), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session
97605	Negative pressure wound therapy (eg, vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters
97606	Negative pressure wound therapy (eg, vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters
0183T	Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day

B. Enforcement Instruction for the Supervision of Outpatient Therapeutic Services in CAHs and Certain Small Rural Hospitals

As we indicated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74371), we extended through CY 2012 the notice of nonenforcement of the requirement for direct supervision of outpatient therapeutic services furnished in CAHs and small rural hospitals having 100 or fewer beds (available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html?redirect=/HospitalOutpatientPPS/01_overview.asp*). We extended this enforcement instruction to our contractors for another year, through CY 2012, to allow time for the initiation of supervision reviews by the Advisory Panel on Hospital Outpatient Payment (the Panel), which began in early 2012 and are continuing in accordance with the provisions of the CY 2012 OPPS/ASC final rule with comment period.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45154), we requested that CAHs and small rural hospitals submit to CMS for potential evaluation by the Panel at its summer meeting any services for which they anticipate difficulty complying with the direct supervision standard in CY 2013. We stated that, in developing evaluation requests, hospitals should refer to the evaluation criteria that we finalized in the CY 2012 OPPS/ASC final rule with comment period. In order to give hospitals additional opportunity during CY 2012 to become familiar with the new submission and review process at the summer Panel meeting, and to allow hospitals time to meet the required supervision levels for the services that would be considered for CY 2013, we indicated that we anticipated extending the nonenforcement instruction one

additional year through CY 2013. We stated that we expect that CY 2013 will be the final year for the instruction, regardless of the services reviewed by the Panel during its summer meeting.

Comment: Most commenters supported an extension of the enforcement instruction another year through CY 2013, and reiterated requests made in previous years that we limit CAHs to the requirements in their staffing Conditions of Participation (CoPs) by making the definition of ''direct supervision'' in § 410.27 consistent with the CAH staffing CoPs. These CoPs require that a doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant be available to furnish patient care services at all times the CAH operates (§ 485.631) and be available on site within 30 minutes (§ 485.618). They apply to all services that are furnished by a CAH. In contrast, for payment of most outpatient therapeutic services, under § 410.27 the CAH (like all OPPS hospitals) must furnish direct supervision, meaning the supervising physician or appropriate nonphysician practitioner is immediately available to furnish assistance and direction for the duration of the service. The requirement in § 410.27 does not apply to CAH inpatient services or to CAH outpatient diagnostic services.) Some commenters similarly requested that CMS require only general supervision in CAHs and small rural hospitals, meaning the services would be furnished under the supervising physician's or appropriate nonphysician practitioner's overall direction and control but he or she need not be physically present.

One commenter stated that while the commenter understands the need to allow CAHs and small rural hospitals to become compliant with the recent clarifications regarding the outpatient supervision requirements, and while the commenter shares the concerns of these facilities regarding the available supply of certain types of physicians, the supervision requirements should be applied uniformly across all care settings for reasons of patient safety. In addition, several commenters offered suggestions for improving the subregulatory supervision review process.

Response: We appreciate the suggestions for improving the supervision review process and will take them into consideration for future Panel meetings. Regarding the supervision requirements for payment of hospital and CAH outpatient services, we previously discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74362) that 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). As we indicated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72000 through 72005), we elected not to limit the CAHs to their CoPs or to exclude them from the direct supervision requirement for payment because we believe that Medicare should purchase outpatient services from CAHs and other hospitals that are of the same basic level of safety and quality. In addition, while CoPs apply to all services that a hospital or a CAH furnishes, the payment rule in § 410.27 applies only to outpatient therapeutic services.

Regarding the enforcement instruction, as we discussed in the CY 2013 OPPS/ASC proposed rule, we will extend the enforcement instruction one additional year through CY 2013. This additional year, which we expect to be the final year of the extension, will provide additional opportunities for stakeholders to bring their issues to the Panel, and for the Panel to evaluate and provide us with recommendations on those issues.

The Panel held its second meeting on supervision levels for outpatient therapeutic services in August 2012, and considered several stakeholder requests for a reduction in the minimum required level of supervision for certain services. These included observation services; administration of certain drugs and agents; and selected bladder, skin/wound care, injection/infusion, intravenous and central venous access services. In accordance with the subregulatory review process finalized in the CY 2012 OPPS/ASC final rule with comment period, we are currently reviewing public comments on the agency's preliminary decisions regarding supervision levels for these services based upon the Panel's recommendations. We will issue our final decisions on these services prior to January 1, 2013 on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

XI. Outpatient Status: Solicitation of Public Comments in the CY 2013 OPPS/ASC Proposed Rule

A. Background

Under section 402(a)(1)(A) of the Social Security Amendments of 1967 (Pub. L. 90–248), the Secretary is permitted to engage in demonstration projects to determine whether changes in the methods of payment for health care and services under the Medicare program would increase the efficiency and economy of those services through the creation of incentives to those ends without adversely affecting the quality of such services. Under this statutory authority, CMS has implemented the Medicare Part A to Part B Rebilling (AB Rebilling) Demonstration, which allows participating hospitals to receive 90 percent of the allowable Part B payment for Part A short-stay claims that are denied on the basis that the inpatient admission was not reasonable and necessary. Participating hospitals can rebill these denied Part A claims under Part B and be paid for additional Part B services than would usually be payable when an inpatient admission is deemed not reasonable and necessary. This demonstration is slated to last for 3 years, from CY 2012 through CY 2014.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45155 through 45157), we provided an update of the status of the demonstration. In addition, we solicited public comments on a related issue: potential policy changes we could make to improve clarity and consensus among providers, Medicare, and other stakeholders regarding the relationship between admission decisions and appropriate Medicare payment, such as when a Medicare beneficiary is appropriately admitted to the hospital as an inpatient and the cost to hospitals associated with making this decision.

In the proposed rule, we discussed that when a Medicare beneficiary arrives at a hospital in need of medical or surgical care, the physician or other qualified practitioner must decide whether to admit the beneficiary for inpatient care or treat him or her as an outpatient. In some cases, when the physician admits the beneficiary and the hospital provides inpatient care, a Medicare claims review contractor, such as the Medicare Administrative Contractor (MAC), the Recovery Audit Contractor (RAC), or the Comprehensive Error Rate Testing (CERT) Contractor, determines that inpatient care was not reasonable and necessary under section 1862(a)(1)(A) of the Act and denies the hospital inpatient claim for payment. In these cases, under Medicare's longstanding policy, hospitals may rebill a separate inpatient claim for only a limited set of Part B services, referred to as ''Inpatient Part B'' or ''Part B Only'' services (Section 10, Chapter 6 of the Medicare Benefit Policy Manual (Pub. 100–02)). The hospital also may bill Medicare Part B for any outpatient services that were provided in the 3-day payment window prior to the admission (Section 10.12, Chapter 4 of the Medicare Claims Processing Manual

(Pub. 100–04)). These claims are subject to the timely filing restrictions.

Once a Medicare beneficiary is discharged from the hospital, the hospital cannot change the beneficiary's patient status from inpatient to outpatient and then submit an outpatient claim because of the potentially significant impact on beneficiary liability. As we discuss below, hospital inpatients have significantly different Medicare benefits and liabilities than hospital outpatients, notably coverage of self-administered drugs and, for patients who are admitted to the hospital as inpatients for 3 or more consecutive calendar days, Medicare coverage of postacute SNF care (to the extent all other SNF coverage requirements are met). To enable beneficiaries to make informed financial and other decisions prior to hospital discharge, Medicare allows the hospital to change a beneficiary's inpatient status to outpatient (using condition code 44 on an outpatient claim) and bill all medically necessary services that it provided to Part B as outpatient services, but only if the change in patient status is made prior to discharge, the hospital has not submitted a Medicare claim for the admission, and both the practitioner responsible for the care of the patient and the utilization review committee concur with the decision (Section 50.3, Chapter 1 of the Medicare Claims Processing Manual (Pub. 100–04); MLN Matters article SE0622, Clarification of Medicare Payment Policy When Inpatient Admission Is Determined Not To Be Medically Necessary, Including the Use of Condition Code 44: ''Inpatient Admission Changed to Outpatient,'' September 2004). Medicare beneficiaries are provided with similar protections, which are outlined in the Hospital Conditions of Participation (CoPs). For example, in accordance with 42 CFR 482.13(b), Medicare beneficiaries have the right to participate in the development and implementation of their plan of care and treatment, to make informed decisions, and to accept or refuse treatment. Informed discharge planning between the patient and the physician is important for patient autonomy and for achieving efficient outcomes.

In the proposed rule, we stated that while the limited scope of allowed rebilling for ''Inpatient Part B'' services protects Medicare beneficiaries and provides disincentives for hospitals to admit patients inappropriately, hospitals have expressed concern that this policy provides inadequate payment for resources that they have expended to take care of the beneficiary in need of medically necessary hospital care, although not necessarily at the level of inpatient care. A significant proportion of the Medicare CERT error rate consists of short (1- or 2-day) stays where the beneficiary received medically necessary services that the CERT contractor determined should have been provided as outpatient services and not as inpatient services. Hospitals have indicated that often they do not have the necessary staff (for example, utilization review (UR) staff or case managers) on hand after normal business hours to confirm the physician's decision to admit the beneficiary. Thus, for a short-stay admission, the hospital may be unable to timely review and change a beneficiary's patient status from inpatient to outpatient prior to discharge in accordance with the condition code 44 requirements.

In the proposed rule, we indicated that we have heard from various stakeholders that hospitals appear to be responding to the financial risk of admitting Medicare beneficiaries for inpatient stays that may later be denied upon contractor review by electing to treat beneficiaries as outpatients receiving observation services, often for longer periods of time, rather than admitting them as inpatients. In recent years, the number of cases of Medicare beneficiaries receiving observation services for more than 48 hours, while still small, has increased from approximately 3 percent in 2006 to approximately 7.5 percent in 2010. This trend is concerning because of its effect on Medicare beneficiaries. There could be significant financial implications for Medicare beneficiaries of being treated as outpatients rather than being admitted as inpatients, of which CMS has informed beneficiaries.[1] For instance, if a beneficiary is admitted as an inpatient, the beneficiary pays a one-time deductible for all hospital services provided during the first 60 days in the hospital. As a hospital inpatient, the beneficiary would not pay for self-administered drugs or have any copayments for the first 60 days; whereas if the beneficiary is treated as an outpatient, the beneficiary has a copayment for each individual outpatient hospital service received. While the Medicare copayment for a single outpatient hospital service cannot be more than the inpatient hospital deductible, the beneficiary's total copayment for all outpatient services received may be more than the inpatient hospital deductible. In addition, usually self-administered drugs provided in an outpatient setting are not covered by Medicare Part B and hospitals may charge the beneficiary for them. Also, the time spent in the hospital as an outpatient is not counted towards the 3-day qualifying inpatient stay that section 1861(i) of the Act requires for Medicare Part A coverage of postacute care in a SNF.

As a result of these concerns related to the impact of extended time as an outpatient on Medicare beneficiaries, the CERT error rate, and the impact on hospitals of a later inpatient denial, CMS initiated the AB Rebilling Demonstration for a 3-year period for hospitals. This demonstration is voluntary and allows participating hospitals to rebill outside of the usual timely filing requirements for services relating to all inpatient short-stay claims that are denied for lack of medical necessity because the inpatient admission was not medically necessary. Under the demonstration, hospitals may receive 90 percent of the Medicare allowable payment for all Part B services that would have been medically necessary had the beneficiaries originally been treated as outpatients and not admitted as inpatients. We note that hospitals cannot rebill for observation services, which, by definition, must be ordered prospectively to determine whether an inpatient admission is necessary (Chapter 1, Section 50.3.2 of the Medicare Claims Processing Manual (Pub. 100–04); FAQ 2723, available on the CMS Web site at *https://questions.cms.gov/faq.php?id=5005&faqId=2723*). Hospitals that participate in the AB Rebilling Demonstration will waive any appeal rights associated with the denied inpatient claims eligible for rebilling. Under the demonstration, Medicare beneficiaries are protected from any adverse impacts of expanded rebilling. For example, hospitals cannot bill beneficiaries for self-administered drugs or additional cost-sharing that would be required under Medicare Part B. The demonstration will inform us on the impact that expanded rebilling may have on the Medicare Trust Funds, beneficiaries, hospitals, and the CERT error rate. The demonstration is designed to evaluate potential impacts of expanded rebilling on admission and utilization patterns, including whether expanded rebilling would reduce hospitals' incentive to make appropriate initial admission decisions.

Hospitals expressed significant interest in the AB Rebilling

[1] CMS Pamphlets: ''Are You a Hospital Inpatient or Outpatient? If You Have Medicare—Ask!'', CMS Product No. 11435, Revised, February 2011; ''How Medicare Covers Self-Administered Drugs Given in Hospital Outpatient Settings,'' CMS Product No. 11333, Revised, February 2011.

Demonstration, which began on January 1, 2012. The demonstration was approved to accept up to 380 hospitals. In order to participate in the demonstration, a hospital must not be receiving periodic interim payments from CMS, and must be a Medicare-participating hospital as defined by section 1886(d) of the Act, a category that includes all hospitals paid under the Medicare IPPS, but excludes hospitals paid under the IPF PPS, the IRF PPS, and the LTCH PPS, and cancer hospitals, CAHs, and children's hospitals.

The hospitals that volunteered to participate and were accepted in the demonstration began rebilling in early spring of 2012. More information about the demonstration is available on the CMS Web site at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/CERT/Part_A_to_Part_B_Rebilling_Demonstration.html.* We stated in the proposed rule that we plan to conduct an evaluation of the demonstration during and after its completion.

B. Summary of Public Comments Received

While we are implementing the AB Rebilling Demonstration, we also solicited public comments in the CY 2013 OPPS/ASC proposed rule on other actions that we could potentially undertake to address stakeholders' concerns. In the proposed rule, we stated that there may be several ways of approaching the multifaceted issues that have been raised in recent months around a beneficiary's patient status and Medicare hospital payment. Given the complexity of this topic, we sought public perspectives on potential options the agency might adopt to provide more clarity and consensus regarding patient status for purposes of Medicare payment. We invited commenters to draw on their knowledge of these issues to offer any suggestions that they believe would be most helpful to them in addressing the current challenges, while keeping in mind the various impacts in terms of recently observed increases in the length of time for which patients receive observation services, beneficiary liability, Medicare spending, and the feasibility of implementation of any suggested changes for both the Medicare program and hospitals.

We received approximately 350 public comments in response to our solicitation in the CY 2013 OPPS/ASC proposed rule from hospitals and hospital associations, physician associations, rehabilitative and long-term care facilities, beneficiaries, beneficiary advocacy organizations, Quality Improvement Organizations (QIOs), organizations specializing in medical necessity review, and other interested parties. The commenters provided significant input, and the majority requested that CMS not implement a comprehensive solution or set of solutions regarding patient status in the CY 2013 OPPS/ASC final rule with comment period. Instead, many commenters recommended that CMS develop an informed course of action in the upcoming months through a formal, ongoing dialogue with all interested stakeholders (for example, through open door forums or a task force). A few commenters recommended a more immediate course of action to limit beneficiary liability for SNF care and for the difference in beneficiary cost-sharing between hospital inpatient and outpatient services.

In this section, we summarize the feedback we received in response to our solicitation of public comments in the CY 2013 OPPS/ASC proposed rule. We are not providing responses to the public comments we received because in the proposed rule we strictly solicited public comments, and did not propose any changes in policy. We will consider the feedback we received from the public as we move forward. We structured our summary of the public comments around key suggestions that we have heard from stakeholders in the following areas: (1) Part A to Part B Rebilling; (2) Clarifying Current Admission Instructions or Establishing Specified Clinical Criteria; (3) Hospital Utilization Review; (4) Prior Authorization; (5) Time-Based Criteria for Inpatient Admission; (6) Payment Alignment; and (7) Public Comments on Other Topics (including Rules for External Review of Inpatient Claims, Improving Beneficiary Protections, and Revising the Qualifying Criteria for SNF Coverage). We summarize the public comments below in the context of each of these suggestions.

1. Part A to Part B Rebilling

Some stakeholders have suggested that, when a Part A inpatient claim is denied because an inpatient level of care was not reasonable and necessary although some medical care was necessary, CMS allow hospitals to rebill Medicare and receive payment for all Part B services that would have been payable had the patient originally been treated as an outpatient rather than an inpatient. As we describe above, the AB Rebilling Demonstration allows participating providers to receive 90 percent of the allowable payment amount for such services (except observation services) as Part B Inpatient services. Because establishing such a policy on a national basis could result in increases in Medicare expenditures and could affect beneficiary liability for hospital care, CMS implemented the demonstration to assess Medicare spending and other outcomes while protecting beneficiaries from any increase in liability.

Comments: Commenters expressed some support for the AB Rebilling Demonstration as an important step in determining what types of policy clarifications are needed. The commenters noted that the beneficiary protections against changes in liability are a key benefit of the demonstration. While some commenters expressed appreciation for the opportunity for increased Part B payment to hospitals, they disagreed with the demonstration's requirement to forego appeals of the denied inpatient claims eligible for rebilling. One commenter requested that CMS provide interim reports to stakeholders describing the demonstration's evaluation criteria and its progress towards meeting its goals.

Some commenters recommended that CMS establish a national policy allowing the rebilling of all Part B services that would have been payable if the patient had been treated as an outpatient rather than admitted as an inpatient because, according to the commenters, outpatient and inpatient services are sometimes indistinguishable. The commenters believed that the Medicare statute does not preclude such a policy and that, due to the recent focus on claims audit and review, hospitals would have no incentive to admit beneficiaries inappropriately in response to a more generous rebilling policy. However, other commenters expressed concern that there would be such an incentive. They indicated that allowing expanded rebilling with a change in bill type from a Part A claim to a Part B claim would remove the incentive to bill accurately, as hospitals would file more inpatient claims under Part A in order to receive the (typically higher) Diagnosis-Related Group (DRG) payment under the IPPS, knowing that, in the event of the inpatient claim being denied, they could rebill under Part B and receive the same (typically lower) OPPS payment they would have received if they had billed an outpatient claim initially.

Several commenters suggested that allowing full Part B rebilling would negate and undermine the designs of the OPPS and the IPPS. The commenters stated that OPPS payments are established to compensate hospitals for the care provided in the outpatient setting, and that they act as a natural

complement to the IPPS. They indicated that making the two payment systems retroactively interchangeable would result in the payment rates calculated under each system being miscalibrated and failing to adjust appropriately over time to migration of services from the inpatient to the outpatient setting. In addition, according to the commenters, a national policy allowing full Part B rebilling would provide an unfair market advantage to providers who make inappropriate inpatient admission determinations over those who do not. The commenters reasoned that Medicare's current policies are well-founded, longstanding, widely known and largely followed, and that the current challenges do not warrant the extensive resources that full rebilling and other policy changes would entail.

Some commenters indicated that a national policy allowing full Part B rebilling following the denial of an inpatient claim would have limited utility because typically the timely filing period has lapsed by the time the inpatient claim is denied, providers could not appeal the inpatient claim, and providers would not receive the Part A payment that they seek. In addition, according to the commenters, the manual process of recoding the inpatient claim as an outpatient claim is costly. A few commenters suggested that CMS allow rebilling of all Part B services but apply a penalty by limiting payment to a discounted amount. Other commenters were concerned about the significant financial burden of Part B rebilling for beneficiaries who have Part A coverage but do not have coverage for Part B services.

Some commenters also suggested that CMS allow hospitals to change a beneficiary's inpatient status to outpatient after discharge in order to submit a Part B outpatient claim either prior to or after submitting an inpatient claim. Other commenters recommended that CMS extend the timely filing deadline to 1 year from the date of service or 6 months to 1 year from the date of the inpatient claim denial, whichever is later. Some commenters suggested that CMS extend the timely filing deadline only for claims that are denied after a significant amount of time has passed since the date of service.

Commenters suggested mechanisms to protect beneficiaries from increases in their liability associated with any of these policy changes. For example, several commenters believed that hospitals could waive any increases in beneficiary cost-sharing or that CMS could provide coverage for self-administered drugs in the outpatient department, cap the sum of outpatient services at the inpatient deductible, or establish annual maximum out-of-pocket costs. Many commenters also recommended the modernization and reform of the SNF qualification criteria (we describe these comments further below).

2. Clarifying Current Admission Instructions or Establishing Specified Clinical Criteria

In recent months, we have heard from some stakeholders who suggested a need for us to clarify our current instructions regarding the circumstances under which Medicare will pay for an admission in order to improve hospitals' ability to make appropriate admission decisions. Stakeholders have suggested the establishment of more specific clinical criteria for admission and payment such as adopting specific clinical measures because, according to the commenters, the current criteria are not clear-cut. We have issued longstanding instructions that the need for admission is a complex medical judgment that depends upon multiple factors, including an expectation that the beneficiary will require an overnight stay in the hospital or need more than 24 hours of care, the patient's medical history and current medical needs, the types of facilities available to inpatients and to outpatients, the hospital's policies, the relative appropriateness of outpatient and inpatient treatment, and other factors (Section 10, Chapter 1 of the Medicare Benefit Policy Manual (Pub. 100–02)). We stated in the CY 2013 OPPS/ASC proposed rule that we are interested in receiving public comments and suggestions regarding whether and how we might improve our current instructions and clarify the application of Medicare payment policies for both hospitals and physicians, keeping in mind the challenges of implementing national standards that are broad enough to contemplate the range of clinical scenarios but prescriptive enough to provide greater clarity.

Comments: The public comments reflected a widespread understanding and agreement with CMS' guidance that the inpatient admission decision is ultimately a complex medical judgment that involves the consideration of many factors. Many commenters indicated that if Medicare adopted more specific guidelines or criteria, the clinical judgment of the treating physician should have primacy. A recurrent comment was that this judgment would always be necessary in certain cases, and should take precedence over other criteria that may be used. Many commenters were concerned that decision-making tools (such as Interqual Clinical Decision Support or the Milliman Care Guidelines, alternatively described by commenters as commercial or proprietary screening tools), which are designed for use as guidelines rather than prescriptive tools, do not take into account patient ''risk'' and may undermine the physician's judgment.

In addition, many commenters believed that any selected criteria must apply equally to Medicare contractors, hospitals, and others and should match the audit review criteria. Many commenters expressed concern that Medicare's claims review contractors inappropriately disregard the physician's judgment, and do not employ a physician in making their determinations. (We describe the comments on external review criteria in further detail below). One commenter indicated that commercial screening tools do not always comport with Medicare rules. The commenter provided as an example that one popular tool fails to distinguish scheduled replacement pacemaker procedures from the placement of a new pacemaker on an emergency basis. Some of the public comments received from physicians identified what they characterized as significant problems with the accuracy, validity, and transparency of proprietary screening tools, including use of appropriateness standards that are not accepted by the relevant physician specialties and failure to follow Medicare payment policy.

Nevertheless, many commenters expressed support for various types of national criteria. These criteria included evidence-based guidelines such as the Agency for Healthcare Research and Quality's National Clearinghouse Guidelines or other rules developed in consultation with physician societies. Some commenters supported the use of specific proprietary screening tools such as Interqual Clinical Decision Support or the Milliman Care Guidelines. Other commenters favored more transparent criteria similar to the Correct Coding Initiative (CCI) that are adapted for Medicare and are developed using physician input. One commenter indicated that the CCI edits have proven more cost-effective than proprietary tools. A few commenters suggested that use of the Program for Evaluating Payment Patterns Electronic Report (PEPPER) reports, which provide hospital-specific Medicare data statistics for discharges that are vulnerable to improper payments, would allow for continuous improvement in utilization and coding. One commenter noted that it would be useful to choose the set of

criteria that are used by Medicaid and other payers, in order to facilitate uniform documentation that supports the specific criteria required by the various screening tools.

Some commenters pointed out process improvements that hospitals and physicians should make, regardless of whether CMS adopts specific clinical criteria or issues more specific admission instructions. Several commenters stated that physicians should improve their documentation in support of the patient status that they order, and that sometimes it is not clear whether the physician ordered inpatient admission or outpatient observation services. The commenters suggested that physicians document the need for admission in a standardized field on electronic health records or elsewhere. Other commenters emphasized the importance of the role of the hospital in selecting patient status for purposes of billing because they believed that the physician is focused on ordering the necessary care and, for good reason according to the commenters, is not occupied with the nuances of patient status designation for payment purposes.

3. Hospital Utilization Review

In the proposed rule, we asked commenters to consider the responsibility of hospitals to utilize all of the tools necessary to make appropriate initial admission decisions. We stated that we believe this is important because some hospitals have indicated that simply having case management and UR staff available to assist in decision-making outside of regular business hours may improve the accuracy of admission decisions.

Comments: Several commenters stated that some hospitals do not have UR staff on hand outside normal business hours or on weekends to assist with patient status determinations, and that this is especially problematic for patients with short inpatient stays. The commenters expressed varying opinions on hospital UR. Some commenters recognized that Medicare's regulations require the collaboration of the treating physician and the hospital's UR staff in making the appropriate patient status determination, and believed that neither party is dispensable. Several commenters indicated that 24-hour, 7 days a week availability of hospital UR and/or case management staff should be a hospital best practice, as it assists in making appropriate admission determinations for short-stay cases where the need for admission is unclear. Several commenters opined that Medicare should require the availability of hospital UR on a 24-hour/7 days a week basis. One commenter stated that CMS should develop a certification process of ''deeming'' acceptable individual hospital UR processes, using a standard of 24-hour/7 days a week availability, confirmation by an external physician, and adherence to the hospital CoPs. Another commenter recommended the use of a condition code on claims to track whether UR confirmation of appropriate patient status is associated with fewer claim denials. Some commenters preferred reinforcement of hospital UR over the institution of external guidelines for admission.

However, several commenters indicated that Medicare's current UR requirements in the CoPs should be eliminated because of the administrative cost to the hospital, or because they do not result in more accurate admission determinations that are commensurate with their associated cost. One association believed that hospital UR will have limited utility as long as admission criteria are unclear. Yet another physician professional association stated that hospitals should be required to submit their claims based on the admitting physician's judgment rather than the opinion of another physician in the hospital.

4. Prior Authorization

In our proposed rule, we also invited public comments on the potential use of prior authorization for payment of a hospital inpatient admission.

Comments: Many commenters believed that the concept of using prior authorization on a targeted basis was promising and worthy of consideration. To facilitate administrative feasibility, many commenters suggested that it be used selectively for elective procedures, specific services that are not designated as inpatient-only services under the OPPS, or conditions that are at high-risk for inappropriate inpatient admission. The commenters were concerned that mandatory prior authorization could become a barrier to the provision of urgent care, and some recommended that CMS exclude patients in the emergency department or those receiving critical care. Alternatively, the commenters suggested that prior authorization be used as an adjunct method for cases not meeting the admission criteria of commercial screening tools.

Several commenters believed that prior authorization is feasible because hospitals already have an infrastructure for obtaining prior authorization for commercial insurers. The commenters suggested that CMS could similarly redirect current resources towards a prior authorization program. Several commenters suggested an online tool for prior authorization.

A few commenters opposed prior authorization altogether based on administrative burden, and many commenters believed that it would need to result in guaranteed payment in order to be useful. One commenter observed that retrospective review is still required in many cases when prior authorizations are obtained from commercial insurers, due to incomplete or inaccurate prior authorization information and changes in what was planned or expected when the initial clinical information was submitted. The commenter stated that for this reason, commercial insurers reserve the right to perform, and often do perform, retrospective audits based on the completed medical record. In addition, the commenter stated that the CERT error rate evidences that the vast majority of providers understand and follow the current Medicare statutes and rules. Thus, according to the commenter, requiring prior authorization will add significant cost to the program without eliminating the inpatient error rate, at a time when the Medicare Trust Fund is at risk.

5. Time-Based Criteria for Inpatient Admission

In the proposed rule, we stated that some stakeholders have suggested that CMS has authority to define whether a patient is an inpatient or an outpatient. They believed that it may be permissible and appropriate for us to redefine ''inpatient'' using parameters in addition to medical necessity and a physician order that we currently use, such as length of stay (LOS) or other variables. For example, currently a beneficiary's anticipated LOS at the hospital may be a factor in determining whether the beneficiary should be admitted to the hospital, but is not the only factor. We have issued instructions that state that, typically, the decision to admit should be made within 24 to 48 hours, and that expectation of an overnight stay may be a factor in the admission decision (Section 20.6, Chapter 6 and Section 10, Chapter 1 of the Medicare Benefit Policy Manual (Pub. 100–02)). However, we stated in the proposed rule that we are interested in hearing from stakeholders regarding whether it may be appropriate and useful to establish a point in time after which the encounter becomes an inpatient stay if the beneficiary is still receiving medically necessary care to treat or evaluate his or her condition. We indicated that such a policy could

potentially limit the amount of time that a beneficiary is treated as an outpatient receiving observation services before the hospital encounter becomes inpatient, provided the additional time in the hospital is medically necessary. Currently, we do not specify a limit on the time a beneficiary may be an outpatient receiving observation services, although, in the past, we have limited payment of observation services to a specific timeframe, such as 24 or 48 hours. Some in the hospital community have indicated that it may be helpful for the agency to establish more specific criteria for patient status in terms of how many hours the beneficiary is in the hospital, or to provide a limit on how long a beneficiary receives observation services as an outpatient. We invited public comments regarding whether there would be more clarity regarding patient status under such alternative approaches to defining inpatient status. We also noted that it is important for CMS to maintain its ability to audit and otherwise carry out its statutory obligation to ensure that the Medicare program pays only for reasonable and necessary care. We asked that commenters consider opportunities for inappropriately taking advantage of the Medicare system that time-based and other changes in criteria for patient status may create.

Comments: Some commenters expressed interest and support for criteria that are strictly time-based, based largely on a primary goal of eliminating extended observation cases. These commenters supported defining a patient as an inpatient after 24, 48, or 72 hours, and noted that such a policy could improve the problem of beneficiaries not qualifying for needed SNF care due to their outpatient status. One commenter believed that a 48-hour benchmark made sense because it is consistent with the activities that are required under the CoPs within the first 48 hours of a hospital stay. Another commenter suggested establishing a second decision point during the observation period, when the physician must reevaluate whether the patient needs to be admitted as an inpatient. However, the commenter noted that this may increase administrative complexity without commensurate benefit.

Some commenters representing the hospital community believed that patients who have been actively monitored for more than 24 to 48 hours as outpatients under observation and cannot be safely discharged are likely sufficiently complex cases that would benefit from being admitted as an inpatient, regardless of whether they technically meet inpatient admission criteria. The commenters posited that observation services are more comparable to inpatient care than they are to other outpatient services, and that this fact would be more accurately reflected by a time-based admission policy. A few commenters suggested that CMS limit observation care to 24 hours, with exceptions for physician discretion. Several commenters suggested that CMS clarify the definition and parameters of outpatient observation services to help stakeholders determine when it is appropriate to furnish observation services and for how long. Another commenter suggested that CMS limit a patient's time in observation by requiring additional assessments and increased documentation of involvement by the physician.

In contrast, many commenters expressed reservations about a time-based approach. Some commenters posited that inpatient and outpatient services are different in nature. One physician association stated that the primary difference between the inpatient and outpatient setting is the availability of nurses (and related staff) and advanced technology in the inpatient setting, which accounts for the added cost of inpatient care. The commenter recommended structuring an inpatient DRG payment around short-stay admissions where the physician believes that these added components of care are necessary. Other commenters were concerned that under a time-based policy, the level of service would no longer be taken into account in hospital payment and that such a policy would inappropriately negate the need for medical necessity review. Some commenters stated that the medical review would simply shift to assessing the necessity of the patient's LOS as an outpatient or whether the patient needed continuing hospital care at the time they became an inpatient. Some commenters believed that a time-based policy would result in additional short inpatient stays than under current Medicare guidance. Therefore, these commenters believed that hospitals would continue to be subject to audit risk and that short-stay audits would simply increase.

Another commenter expressed concern that hospitals may be substituting outpatient observation services for inpatient admissions in order to maximize their outpatient drug revenues under the Federal 340B Drug Pricing Program. The commenter recommended that CMS modify the definitions of ''outpatient'' and ''inpatient'' to explicitly clarify that a patient's status determination should be based solely on appropriate clinical judgment, and should not be influenced by financial motives under programs such as the 340B Drug Pricing Program.

Some commenters opposed time-based rules because, according to the commenters, it would undermine the judgment of the treating physician. Other commenters noted that the absence of objective clinical criteria for choosing a timeframe would render time-based criteria for admission arbitrary. Several commenters opposed limiting observation services to 24 hours because hospitals often need more time (particularly up to 48 hours) to evaluate diagnostic testing and develop the right treatment plan. They noted that practice patterns vary widely nationally and among facilities in the same region. Other commenters were concerned that a policy of never counting certain days as inpatient days could actually reduce beneficiary access to SNF care. Other commenters believed that a time-based policy would need refinement around issues like requirement of a physician order for inpatient admission.

Several commenters opposed time-based criteria because such criteria may conflict with the provision of inpatient surgical care for patients who require only short admissions. The commenters pointed out that such a policy could conflict with Medicare's inpatient only list, and that as the standard of practice evolves to enable longer inpatient services to be furnished during short (1- or 2-day) inpatient stays, those services would no longer qualify as inpatient services. One commenter stated that there are some procedures that are so inherently complex that they may be performed only on an inpatient basis, regardless of how long (or short) the time was that the patient spent in the hospital. The commenter stated that establishing a bright-line time rule could create a situation whereby these services could be denied solely on the basis of the time spent in the hospital while ignoring the level of service required for subjecting a patient to an inherently risky procedure. The commenter expressed concern that CMS might require that all patients, regardless of clinical presentation, first undergo a period of 48 hours of observation before being admitted as inpatients to the hospital, despite the fact that their medical condition and treatment plan may be wholly consistent with an inpatient admission upon presentation to the hospital.

Several commenters recommended that rather than limiting the timeframe for observation services, observation care should be furnished in dedicated observation units in emergency

departments rather than on floor units. They cited studies showing that the dedicated units save costs compared to inpatient care and demonstrate shorter timeframes than the floor units for diagnosing or discharging.

6. Payment Alignment

In the proposed rule, we asked commenters to consider how aligning payment rates more closely with the resources expended by a hospital when providing outpatient care versus inpatient care of short duration might reduce payment disparities and influence financial incentives and disincentives to admit.

Comments: Commenters expressed significant interest in various means of improving the alignment of payment for what they termed equivalent outpatient and short inpatient hospital stays. Most of the commenters who supported payment alignment suggested developing a DRG for short inpatient stays, although several commenters recommended an expanded outpatient APC payment in addition to or in lieu of a short-stay DRG. Some commenters suggested basing the payment for short-stay inpatient admissions on a percentage of the related DRG by mean LOS. For example, if the mean LOS for a given DRG is 3 days, then the hospital would be paid one-third of that DRG for an inpatient admission with a 1-day stay. Several commenters suggested a short-stay outlier policy similar to the LTCH PPS, or a policy similar to the IPPS transfer policy. Other commenters more broadly suggested developing a resource-based payment structure specifically for short-stay, lower acuity admissions.

Some commenters noted, however, that aligning payment rates would reduce but not eliminate the financial risk of claim denial. According to the commenters, a payment alignment approach would not eliminate the potential for continued use of observation care over inpatient admission. One commenter asserted that the resources expended by a hospital for inpatient and outpatient care are already aligned when the care is billed appropriately.

7. Public Comments on Other Topics

We received a number of public comments on other related issues.

a. Rules for the External Review of Inpatient Claims

Comments: Many commenters expressed concerns about the criteria that are used by Medicare's contractors to determine the medical necessity of hospital inpatient admissions. The commenters were concerned that the review criteria being utilized by contractors do not match the admission criteria set forth in Medicare's guidance. In particular, according to the commenters, contractors are not employing physicians in making their medical necessity determinations, even though Medicare instructs that the admission decision is a complex medical judgment that involves forecasting a potential (not definite) need for an overnight stay or more than 24 hours of hospital care, or the risk of harm to the patient if not admitted (predictability of an adverse event). The commenters asserted that, as a result, claims reviewers inappropriately base their judgment on information that was not predictable or available to the physician at the time of admission.

Many commenters recommended that CMS increase its oversight of the Agency's medical review contractors, and ensure that its review rules are being followed. Commenters asked that CMS require all review contractors to use the same criteria to determine medical necessity that physicians and hospitals are required to use in making the inpatient admission decision; to use a physician reviewer in accordance with the QIO claim review standard, or to consult with the treating physician or a physician in the same specialty as the admitting physician; and to provide justification to the treating physician in support of a claim denial. According to the commenters, the review criteria that are used should apply uniformly to Medicare contractors, hospitals, and others.

Several commenters indicated that physician payment for professional services should be denied whenever inpatient hospital payment is denied, due to the role of the physician in the admission decision. In contrast, some physician commenters were concerned that they already are often inappropriately at risk for denial of their Part B claim when a hospital inpatient claim is denied, or when a hospital changes a patient's status to outpatient without their knowledge such that the place of service on the physician claim does not match that claimed by the hospital. They stated that, in some cases, the hospital does not bill Medicare, so there is no companion claim at all. Similarly, some physicians expressed concern that hospitals use ''black box'' proprietary tools to identify allegedly inappropriate admissions and change the patient's status to outpatient without the knowledge of the patient or the physician. These commenters also expressed concern for any adverse impact on beneficiary liability.

b. Improving Beneficiary Protections

Comments: Many commenters suggested means of improving beneficiary protections against unforeseen changes in his or her liability. These included providing Medicare coverage for self-administered drugs in the hospital outpatient department, waiving beneficiary coinsurance, capping the sum of outpatient services at the inpatient deductible, or establishing annual maximum out-of-pocket costs. Some commenters suggested that Medicare clarify and strengthen beneficiary notification and appeal rights regarding changes in patient status and the receipt of observation care. For example, according to the commenters, Medicare should require a straightforward explanation to beneficiaries of the cost-sharing implications of being an outpatient receiving observation services compared to being an inpatient. One QIO noted that as part of their case review activities, QIOs review beneficiary appeals of inpatient hospital discharges to assure that patients are medically ready to move to the next level of care. The QIO believed that if a beneficiary receives only outpatient observation services and is not an inpatient, he or she has no right to appeal his or her discharge from the hospital to the QIO. The QIO stated that it often receives complaints from beneficiaries who believe they are being discharged prematurely, only to find out that the QIO cannot review that care because the hospital classified the stay as observation rather than inpatient.

Some commenters suggested means of penalizing hospitals for inappropriate admission patterns. They provided examples such as developing quality measures with payment penalties to identify instances of inappropriate use of observation care for patients meeting inpatient admission criteria, or counting time spent receiving observation services as inpatient time for the purposes of hospital readmission penalties. Other commenters recommended improving physician education regarding the beneficiary liabilities that are associated with patient status to facilitate patient status determinations that take beneficiary cost-sharing into account.

c. Revising the Qualifying Criteria for Skilled Nursing Facility (SNF) Coverage

Comments: Many commenters recommended that Congress and/or CMS modernize and revise the SNF qualification rules. Many beneficiaries, beneficiary representatives, SNFs, and others requested that CMS count the

time a beneficiary spends as an outpatient receiving observation services towards the 3-day hospital inpatient stay that is required for coverage of SNF care. Many commenters indicated that the statutory time-based rule that requires a beneficiary to have a 3-day inpatient hospital stay in order to qualify for SNF care is obsolete, given the advances in medical care, the trend towards reduced LOS, and the migration of services from inpatient to outpatient over the course of the Medicare program's history. These commenters recommended that this rule be replaced with clinically meaningful criteria that are not time-based or based on patient status.

A few commenters asserted that CMS could use its statutory authority under section 1812(f) of the Act (as enacted by section 123 of the Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. 97–248) to waive the 3-day qualification rule. Some commenters asserted that the criteria for using this authority would be met, namely that there would be no increase in associated costs to the Medicare program and that the acute nature of the SNF benefit would be maintained. The Act provides that the Secretary shall provide for coverage of extended care services which are not post-hospital extended care services at such time and for so long as the Secretary determines that the inclusion of such services will not result in any increase in the total payments made under Title XVIII, and will not alter the acute care nature of the SNF benefit. Other commenters believed that new statutory authority would be required to change the SNF criteria, and they expressed their support for bills they stated have been introduced in the Congress to count time in observation as inpatient time for purposes of SNF qualification. Some commenters recommended waiving the 3-day rule for certain diagnoses that benefit from short inpatient stays and speedy access to postacute rehabilitative services. They indicated that some beneficiaries require only a brief hospital assessment, rather than a lengthy stay in acute care, prior to long-term skilled care, and that it is not uncommon for patients with hospital stays of less than 3 days to require follow up care in a SNF.

C. Summary

We appreciate all of the public comments that we received on this multi-faceted topic. We will take all of the public comments that we received into consideration as we consider future actions that we could potentially undertake to provide more clarity and consensus regarding patient status for purposes of Medicare payment.

XII. CY 2013 OPPS Payment Status and Comment Indicators

A. CY 2013 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 2013 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/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. 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 OPPS/ASC 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/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

We did not receive any public comments related to the definitions of the OPPS status indicators, and therefore, as we proposed in the CY 2013 OPPS/ASC proposed rule (77 FR 45157), for CY 2013, we are not making any changes to the definitions of status indicators that were listed in Addendum D1 of the CY 2012 OPPS/ASC final rule with comment period. We believe that these definitions of the OPPS status indicators continue to be appropriate for CY 2013.

The complete list of the final CY 2013 status indicators and their definitions is displayed in Addendum D1 on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

B. CY 2013 Comment Indicator Definitions

In the CY 2013 OPPS/ASC proposed rule (77 FR 45158), for the CY 2013 OPPS, we proposed to use the same two comment indicators that are in effect for the CY 2012 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 to use the ''CH'' comment indicator in the CY 2013 OPPS/ASC proposed rule to indicate HCPCS codes for which the status indicator or APC assignment, or both, are proposed for change in CY 2013 compared to their assignment as of June 30, 2012. We stated that we believed that using the ''CH'' indicator in the CY 2013 OPPS/ASC proposed rule would facilitate the public's review of the changes that we were proposing for CY 2013. We stated that the use of the comment indicator ''CH'' in association with a composite APC indicates that the configuration of the composite APC is proposed to be changed in the CY 2013 OPPS/ASC final rule with comment period.

We proposed to use the ''CH'' comment indicator in the CY 2013 OPPS/ASC final rule with comment period to indicate HCPCS codes for which the status indicator or APC assignment, or both, would change in CY 2013 compared to their assignment as of December 31, 2012.

In addition, any existing HCPCS codes with substantial revisions to the code descriptors for CY 2013 compared to the CY 2012 descriptors are labeled with comment indicator ''NI'' in Addendum B to the CY 2013 OPPS/ASC final rule with comment period. However, as we stated in the proposed rule, in order to receive the comment indicator ''NI,'' the CY 2013 revision to the code descriptor (compared to the CY 2012 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 for comment as part of the CY 2013 OPPS/ASC final rule with comment period. Like all codes labeled with comment indicator ''NI,'' as we stated in the CY 2013 OPPS/ASC proposed rule, we will respond to public comments and finalize their OPPS treatment in the CY 2014 OPPS/ASC final rule with comment period.

In accordance with our usual practice, CPT and Level II HCPCS codes that are

new for CY 2013 are also labeled with comment indicator ''NI'' in Addendum B to the CY 2013 OPPS/ASC final rule with comment period.

Only HCPCS codes with comment indicator ''NI'' in this CY 2013 OPPS/ASC final rule with comment period are subject to comment. HCPCS codes that do not appear with comment indicator ''NI'' in this CY 2013 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 2013 treatment of HCPCS codes that appear in this CY 2013 OPPS/ASC final rule with comment period to which comment indicator ''NI'' is not appended was open for public comment during the comment period for the proposed rule, and we indicated that we would respond to those comments in this CY 2013 OPPS/ASC final rule with comment period.

We did not receive any public comments on the proposed comment indicators. We believe that the CY 2012 definitions of the OPPS status indicators continue to be appropriate for CY 2013, and therefore, as proposed, we are continuing to use those definitions without modification for CY 2013. The final definitions are listed in Addendum D2 on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

XIII. OPPS Policy and Payment Recommendations

A. MedPAC Recommendations

The Medicare Payment Advisory Commission (MedPAC) was established under section 1805 of the Act to advise the Congress on issues affecting the Medicare program. As required under the statute, MedPAC submits reports to Congress no later than March and June of each year that contain its Medicare payment policy recommendations. In our CY 2013 OPPS/ASC proposed rule, we noted several recommendations regarding the OPPS from the March 2012 report (''Report to the Congress: Medicare Payment Policy,'' available on MedPAC's Web site at: *http://www.medpac.gov/documents/Mar12_EntireReport.pdf*). Since the publication of the proposed rule, MedPAC has not made any other recommendations regarding the OPPS, although we discuss MedPAC's public comments to our proposed rule in the applicable sections of this final rule with comment period.

In its March report, MedPAC recommended that Congress increase payment rates for the OPPS in CY 2013 by 1.0 percent. We discuss our final policy to follow the statutory requirements for the CY 2013 OPD fee schedule increase factor in section II.B of this final rule with comment period.

In addition, MedPAC recommended that Congress enact legislation to reduce payment rates for evaluation and management office visits provided in hospital outpatient departments to the rates paid for these services in physician offices. MedPAC recommended that the change be phased in over 3 years. During the phase-in, MedPAC stated that the associated payment reductions to hospitals with a disproportionate share patient percentage at or above the median should be limited to 2 percent of overall Medicare payments. MedPAC also recommended that the Secretary of Health and Human Services conduct a study by January 2015 to examine whether this policy change would reduce access to ambulatory physician and other services for low-income patients. Congress has not enacted such legislation.

B. GAO Recommendations

Congress established the U.S. Government Accountability Office (GAO) under the Budget and Accounting Act of 1921 (Pub. L. 67–13) as an independent agency that advises Congress and the heads of Executive agencies regarding Federal program expenditures. The GAO conducts audits and other analyses to ensure that Federal funds are being spent efficiently and effectively. Since the issuance of the CY 2012 OPPS/ASC final rule with comment period, the GAO has not released any reports regarding the OPPS.

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 Department of Health and Human Services programs and the health and welfare of program beneficiaries. The OIG conducts independent audits, inspections, and investigations to improve the efficiency of these programs and to identify and prevent fraud, waste and abuse. Since the issuance of the CY 2012 OPPS/ASC final rule with comment period, the OIG has not made any recommendations regarding the OPPS.

XIV. Updates to the Ambulatory Surgical Center (ASC) Payment System

A. Background

1. Legislative History, Statutory Authority, and Prior Rulemaking for the ASC Payment System

For a detailed discussion of the legislative history and statutory authority related to ASCs, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74377 through 74378) and the June 12, 1998 proposed rule (63 FR 32291 through 32292). For a discussion of prior rulemaking on the ASC payment system, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74378 through 74379).

2. Policies Governing Changes to the Lists of Codes and Payment Rates for 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 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 directly crosswalk or are clinically similar to ASC covered surgical procedures (72 FR 42478).

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: (1) Brachytherapy sources; (2) certain implantable items that have pass-through status under the OPPS; (3) certain items and services that we designate as contractor-priced, including, but not limited to, procurement of corneal tissue; (4) certain drugs and biologicals for which separate payment is allowed under the

OPPS; and (5) 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 XIV.B. of 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 update change requests (CRs) for ASC services throughout the year (January, April, July, and October). CMS releases new Level II 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 these ASC quarterly update CRs. Thus, 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 only through the January quarterly update. New Category I CPT vaccine codes are released twice a year and, therefore, are implemented through the January and July quarterly updates. We refer readers to Table 41 in the CY 2012 OPPS/ASC proposed rule for the process used to update the HCPCS and CPT codes (76 FR 42291).

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. We did not receive any public comments on this process. Therefore, we are continuing our established process without modification for determining the list 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

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 surgical 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.

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 during the annual OPPS/ASC rulemaking process regarding whether or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether or not 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.

We have separated our discussion below into two sections based on whether we proposed to solicit public comments in the CY 2013 OPPS/ASC proposed rule (and respond to those comments in this CY 2013 OPPS/ASC final rule with comment period) or whether we are soliciting public comments in this CY 2013 OPPS/ASC final rule with comment period (and responding to those comments in the CY 2014 OPPS/ASC final rule with comment period).

We note that we sought public comment in the CY 2012 OPPS/ASC final rule with comment period on the new CPT and Level II HCPCS codes that were effective January 1, 2012. We also sought public comments in the CY 2012 OPPS/ASC final rule with comment period on the new Level II HCPCS codes effective October 1, 2011. These new codes, with an effective date of October 1, 2011, or January 1, 2012, were flagged with comment indicator ''NI'' in Addenda AA and BB to the CY 2012 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 2012 OPPS/ASC final rule with comment period. In the proposed rule, we stated that we would respond to public comments and finalize the ASC treatment of these codes in this CY 2013 OPPS/ASC final rule with comment period.

We did not receive any public comments regarding our process for recognizing new Category I and Category III CPT codes and Level II HCPCS codes under the ASC payment system and are implementing our proposed policy as final, without modification, for CY 2013.

2. Treatment of New Level II HCPCS Codes and Category III CPT Codes Implemented in April and July 2012 for Which We Solicited Public Comments in the CY 2013 OPPS/ASC Proposed Rule

In the April and July CRs, we made effective for April 1, 2012 or July 1, 2012, respectively, a total of 12 new Level II HCPCS codes and 5 new Category III CPT codes that were not addressed in the CY 2012 OPPS/ASC final rule with comment period. The 12 new Level II HCPCS codes describe covered ancillary services.

In the April 2012 ASC quarterly update (Transmittal 2425, CR 7754, dated March 16, 2012), we added one new radiology Level II HCPCS code and four new drug and biological Level II HCPCS codes to the list of covered ancillary services. Specifically, as displayed in Table 36 of the CY 2013 OPPS/ASC proposed rule (77 FR 45160), we added the following codes to the list of covered ancillary services:

- HCPCS code C9288 (Injection, centruroides (scorpion) immune f(ab)2 (equine), 1 vial);
- HCPCS code C9289 (Injection, asparaginase Erwinia chrysanthemi, 1,000international units (I.U.));
- HCPCS code C9290 (Injection, bupivacaine liposome, 1 mg);

- HCPCS code C9291 (Injection, aflibercept, 2 mg vial); and
- HCPCS code C9733 (Non-ophthalmic fluorescent vascular angiography).

In the July 2012 quarterly update (Transmittal 2479, Change Request 7854, dated May 25, 2012), we added seven new drug and biological Level II HCPCS codes to the list of covered ancillary services. Specifically, as displayed in Table 37 of the CY 2013 OPPS/ASC proposed rule (77 FR 45161), we added the following codes to the list of covered ancillary services:

- HCPCS code C9368 (Grafix core, per square centimeter);
- HCPCS code C9369 (Grafix prime, per square centimeter);
- HCPCS code Q2034 (Influenza virus vaccine, split virus, for intramuscular use (Agriflu));
- HCPCS code Q2045 (Injection, human fibrinogen concentrate, 1 mg);
- HCPCS code Q2046 (Injection, aflibercept, 1 mg);
- HCPCS code Q2048 (Injection, doxorubicin hydrochloride, liposomal, doxil, 10 mg); and
- HCPCS code Q2049 (Injection, doxorubicin hydrochloride, liposomal, imported lipodox, 10 mg).

We noted that HCPCS code Q2045 replaced code J1680, HCPCS code Q2046 replaced code C9291, and HCPCS code Q2048 replaced code J9001 beginning July 1, 2012.

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 the 10 new Level II HCPCS codes that are separately paid when provided in ASCs. We assigned payment indicator ''L1'' (Influenza vaccine; pneumococcal vaccine; packaged item/service; no separate payment made) or payment indicator ''N1'' (Packaged service/item; no separate payment made) to the two new Level II HCPCS codes that are packaged when provided in ASCs. In the CY 2013 OPPS/ASC proposed rule (77 FR 45160), we solicited public comment on the proposed CY 2013 ASC payment indicators and payment rates for the covered ancillary services listed in Tables 36 and 37 of the proposed rule (77 FR 45160 through 45161). Those HCPCS codes became payable in ASCs, beginning in April or July 2012, and are paid at the ASC rates posted for the appropriate calendar quarter on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates.html*.

The HCPCS codes listed in Table 36 of the proposed rule were included in Addendum BB to the proposed rule (which was available via the Internet on the CMS Web site). We noted that all ASC addenda are only available via the Internet on the CMS Web site. Because the payment rates associated with the new Level II HCPCS codes that became effective for July 2012 (listed in Table 37 of the 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 2013 OPPS/ASC final rule with comment period. Thus, the codes implemented by the July 2012 ASC quarterly update CR and their proposed CY 2013 payment rates (based on July 2012 ASP data) that were displayed in Table 37 were not included in Addendum BB to the proposed rule (which was available via the Internet on the CMS Web site). The final list of covered ancillary services and the associated payment weights and payment indicators is included in Addendum BB to this CY 2013 OPPS/ASC final rule with comment period, consistent with our annual update policy. We solicited public comment on these proposed payment indicators and the proposed payment rates for the new Level II HCPCS codes that were newly recognized as ASC covered ancillary services in April and July 2012 through the quarterly update CRs, as listed in Tables 36 and 37 of the proposed rule. We proposed to finalize their payment indicators and their payment rates in this CY 2013 OPPS/ASC final rule with comment period.

We did not receive any public comments regarding our proposals. We are adopting as final for CY 2013 the ASC payment indicators for the ancillary services described by the new Level II HCPCS codes implemented in April and July 2012 through the quarterly update CRs as shown below, in Tables 47 and 48, respectively. These new HCPCS codes are also displayed in Addendum BB to this final rule with comment period. We note that after publication of the CY 2013 OPPS/ASC proposed rule, the CMS HCPCS Workgroup created permanent HCPCS J-codes for CY 2013 to replace certain temporary HCPCS C-codes made effective for CY 2012. These permanent CY 2013 HCPCS J-codes are listed alongside the temporary CY 2012 HCPCS C-codes in Tables 47 and 48 below.

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TABLE 47.—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES IMPLEMENTED IN APRIL 2012

CY 2012 HCPCS Code	CY 2013 HCPCS Code	CY 2013 Long Descriptor	Final CY 2013 Payment Indicator
C9288	J0716	Injection, centruroides immune f(ab)2, up to 120 milligrams	K2
C9289	J9019	Injection, asparaginase (Erwinaze), 1,000 IU	K2
C9290	C9290	Injection, bupivacaine liposome, 1 mg	K2
C9291*	J0178	Injection, aflibercept, 1 mg	K2
C9733	C9733	Non-ophthalmic fluorescent vascular angiography	N1

*Note: Level II HCPCS code C9291 (Injection, aflibercept, 2 mg vial) was deleted June 30, 2012, and replaced with HCPCS code Q2046 (Injection, aflibercept, 1 mg), effective July 1, 2012. HCPCS code Q2046 was deleted December 31, 2012, and replaced with HCPCS code J0178 effective January 1, 2013.

TABLE 48.—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES IMPLEMENTED IN JULY 2012

CY 2012 HCPCS Code	CY 2013 HCPCS Code	CY 2013 Long Descriptor	Final CY 2013 Payment Indicator
C9368	Q4132	Grafix core, per square centimeter	K2
C9369	Q4133	Grafix prime, per square centimeter	K2
Q2034	Q2034	Influenza virus vaccine, split virus, for intramuscular use (Agriflu)	L1
Q2045*	J7178	Injection, human fibrinogen concentrate, 1 mg	K2
Q2046*	J0178	Injection, aflibercept, 1 mg	K2
Q2048*	J9002	Injection, doxorubicin hydrochloride, liposomal, doxil, 10 mg	K2
Q2049	Q2049	Injection, doxorubicin hydrochloride, liposomal, imported lipodox, 10 mg	K2

*Note: HCPCS code Q2045 replaced HCPCS code J1680, HCPCS code Q2046 replaced HCPCS code C9291, and HCPCS code Q2048 replaced HCPCS code J9001 beginning July 1, 2012.

Through the July 2012 quarterly update CR, we also implemented ASC payment for five new Category III CPT codes as ASC covered surgical procedures, effective July 1, 2012. These codes were listed in Table 38 of the CY 2013 OPPS/ASC proposed rule (77 FR 45161), along with their proposed payment indicators and proposed payment rates for CY 2013. Because the payment rates associated with the new Category III CPT 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. The codes listed in Table 38 of the proposed

rule and their final payment indicators and rates are included in Addendum AA to this CY 2013 OPPS/ASC final rule with comment period.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45161), 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 three of the five new Category III CPT codes implemented in July 2012 and to assign payment indicator ''J8'' (Device-intensive procedure added to ASC list in CY 2008 or later; paid at adjusted rate) to the remaining two new Category III CPT codes implemented in July 2012. We believe that these procedures would not be expected to pose a significant safety risk to Medicare beneficiaries or would not be expected to 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 2012 through the quarterly update CR, as listed in Table 38 of the proposed rule (77 FR 45161). We proposed to finalize their payment indicators and their payment rates in this CY 2013 OPPS/ASC final rule with comment period.

We did not receive any public comments regarding this proposal. We are adopting as final for CY 2013 the ASC payment indicators for the covered surgical procedures described by the new Category III CPT codes implemented in the July 2012 CR as shown below in Table 49. The new CPT codes implemented in July 2012 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 49.—NEW CATEGORY III CPT CODES IMPLEMENTED IN JULY 2012 AS ASC COVERED SURGICAL PROCEDURES

CY 2013 CPT Code	CY 2013 Long Descriptor	Final CY 2013 Payment Indicator
0302T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; complete system (includes device and electrode)	J8
0303T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; electrode only	G2
0304T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; device only	J8
0307T	Removal of intracardiac ischemia monitoring device	G2
0308T*	Insertion of ocular telescope prosthesis including removal of crystalline lens	G2

*CPT code 0308T replaced HCPCS code C9732 beginning July 1, 2012.

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 2013 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 2013 OPPS/ASC proposed rule (77 FR 45161 through 45162), we proposed to continue this process for CY 2013. Specifically, for CY 2013, we proposed to include in Addenda AA

and BB to the CY 2013 OPPS/ASC final rule with comment period the new Category I and III CPT codes effective January 1, 2013, that would be incorporated in the January 2013 ASC quarterly update CR and the new Level II HCPCS codes, effective October 1, 2012 or January 1, 2013, that would be released by CMS in its October 2012 and January 2013 ASC quarterly update CRs. We stated that these codes would be flagged with comment indicator ''NI'' in Addenda AA and BB to this CY 2013 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 2013 OPPS/ASC final rule with comment period and would be finalized in the CY 2014 OPPS/ASC final rule with comment period.

We did not receive any public comments regarding this proposed process. For CY 2013, 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. In the CY 2013 OPPS/ASC proposed rule (77 FR 45162), we proposed to update the list of ASC covered surgical procedures by adding 16 procedures to the list. We determined that these 16 procedures would not be expected to pose a significant safety risk to Medicare beneficiaries and would not be expected to require an overnight stay if performed in ASCs.

The 16 procedures that we proposed to add to the ASC list of covered surgical procedures, including their HCPCS code long descriptors and proposed CY 2013 payment indicators, were displayed in Table 39 of the proposed rule (77 FR 45162). We invited public comment on this proposal.

Comment: Many commenters supported the addition of the procedures listed in Table 39 of the CY 2013 OPPS/ASC proposed rule to the list of ASC covered surgical procedures.

One commenter believed that CPT codes 0299T (Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound) and 0300T (Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care) should not be added to the list of ASC covered surgical procedures. The commenter agreed with CMS that these codes would not pose a significant safety risk to Medicare beneficiaries and would not be expected to require an overnight stay if performed in an ASC. However, the commenter believed that additional information on the clinical efficacy and outcomes of these services should be collected before adding these procedures to the list of ASC covered surgical procedures.

Response: We appreciate commenters' support of the proposed addition of the procedures listed in Table 39 of the CY 2013 OPPS/ASC proposed rule to the list of ASC covered surgical procedures for CY 2013. With regard to the commenter's belief that CPT codes 0299T and 0300T should not be added to the list of ASC covered surgical procedures until additional information regarding the clinical efficacy and outcomes of these services is collected, our policy is to review all HCPCS codes that are currently paid under the OPPS to identify any procedures that are currently excluded from the ASC list of covered procedures that we believe would not pose a safety risk to Medicare beneficiaries and would not require an overnight stay if performed in an ASC (42 CFR 416.166). We do not make our assessment regarding what codes should be included on the list of covered surgical procedures based on data regarding the clinical efficacy and outcomes of the services. Because it is our expectation that the procedures identified by CPT codes 0299T and 0300T would not pose a significant safety risk to Medicare beneficiaries or require an overnight stay if performed in an ASC, we do not agree with the commenter that these procedures should continue to be excluded from the list of ASC covered surgical procedures.

Comment: One commenter reiterated a previous request that, with knowledge of the anatomic location, CMS should apply the safety criteria to the entire spectrum of services reportable by an unlisted code. The commenter believed that under such an analysis, CMS would determine that the following unlisted codes associated with eye procedures would not compromise patient safety and, therefore, should be added to the list of ASC covered surgical procedures: CPT code 66999 (Unlisted procedure, anterior segment of eye), CPT code 67299 (Unlisted procedure, posterior segment);, CPT code 67399 (Unlisted procedure, ocular muscle); CPT code 67999 (Unlisted procedure, eyelids); CPT code 68399 (Unlisted procedure, conjunctiva); and CPT code 68899 (Unlisted procedure, lacrimal system).

Response: As we have stated in the past (72 FR 42484 through 42486; 75 FR 72032; and 76 FR 74380, and 74399), procedures that are reported by the CPT unlisted codes are not eligible for addition to the ASC list because our charge requires us to evaluate each surgical procedure for potential safety risk and expected need for overnight monitoring and to exclude such procedures from ASC payment. It is not possible to evaluate procedures that would be reported by unlisted CPT codes according to these criteria. This final policy is discussed in detail in the August 2, 2007 final rule (72 FR 42484 through 42486).

Comment: In addition to the procedures listed in Table 39 of the CY 2013 OPPS/ASC proposed rule, commenters requested that CMS add the procedures described by the 57 CPT codes displayed in Table 50 below to the list of ASC covered surgical procedures. Commenters argued that these procedures are as safe as procedures that are currently on the list of ASC covered procedures and, based on a survey, ASCs report positive outcomes when these procedures are performed on non-Medicare patients.

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TABLE 50.--PROCEDURES REQUESTED FOR ADDITION TO THE CY 2013 LIST OF ASC COVERED SURGICAL PROCEDURES

CY 2013 CPT Code	CY 2013 Short Descriptor
0274T	Perq lamot/lam crv/thrc
0275T	Perq lamot/lam lumbarbar
21141*	Reconstruct midface lefort
21142*	Reconstruct midface lefort
22551	Neck spine fuse&remov bel c2
22552*	Addl neck spine fusion
22554	Neck spine fusion
22612	Lumbar spine fusion
22845*	Insert spine fixation device
22846*	Insert spine fixation device
22851	Apply spine prosth device
23470	Reconstruct shoulder joint
22856	Cerv artific diskectomy
27096	Inject sacroiliac joint
27125*	Partial hip replacement
27130*	Total hip arthroplasty
27415	Osteochondral knee allograft
27447*	Total knee arthroplasty
27524	Treat kneecap fracture
27556*	Treat knee dislocation
27558*	Treat knee dislocation
27702*	Reconstruct ankle joint
27703*	Reconstruct ankle joint
27715*	Revision of lower leg
54332	Revise penis/urethra
54336	Revise penis/urethra
54411*	Remov/replc penis pros comp
54417*	Remv/replc penis pros compl
54535	Extensive testis surgery
54650	Orchiopexy (Fowler-Stephens)
57310	Repair urethrovaginal lesion
58541	Lsh uterus 250 g or less
58542	Lsh w/t/o ut 250 g or less
58570	Tlh uterus 250 g or less
58571	Tlh w/t/o 250 g or less
63001	Removal of spinal lamina
63003	Removal of spinal lamina
63005	Removal of spinal lamina
63012	Removal of spinal lamina

CY 2013 CPT Code	CY 2013 Short Descriptor
63015	Removal of spinal lamina
63017	Removal of spinal lamina
63020	Neck spine disk surgery
63030	Low back disk surgery
63035	Spinal disk surgery add-on
63042	Laminotomy single lumbar
63043*	Laminotomy addl cervical
63047	Removal of spinal lamina
63048	Remove spinal lamina add-on
63050*	Cervical laminoplasty
63056	Decompress spinal cord
63075	Neck spine disk surgery
63076	Neck spine disk surgery
63081*	Removal of vertebral body
63265*	Excise intraspinal lesion
63267*	Excise intraspinal lesion
63275*	Biopsy/excise spinal tumor
63277*	Biopsy/excise spinal tumor

*Indicates that these procedures are paid only as inpatient procedures.

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Response: We reviewed all of the eligible surgical procedures that commenters requested for addition to the ASC list of covered surgical procedures. Of the 57 requested procedures, we did not review the 22 procedures that are reported by CPT codes that are on the OPPS inpatient list. These procedures are not paid under the OPPS and, therefore, are not eligible for addition to the list of ASC covered procedures. The procedures that are paid only as inpatient procedures are identified with an asterisk in Table 50. In addition, the procedure that is identified by CPT code 27096 (Injection procedure for sacroiliac joint, anesthetic/steroid, with image guidance (fluoroscopy or ct) including arthrography when performed) is not paid under the OPPS and, therefore, is not eligible for addition to the list of ASC covered procedures.

With regard to the remaining procedures in Table 50 that commenters requested be added to the list of ASC covered surgical procedures, we do not agree that most of the procedures 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 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 50, 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. Several of the urology procedures appear to require major invasion of a body cavity. However, we agree with commenters that the procedures described by CPT codes 0274T, 0275T, 58541, 58542, 58570, 58571, 63001, 63003, and 63005 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 codes to the ASC list of covered surgical procedures for CY 2013.

After consideration of the public comments we received, we are finalizing the addition of the 16 procedures that we proposed to add to the list of ASC covered surgical procedures for CY 2013. We are also adding 9 of the procedures requested by the commenters to the CY 2013 list of

ASC covered surgical procedures. The procedures, their descriptors, and payment indicators are displayed in Table 51 below.

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TABLE 51.—NEW ASC COVERED SURGICAL PROCEDURES FOR CY 2013

CY 2013 HCPCS Code	CY 2013 Long Descriptor	Final CY 2013 ASC Payment Indicator**
0274T	Percutaneous laminotomy/laminectomy (interlaminar 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	G2
0275T	Percutaneous laminotomy/laminectomy (interlaminar 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	G2
0299T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound	R2*
0300T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care	R2*
37205	Transcatheter placement of an intravascular stent(s) (except coronary, carotid, vertebral, iliac, and lower extremity arteries), percutaneous; initial vessel	G2
37206	Transcatheter placement of an intravascular stent(s) (except coronary, carotid, vertebral, iliac, and lower extremity arteries), percutaneous; each additional vessel (list separately in addition to code for primary procedure)	G2
37224	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty	G2
37225	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with atherectomy, includes angioplasty within the same vessel, when performed	G2
37226	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed	G2
37227	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s) and atherectomy, includes angioplasty within the	J8

CY 2013 HCPCS Code	CY 2013 Long Descriptor	Final CY 2013 ASC Payment Indicator**
	same vessel, when performed	
37228	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal angioplasty	G2
37229	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with atherectomy, includes angioplasty within the same vessel, when performed	G2
37230	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed	G2
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	J8
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)	G2
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)	G2
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)	G2
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)	G2
58541	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less	G2
58542	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)	G2
58570	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less	G2
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)	G2
63001	Laminectomy with exploration and/or decompression of spinal	G2

CY 2013 HCPCS Code	CY 2013 Long Descriptor	Final CY 2013 ASC Payment Indicator**
	cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), 1 or 2 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), 1 or 2 vertebral segments; thoracic	G2
63005	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), 1 or 2 vertebral segments; lumbar, except for spondylolisthesis	G2

*If designation is temporary.
**Final 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 was being developed for publication, current law authorizes a negative update to the MPFS payment rates for CY 2013. For a discussion of those rates, we refer readers to the CY 2013 MPFS final rule with comment period.

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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 2013 to Covered Surgical Procedures Designated as Office-Based

In developing the CY 2013 OPPS/ASC proposed rule, 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 2011 volume and utilization data and the clinical characteristics for all surgical procedures that are assigned payment indicator ''G2'' (Non-office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) in CY 2012, as well as for those procedures assigned one of the temporary office-based payment indicators, specifically ''P2*,'' ''P3*,'' or ''R2*'' in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74400 through 74408).

In the CY 2013 OPPS/ASC proposed rule (77 FR 45163), we stated that our review of the CY 2011 volume and utilization data resulted in our identification of six covered 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 six CPT codes we proposed to permanently designate as office-based were listed in Table 40 of the CY 2013 OPPS/ASC proposed rule (77 FR 45163), and are listed in Table 52 below. We invited public comments on this proposal.

Comment: One commenter disagreed with the policy to make payment at the lower of the ASC rate or the MPFS nonfacility PE RVU payment amount for procedures that CMS identifies as office-based. This commenter expressed concern that this policy does not provide adequate payment for some services performed in an ASC.

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 prevent 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 the CY 2010, CY 2011, and CY 2012 OPPS/ASC final rules with comment period (74 FR 60605 through 60607; 75 FR 72034 through 72036; and 76 FR 74401, respectively).

After consideration of the public comments we received, we are finalizing our CY 2013 proposal to designate the procedures displayed in Table 52 below as permanently office-based for CY 2013.

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TABLE 52.—ASC COVERED SURGICAL PROCEDURES NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2013

CY 2013 CPT Code	CY 2013 Long Descriptor	CY 2012 ASC Payment Indicator	Proposed CY 2013 ASC Payment Indicator*	Final CY 2013 ASC Payment Indicator*
31295	Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (eg, balloon dilation), transnasal or via canine fossa	G2	P2	P2
31296	Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (eg, balloon dilation)	G2	P2	P2
31297	Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (eg, balloon dilation)	G2	P2	P2
53860	Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence	G2	P2	P2
64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming	G2	P3	P3
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	P2	P2

*Final 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 was being developed for publication, current law authorizes a negative update to the MPFS payment rates for CY 2013. For a discussion of those rates, we refer readers to the CY 2013 MPFS final rule with comment period.

We also reviewed CY 2011 volume and utilization data and other information for the eight procedures finalized for temporary office-based status in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74404 through 74408). Among these eight procedures, there were very few claims data for six 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 C9800 (Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies); 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 2013 OPPS/ASC proposed rule (77 FR 45163) to maintain their temporary office-based designations for CY 2013.

The volume and utilization data for the remaining two procedures that have temporary office-based designations for CY 2012 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 2013. Consequently, we proposed to assign payment indicator ''G2'' to the following two covered surgical procedure codes in CY 2013:

- CPT code 37761 (Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg); and
- CPT code 0232T (Injection(s), platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed).

The proposed CY 2013 payment indicator designations for the eight procedures that were temporarily designated as office-based in CY 2012 were displayed in Table 41 of the CY 2013 OPPS/ASC proposed rule (77 FR 45164). The procedures for which the proposed office-based designations for CY 2013 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 invited public comments on this proposal.

We did not receive any public comments that addressed our proposal to continue to designate six of the eight procedures, which were designated as temporarily office-based for CY 2012, as temporarily office-based for CY 2013. Therefore, we are finalizing our proposal to designate the six procedures listed in Table 41 of the CY 2013 OPPS/ASC proposed rule (77 FR 45164) and restated in Table 53 below, which were designated as temporarily office-based for CY 2012, as temporarily office-based for CY 2013. In addition, we did not receive any public comments that addressed our proposal to not designate as office-based in CY 2013 the two remaining procedures that were designated as temporarily office-based for CY 2012. Therefore, we are finalizing our proposal to not provide an office-based designation to the 2 procedures listed in Table 41 of the CY 2013 OPPS/ASC proposed rule (77 FR 45164), and restated below in Table 53, which were designated as temporarily office-based for CY 2012.

TABLE 53.—CY 2013 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2012 OPPS/ASC FINAL RULE WITH COMMENT PERIOD

CY 2013 CPT Code	CY 2013 Long Descriptor	CY 2012 ASC Payment Indicator	CY 2013 ASC Payment Indicator**
37761	Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg	R2*	G2
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*	G2
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.

** Final 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 was being developed for publication, current law authorizes a negative update to the MPFS payment rates for CY 2013. For a discussion of those rates, we refer readers to the CY 2013 MPFS final rule with comment period.

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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.

(2) Changes to List of Covered Surgical Procedures Designated as Device-Intensive for CY 2013

In the CY 2013 OPPS/ASC proposed rule (77 FR 45164), we proposed for CY 2013 to update the ASC list of covered surgical procedures that are eligible for payment according to our device-intensive procedure payment methodology, 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 2011 OPPS claims and cost report data available for the proposed rule. The OPPS device-dependent APCs are discussed further in section II.A.2.d.(1) of this final rule with comment period.

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 2013 were listed in Table 42 of the CY 2013 OPPS/ASC proposed rule (77 FR 45165 through 45166). The CPT code, the CPT code short descriptor, the proposed CY 2013 ASC payment indicator (PI), the proposed CY 2013 OPPS APC assignment, the proposed CY 2013 OPPS APC device offset percentage, and an indication if the full credit/partial credit (FB/FC) device adjustment policy would apply were also listed in Table 42 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 this proposal.

Comment: Some commenters expressed the same general concerns made in previous rulemakings 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 apply the device-intensive payment methodology to all procedures for which CMS can establish a median device cost, regardless of whether the procedures are assigned to APCs that are designated as device-dependent under the OPPS. In a related suggestion, the commenters urged CMS to establish the threshold used to determine device-intensive procedures at 50 percent of the ''unadjusted'' ASC payment rate (OPPS relative weight X ASC conversion factor) instead of the OPPS payment rate. 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.

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.

We do not agree with the commenters that the device-intensive methodology should be applied to all procedures where a device offset can be established, regardless of whether the procedure is assigned to a device-dependent APC under the OPPS. Nor do we agree with the commenters who suggest using a threshold to determine device-intensive procedures that is based on 50 percent of the ASC payment rate instead of the OPPS payment rate. 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 the CY 2010, CY 2011, and CY 2012 OPPS/ASC final rules with comment period (74 FR 60608 and 60609; 75 FR 72039; and 76 FR 74409, respectively).

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 the CY 2009, CY 2010, CY 2011, and CY 2012 OPPS/ASC final rules with comment period (73 FR 68735; 74 FR 60608 through 60609; 75 FR 72039; and 76 FR 74409, respectively).

After consideration of the public comments we received, we are designating the ASC covered surgical procedures displayed in Table 54 below as device-intensive for CY 2013. The CPT code, the CPT code short descriptor, the final CY 2013 ASC payment indicator (PI), the final CY 2013 OPPS APC assignment, the final CY 2013 OPPS APC device offset percentage, and an indication if the full credit/partial credit (FB/FC) device adjustment policy will apply are also listed in Table 54 of this final rule with comment period. As we discuss in section XIII.B.3. of the CY 2013 OPPS/ASC proposed rule (77 FR 45161 through 45162) 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, 2012 and January 1, 2013 in this final rule with comment period. Because these codes were not available to us until after the CY 2013 OPPS/ASC proposed rule was published, these codes were not included in that rule. We have reviewed these new codes and have added six of these CPT codes to Table 54 because they are ASC covered surgical procedures and are assigned to device-dependent APCs that meet the ASC device-intensive criteria. Specifically, we added the following new codes to the list of ASC device-intensive procedures: CPT code 0316T (Vagus nerve blocking therapy (morbid obesity); replacement of pulse generator); CPT code 0319T (Insertion or replacement of subcutaneous implantable defibrillator system with subcutaneous electrode); CPT code 0321T (Insertion of subcutaneous implantable defibrillator pulse generator only with existing subcutaneous electrode); CPT code 0323T (Removal of subcutaneous implantable defibrillator pulse generator with replacement of subcutenous implantable defibrillator pulse generator only); CPT code 24370 (Revision of total elbow arthroplasty, including allograft when performed; humeral or ulnar component); and CPT code 24371 (Revision of total elbow arthroplasty, including allograft when performed; humeral and ulnar component). These new device-intensive procedures are flagged with comment indicator ''NI'' in Addendum AA to this OPPS/ASC final rule with comment period to indicate that we are assigning them an interim payment status which is subject to public comment. We will respond to any public comments received in the CY 2014 OPPS/ASC final rule with

comment period. 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.

d. Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

We generally discuss the no cost/full credit and partial credit devices under the heading entitled ''ASC Payment for Covered Surgical Procedures.'' However, because the no cost/full credit and partial credit device policy applies to a subset of device-intensive procedures, we believe it would be clearer to discuss the device-intensive procedure policy and the no cost/full credit and partial credit device policy consecutively and to consolidate the tables that we usually publish separately. 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 and final CY 2013 OPPS APCs and devices subject to the adjustment policy are discussed in section IV.B.2. of this final rule with comment period. The established ASC policy adopts the OPPS policy and reduces payment to ASCs when a specified device is furnished without cost or with 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 68744).

Consistent with the OPPS, in the CY 2013 OPPS/ASC proposed rule (77 FR 45165), 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 2013. Table 42 of the proposed rule (77 FR 45165 through 45166) 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 2013. Specifically, we stated that when a procedure that is listed in Table 42 of the proposed rule is subject to the no cost/full credit or partial credit device adjustment policy and is performed to implant a device that is listed in Table 43 of the proposed rule (77 FR 45166 through 45167), 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 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.

For partial credit, we proposed to reduce the payment for implantation procedures listed in Table 42 of the proposed rule that are subject to the no cost/full credit or partial credit device adjustment policy 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 42 of the proposed rule that is subject to the no cost/full credit or partial credit device adjustment policy, when the facility receives a partial credit of 50 percent or more of the cost of a device listed in Table 43 of the proposed rule. 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 invited public comments on these proposals

We did not receive any comments on our CY 2013 proposal to continue the no cost/full credit and partial credit device adjustment policy for ASCs. For CY 2013, as we proposed, we will reduce the payment for the device implantation procedures listed in Table 54 below that are subject to the adjustment 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 55, below, and the associated implantation procedure code is listed in Table 54. In addition, for CY 2013, we will reduce the payment for implantation procedures listed in Table 54 that are subject to the adjustment 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 55, the ASC must append the modifier ''FC'' to the associated implantation procedure code if the procedure is listed in Table 54.

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TABLE 54.—ASC COVERED SURGICAL PROCEDURES DESIGNATED AS DEVICE-INTENSIVE FOR CY 2013, INCLUDING ASC COVERED SURGICAL PROCEDURES FOR WHICH THE NO COST/FULL CREDIT OR PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WILL APPLY

CPT Code	Short Descriptor	Final CY 2013 ASC PI	Final CY 2013 OPPS APC	Final CY 2013 Device-Dependent APC Offset Percent	FB/FC Policy Will Apply
0282T	Periph field stimul trial	J8	0040	56%	Yes
0283T	Periph field stimul perm	J8	0318	89%	Yes
0302T	Icar ischm mntrng sys compl	J8	0089	69%	Yes
0304T	Icar isch mntrng sys device	J8	0090	71%	Yes
0316T	Replc vagus nerve pls gen	J8	0039	87%	Yes
0319T	Insert subq defib w/eltrd	J8	0107	84%	Yes
0321T	Insert subq defib pls gen	J8	0107	84%	Yes
0323T	Rmvl & replc subq pls gen	J8	0107	84%	Yes
19296	Place po breast cath for rad	J8	0648	50%	Yes
19297	Place breast cath for rad	J8	0648	50%	Yes
19298	Place breast rad tube/caths	J8	0648	50%	Yes
19325	Enlarge breast with implant	J8	0648	50%	Yes
19342	Delayed breast prosthesis	J8	0648	50%	Yes
19357	Breast reconstruction	J8	0648	50%	Yes
24361	Reconstruct elbow joint	J8	0425	59%	Yes
24363	Replace elbow joint	J8	0425	59%	Yes
24366	Reconstruct head of radius	J8	0425	59%	Yes
24370	Revise reconst elbow joint	J8	0425	59%	Yes
24371	Revise reconst elbow joint	J8	0425	59%	Yes
25441	Reconstruct wrist joint	J8	0425	59%	Yes
25442	Reconstruct wrist joint	J8	0425	59%	Yes
25446	Wrist replacement	J8	0425	59%	Yes
27446	Revision of knee joint	J8	0425	59%	Yes
33206	Insertion of heart pacemaker	J8	0089	69%	Yes
33207	Insertion of heart pacemaker	J8	0089	69%	Yes
33208	Insertion of heart pacemaker	J8	0655	73%	Yes
33212	Insertion of pulse generator	J8	0090	71%	Yes
33213	Insertion of pulse generator	J8	0654	74%	Yes
33214	Upgrade of pacemaker system	J8	0655	73%	Yes

CPT Code	Short Descriptor	Final CY 2013 ASC PI	Final CY 2013 OPPS APC	Final CY 2013 Device-Dependent APC Offset Percent	FB/FC Policy Will Apply
33221	Insert pulse gen mult leads	J8	0654	74%	Yes
33224	Insert pacing lead & connect	J8	0655	73%	Yes
33225	Lventric pacing lead add-on	J8	0655	73%	Yes
33227	Remove&replace pm gen singl	J8	0090	71%	Yes
33228	Remv&replc pm gen dual lead	J8	0654	74%	Yes
33229	Remv&replc pm gen mult leads	J8	0654	74%	Yes
33230	Insrt pulse gen w/dual leads	J8	0107	84%	Yes
33231	Insrt pulse gen w/dual leads	J8	0107	84%	Yes
33240	Insert pulse generator	J8	0107	84%	Yes
33249	Eltrd/insert pace-defib	J8	0108	84%	Yes
33262	Remv&replc cvd gen sing lead	J8	0107	84%	Yes
33263	Remv&replc cvd gen dual lead	J8	0107	84%	Yes
33264	Remv&replc cvd gen mult lead	J8	0107	84%	Yes
33282	Implant pat-active ht record	J8	0680	74%	Yes
37227	Fem/popl revasc stnt & ather	J8	0319	53%	No
37231	Tib/per revasc stent & ather	J8	0319	53%	No
53440	Male sling procedure	J8	0385	62%	Yes
53444	Insert tandem cuff	J8	0385	62%	Yes
53445	Insert uro/ves nck sphincter	J8	0386	70%	Yes
53447	Remove/replace ur sphincter	J8	0386	70%	Yes
54400	Insert semi-rigid prosthesis	J8	0385	62%	Yes
54401	Insert self-contd prosthesis	J8	0386	70%	Yes
54405	Insert multi-comp penis pros	J8	0386	70%	Yes
54410	Remove/replace penis prosth	J8	0386	70%	Yes
54416	Remv/repl penis contain pros	J8	0386	70%	Yes
55873	Cryoablate prostate	J8	0674	55%	No
61885	Insrt/redo neurostim 1 array	J8	0039	87%	Yes
61886	Implant neurostim arrays	J8	0315	88%	Yes
62361	Implant spine infusion pump	J8	0227	82%	Yes
62362	Implant spine infusion pump	J8	0227	82%	Yes
63650	Implant neuro-electrodes	J8	0040	56%	Yes
63655	Implant neuro-electrodes	J8	0061	69%	Yes
63663	Revise spine eltrd perq aray	J8	0040	56%	Yes

CPT Code	Short Descriptor	Final CY 2013 ASC PI	Final CY 2013 OPPS APC	Final CY 2013 Device-Dependent APC Offset Percent	FB/FC Policy Will Apply
63664	Revise spine eltrd plate	J8	0040	56%	Yes
63685	Insrt/redo spine n generator	J8	0039	87%	Yes
64553	Implant neuro-electrodes	J8	0040	56%	Yes
64555	Implant neuro-electrodes	J8	0040	56%	Yes
64561	Implant neuro-electrodes	J8	0040	56%	Yes
64565	Implant neuro-electrodes	J8	0040	56%	Yes
64568	Implant neuro-electrodes	J8	0318	89%	Yes
64569	Revise/repl vagus n eltrd	J8	0040	56%	Yes
64575	Implant neuro-electrodes	J8	0061	69%	Yes
64580	Implant neuro-electrodes	J8	0061	69%	Yes
64581	Implant neuro-electrodes	J8	0061	69%	Yes
64590	Insrt/redo pn/gastr stimul	J8	0039	87%	Yes
65770	Revise cornea with implant	J8	0293	63%	No
69714	Implant temple bone w/stimul	J8	0425	59%	Yes
69715	Temple bne implnt w/stimulat	J8	0425	59%	Yes
69717	Temple bone implant revision	J8	0425	59%	Yes
69718	Revise temple bone implant	J8	0425	59%	Yes
69930	Implant cochlear device	J8	0259	84%	Yes
G0448	Place perm pacing cardiovert	J8	0108	84%	Yes

TABLE 55.—DEVICES FOR WHICH THE "FB" OR "FC" MODIFIER MUST BE REPORTED WITH THE PROCEDURE CODE IN CY 2013 WHEN FURNISHED AT NO COST OR WITH FULL OR PARTIAL CREDIT

CY 2013 Device HCPCS Code	CY 2013 Short Descriptor
C1721	AICD, dual chamber
C1722	AICD, single chamber
C1728	Cath, brachytx seed adm
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
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
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
L8600	Implant breast silicone/eq

CY 2013 Device HCPCS Code	CY 2013 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

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e. ASC Treatment of Surgical Procedures Removed From the OPPS Inpatient List for CY 2013

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. As stated in the CY 2013 OPPS/ASC proposed rule (77 FR 45167), we evaluated each of the two procedures we proposed to remove from the OPPS inpatient list for CY 2013 based on the criteria for exclusion from the list of covered ASC surgical procedures. As stated in the proposed rule, we believe that these two procedures should continue to be excluded from the ASC list of covered surgical procedures for CY 2013 because they would be expected to pose a significant risk to beneficiary safety or to require an overnight stay in ASCs. The CPT codes for these two procedures and their long descriptors were listed in Table 44 of the proposed rule (77 FR 45167). We invited public comments on this proposal.

We did not receive any public comments regarding the procedures that we proposed to exclude from the list of ASC covered procedures for CY 2013 that were proposed for removal from the CY 2013 OPPS inpatient list. However, as detailed in section IX of this final rule with comment period, the proposal to remove the procedure described by CPT code 27447 (Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty)) from the OPPS inpatient list is not being finalized for CY 2013. Based on public comments received, CPT code 27447 will remain on the OPPS inpatient list for CY 2013. Therefore, we are finalizing our proposal to continue to exclude the procedure described by the CPT code 22856, which is listed in Table 56 below, from the list of ASC covered surgical procedures for CY 2013. In addition, we are excluding CPT code 27447 because it will remain on the OPPS inpatient list for CY 2013.

TABLE 56.—PROCEDURE EXCLUDED FROM THE ASC LIST OF COVERED PROCEDURES FOR CY 2013 THAT WAS REMOVED FROM THE CY 2013 OPPS INPATIENT LIST

CPT Code	Long Descriptor
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical

2. Covered Ancillary Services

Consistent with the established ASC payment system policy, in the CY 2013 OPPS/ASC proposed rule (77 FR 45167), we proposed to update the ASC list of covered ancillary services to reflect the proposed payment status for the services under the CY 2013 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 2013. For example, a covered ancillary service that was separately paid under the revised ASC payment system in CY 2012 may be proposed for packaged status under the CY 2013 OPPS and, therefore, also under the ASC payment system for CY 2013. Comment indicator ''CH,'' discussed in section XIV.F. of the CY 2013 OPPS/ASC proposed rule (77 FR 45172), 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 2013.

Except for the Level II HCPCS codes listed in Table 37 of the CY 2013 OPPS/ASC proposed rule (77 FR 45161), all ASC covered ancillary services and their proposed payment indicators for CY 2013 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 2013 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 indicators ''G2'' and ''A2.'' Payment indicator ''A2'' was 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. Although the 4-year transitional period has ended and payment indicator ''A2'' is no longer required to identify surgical procedures subject to transitional payment, we retained payment indicator ''A2'' because it is used to identify procedures that are exempted from application of the office-based designation.

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 2012 OPPS/ASC final rule with comment period (76 FR 74377 through 74451), we updated the CY 2011 ASC payment rates for ASC covered surgical procedures with payment indicators of ''A2,'' ''G2,'' and ''J8'' using CY 2010 data, consistent with the CY 2012 OPPS update. Payment rates for device-intensive procedures also were updated to incorporate the CY 2012 OPPS device offset percentages.

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 2013 MPFS final rule with comment period) or the amount calculated using the ASC standard ratesetting methodology for the procedure. In the CY 2012 OPPS/ASC final rule with comment period, 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 2012 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 2012 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 2013

In the CY 2013 OPPS/ASC proposed rule (77 FR 45168), we proposed to update ASC payment rates for CY 2013 using the established rate calculation methodologies under § 416.171. We note that, as discussed in section II.A.2.f. of that proposed rule (77 FR 45094 through 45098), because we proposed to base the OPPS relative payment weights on geometric mean costs for CY 2013, the ASC system would shift to the use of geometric means to determine relative payment weights under the ASC standard ratesetting methodology. We proposed to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators ''A2'' and ''G2.''

We proposed that payment rates for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') and device-intensive procedures (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 2013 OPPS proposal that reflects updated proposed OPPS device offset percentages, and to make payment for office-based procedures at the lesser of the proposed CY 2013 MPFS nonfacility PE RVU-based amount or the proposed CY 2013 ASC payment amount calculated according to the standard ratesetting methodology. We invited public comments on these proposals.

We did not receive any public comments on our proposal to calculate CY 2013 payment rates for ASC-covered surgical procedures according to our established methodologies. Therefore, we are finalizing our CY 2013 proposal, without modification, to calculate the CY 2013 final ASC payment rates for ASC-covered surgical procedures according to our established methodologies.

c. Waiver of Coinsurance and Deductible for Certain Preventive Services

As discussed in the CY 2013 OPPS/ASC proposed rule (77 FR 45168), section 1833(a)(1) and section 1833(b)(1) of the Act 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 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 procedures and covered 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 categories of services in the CY 2013 OPPS/ASC proposed rule. We identify the specific services with a double asterisk in Addenda AA and BB to this CY 2013 OPPS/ASC final rule with comment period.

d. 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.'' In the CY 2012 OPPS/ASC final rule with comment period, we finalized our proposal to establish the CY 2012 ASC payment rate for CRT–D services 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. ASCs 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. For a complete discussion of our policy regarding payment for CRT–D services in ASCs, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74427 through 74428). We did not propose any changes to our current policy regarding ASC payment for CRT–D services for CY 2013.

e. Payment for Low Dose Rate (LDR) Prostate Brachytherapy Composite

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 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 on the same date of services to the Medicare beneficiary being treated with LDR brachytherapy for prostate cancer.

As detailed in section II.A.2.e.(2) of the CY 2013 OPPS/ASC proposed rule (77 FR 45088 through 45089), in CY 2008 under the OPPS, 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 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. We implemented this policy in the OPPS because reliance on single procedure claims to set payment rates for these services resulted in the 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 (72 FR 66652 through 66655).

Currently under the ASC payment system, ASCs receive separate payment for the component services that comprise the LDR Prostate Brachytherapy Composite when the two services are provided on the same date of service. Specifically, ASCs that report CPT codes 55875 and 77778 on the same date of service receive a payment for CPT code 55875 where the payment rate is based on the OPPS relative payment weight for single procedure claims, and a separate payment for CPT code 77778 where payment is the lower of the rate based on the OPPS relative payment weight for single procedure claims or the MPFS nonfacility PE–RVU based amount.

A commenter to the CY 2012 OPPS/ASC proposed rule (76 FR 74429 through 74430) requested that CMS pay for LDR prostate brachytherapy services under the ASC payment system based on the composite OPPS payment rate rather than making two separate payments for the service reported by CPT codes 55875 and 77778. The commenter 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 costs from single-service claims that CMS has acknowledged are mostly incorrectly coded claims. We responded that we would 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.

Because we agree that data from OPPS claims reporting both services required for LDR prostate brachytherapy provide the most accurate relative payment weight upon which to base ASC payment for the component services, in the CY 2013 OPPS/ASC proposed rule (77 FR 45169), we proposed to establish an ASC payment rate that is based on the OPPS relative payment weight applicable to APC 8001 when CPT codes 55875 and 77778 are performed on the same date of service in an ASC. We also proposed to create a HCPCS Level II G-code so that ASCs can properly report when the procedures described by CPT codes 55875 and 77778 are performed on the same date of service and, therefore, receive the appropriate LDR Prostate Brachytherapy Composite payment. We stated that the payment rate associated with the LDR prostate brachytherapy composite will be temporarily identified by HCPCS G-code ''GXXX1'' in Addendum AA to the CY 2013 OPPS/ASC proposed rule and the permanent HCPCS G-code that will identify this composite for ASCs will appear in this final rule with comment period. When not performed on the same day as the service described by CPT code 55875, the service described by CPT code 77778 will continue to be assigned to APC 0651. When not performed on the same day as the service described by CPT code 77778, the service described by CPT code 55875 will continue to be assigned to APC 0163. We invited public comment on this proposal.

Comment: Several commenters supported CMS' proposal to establish an ASC payment rate that is based on the OPPS relative payment weight applicable to APC 8001 when CPT codes 55875 and 77778 are performed on the same date of service in an ASC.

Response: We appreciate commenters' support of our proposal. We are finalizing our proposal, without modification, to establish the CY 2013 ASC payment rate for LDR prostate brachytherapy services based on the OPPS relative payment weight applicable to APC 8001 when CPT codes 55875 and 77778 are performed on the same date of service in an ASC. ASCs will use the corresponding HCPCS Level II G-code (G0458) for proper reporting when the procedures described by CPT codes 55875 and 77778 are performed on the same date of service, and therefore receive the appropriate LDR prostate brachytherapy composite payment. When not performed on the same day as the service described by CPT code 55875, the service described by CPT code 77778 will continue to be assigned to APC 0651. When not performed on the same day as the service described by CPT code 77778, the service described by CPT code 55875 will continue to be assigned to APC 0163.

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 or conditionally packaged

(status indicators ''N,'' ''Q1,'' and ''Q2'') under the OPPS. In the CY 2013 OPPS/ASC proposed rule (77 FR 45169), we further clarified our policy regarding the payment indicator assignment of codes that are conditionally packaged in the OPPS (status indicators ''Q1'' and ''Q2''). Under the OPPS, a conditionally packaged code describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are always packaged (payment indictor ''N1'') under the ASC payment system. Thus, our final policy aligns 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 MPFS. We set the payment indicator to ''Z2'' for these 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.

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 MPFS), we finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74429 through 74430) 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.

ASC payment policy for brachytherapy sources mirrors the payment policy under the OPPS. ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS or, if OPPS rates are unavailable, at contractor-priced rates (72 FR 42499). 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 42508 through 42509; 42 CFR 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 four 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), HCPCS code C1840 (Lens, intraocular (telescopic)), and HCPCS code C1886 (Catheter, extravascular tissue ablation, any modality (insertable)). Payment amounts for HCPCS codes C1749, C1830, C1840, and C1886 under the ASC payment system are contractor priced. In the CY 2012 OPPS/ASC final rule with comment period, we finalized the expiration of pass-through payment for HCPCS code C1749, which will expire after December 31, 2012 (76 FR 74278). Therefore, after December 31, 2012, the HCPCS code C1749 device costs will be packaged into the costs of the procedures with which the devices are reported in the hospital claims data used in the development of the OPPS relative payment weights that will be used to establish ASC payment rates for CY 2013.

b. Payment for Covered Ancillary Services for CY 2013

For CY 2013, 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 2013 OPPS and ASC payment rates (77 FR 45170). The proposed CY 2013 OPPS payment methodologies for brachytherapy sources and separately payable drugs and biologicals were discussed in section II.A. and section V.B. of that proposed rule, respectively, and we proposed to set the CY 2013 ASC payment rates for those services equal to the proposed CY 2013 OPPS rates.

Consistent with established ASC payment policy (72 FR 42497), the proposed CY 2013 payment for separately payable covered radiology services was based on a comparison of the CY 2013 proposed MPFS nonfacility PE RVU-based amounts (we referred readers to the CY 2013 MPFS proposed rule) and the proposed CY 2013 ASC payment rates calculated according to the ASC standard ratesetting methodology and then set at the lower of the two amounts (except as discussed below for nuclear medicine procedures and radiology services that use contrast agents). Alternatively, payment for a radiology service may be packaged into the payment for the ASC covered surgical procedure if the radiology service is packaged or conditionally 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. As finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74429 through 74430), payment indicators for radiology services that use contrast agents are set to ''Z2'' 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. In the CY 2013 OPPS/ASC proposed rule (77 FR 45170), we proposed for CY 2013 to continue these modifications to the payment methodology and, therefore, set the payment indicator to ''Z2'' for these covered ancillary radiology services that involve nuclear medicine procedures or that use contrast agents.

Most covered ancillary services and their proposed payment indicators were listed in Addendum BB to the CY 2013 OPPS/ASC proposed rule (which is available via the Internet on the CMS Web site). We invited public comment on these proposals.

Comment: One commenter expressed appreciation to CMS for its responsiveness in the CY 2011 OPPS/ASC final rule with comment period to stakeholder concerns regarding ASC payment for nuclear medicine procedures. However, the commenter suggested that ASC payment policy for nuclear medicine procedures would be further improved by providing separate payment for the diagnostic radiopharmaceuticals that are used in nuclear medicine procedures.

Response: As we stated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050) regarding separate payment for diagnostic radiopharmaceuticals used in ASCs, we do not agree with the commenter that we should establish separate payment for diagnostic radiopharmaceuticals under the ASC payment system because we follow the OPPS packaging policies which require that payment for these items is always packaged.

After consideration of the public comments we received, we are providing CY 2013 payment for covered ancillary services in accordance with the policies finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74430). Covered ancillary services and their final CY 2013 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 Pub. L. 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 major criteria set out at 42 CFR 416.195:

- 42 CFR 416.195(a)(1): The IOL is approved by the FDA;
- 42 CFR 416.195(a)(2): Claims 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;
- 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
- 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 improved 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 with the associated qualifying IOL models, at the link entitled ''NTIOL Application Determination Reference document Updated 01/06/2012,'' posted on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs.html*.

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/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs.html*. 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 2013 and Deadline for Public Comments

As discussed in the CY 2013 OPPS/ASC proposed rule (77 FR 45171), we did not receive any requests for review to establish a new NTIOL class for CY 2013 by the March 2, 2012 due date (this due date was stated in the CY 2012 OPPS/ASC final rule with comment period at 76 FR 74443).

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 in the CY 2013 OPPS/ASC proposed rule (77 FR 45171), we did not propose to revise the payment adjustment amount for CY 2013.

5. Revisions to the Major NTIOL Criteria Described in 42 CFR 416.195

The last significant revisions to the regulations containing the substantive NTIOL evaluation criteria under 42 CFR 416.195 occurred in 2007. In the CY 2013 OPPS/ASC proposed rule (77 FR 45171), we proposed significant revisions to § 416.195(a)(2) and § 416.195(a)(4). We stated our belief that revising § 416.195 is necessary in order to improve the quality of the NTIOL applications. In recent years, we have received low quality NTIOL applications that may have been due in part to overly-broad evaluation criteria.

We proposed to revise § 416.195(a)(2) to require that the IOL's FDA-approved labeling contains a claim of a specific clinical benefit imparted by a new lens characteristic. The IOL would have to have a new lens characteristic in comparison to currently available IOLs. We also proposed to revise § 416.195(a)(4) to require that any specific clinical benefit referred to in § 416.195(a)(2) would have to be supported by evidence that demonstrated that the IOL results in a measurable, clinically meaningful, improved outcome. Improved outcomes include: (i) Reduced risk of intraoperative or postoperative complication or trauma; (ii) accelerated postoperative recovery; (iii) reduced induced astigmatism; (iv) improved postoperative visual acuity; (v) more stable postoperative vision; and (vi) other comparable clinical advantages.

The proposed revision to § 416.195(a)(2) is necessary because recent NTIOL applications have not included FDA labeling claims of clinical benefit. Instead, the candidate IOLs have, in most cases, had some characteristic for which the applicant has tried to prove clinical relevance through various kinds of evidence that have not been evaluated by the FDA because the evidence is not associated with a labeling claim. The result has been the submission of low quality evidence that has been insufficient for NTIOL status. We believe that the quality of the evidence would improve if applicants were required to obtain a labeling claim for the NTIOL benefit and therefore have the evidence for such benefit evaluated by FDA. We believe that this proposed approach would better serve CMS, FDA, and the applicants because any ultimate grant of NTIOL status would be supported by a labeling claim. The manufacturer could then advertise the NTIOL benefit without running afoul of FDA advertising limitations. We would have the benefit of an FDA review of the relevant evidence, which would be particularly valuable because the FDA has a dedicated team of scientists, physicians, and engineers who are experts in evaluating IOLs.

The proposed revision to § 416.195(a)(4) is necessary to insure that the claim is clinically relevant and represents an improved outcome for Medicare beneficiaries. We requested public comments on these proposed revisions to the NTIOL regulations.

Comment: Several commenters supported our proposed changes to the NTIOL regulations. These commenters believed that the proposed changes will better insure that any grants of NTIOL status will be supported by rigorous scientific evidence.

Response: We appreciate these comments and the commenters' support for our efforts to require rigor and accountability in the NTIOL program.

Comment: One commenter disagreed with the proposed revision to 416.195(a)(2), complaining that obtaining a label claim is difficult and time consuming. In addition, this commenter made the following main points:

- It is not the FDA's job to review evidence related to an NTIOL application;
- FDA does not typically evaluate claims of comparative clinical benefits, and is not obligated to do so;
- Clinical studies to support a label claim require substantial time and resources, and there is no guarantee that such efforts will be successful;
- Other new technology programs, such as transitional pass-through payments, do not require a claim of clinical benefit;
- Requiring a claim of clinical benefit would provide extended exclusivity to the first company to establish the NTIOL class;
- Requiring a claim of clinical benefit will limit patient access to new technology.

Response: We believe that this commenter's objections reflect at least a partial misunderstanding of the proposal. Our current regulations require that the FDA approved label contain information about the clinical benefit of a candidate IOL. They provide two options for satisfying this requirement; the candidate lens must have either: (1) claims of specific clinical benefits in comparison with currently available IOLs approved by the FDA for use in labeling and advertising; or (2) lens characteristics with established clinical relevance in comparison with currently available IOLs approved by the FDA for use in labeling and advertising. Both of these options require evaluation by the FDA. In recent years, lens manufacturers have used Option 2 to claim, for example, that the applicant lens had a specific lens characteristic (for example, blue filter, availability in .25 D increments, absence of glistenings, packaging in a disposable injector) listed somewhere in the FDA labeling; however, the manufacturer would provide no information about the clinical relevance of this characteristic in the FDA's labeling. The manufacturer would submit to CMS weak or nonexistent evidence of a clinical benefit that it claimed could be attributed to the characteristic described on the FDA-approved label. We believe that to remedy this problem and to clarify the intent of this regulation it is necessary that the label contain a claim of a clinical benefit, which would be supported by evidence evaluated by the FDA.

Regarding this commenter's statement about the scope of FDA's duties, the evaluation of clinical evidence in support of a labeling claim is a core function of the FDA and is something that they do on a daily basis. There is nothing unusual about the FDA's proposed role as it relates to evaluating evidence in support of a labeling claim

that could be used to satisfy the requirements for NTIOL status. This rule does not usurp or interfere with any functions currently carried out by the FDA.

Regarding this commenter's other points, the various new technology payment programs we administer have somewhat different requirements, depending on the statutory authority and the specific purposes of the various programs. We believe that Congress intended that NTIOL status function as an incentive for innovation. If requiring a claim of clinical benefit results in a longer period of a single manufacturer utilizing a new NTIOL class exclusively, we believe that such extended exclusivity would serve as an additional inducement for manufacturers to innovate and seek NTIOL status for their innovations. While we agree with the commenter that seeking a label claim requires time and effort, we believe that this process will better serve NTIOL applicants in that having a claim of a clinical benefit will substantially increase the likelihood of ultimate NTIOL approval.

Finally, this commenter predicted that if we finalize these proposed changes to the regulations, then Medicare beneficiaries will have reduced access to new IOL technology. We disagree that the proposed changes to the NTIOL regulations will affect patient access to IOLs. For example, one of the 2012 NTIOL candidate IOLs had been on the market for 10 years and was the U.S. market leader at the time of NTIOL application. Lack of NTIOL status did not limit patient access to this IOL and we believe that it would also be unlikely to result in limited access to future IOLs. We also believe that having NTIOLs supported by a labeling claim of clinical benefit will increase patient confidence that they are receiving a medical device with a real evidence-based benefit versus existing technology.

After consideration of the public comments we received, we are finalizing the proposed changes to the NTIOL regulations.

6. Request for Public Comment on the ''Other Comparable Clinical Advantages'' Improved Outcome

Section 416.195(a)(4)), discussed above, lists the following improved outcomes: (i) Reduced risk of intraoperative or postoperative complication or trauma; (ii) accelerated postoperative recovery; (iii) reduced induced astigmatism; (iv) improved postoperative visual acuity; (v) more stable postoperative vision; and (vi) other comparable clinical advantages.

This list is from the original 1994 NTIOL statutory provision. Because this provision is almost 20 years old, outcomes (i) through (v) have only limited relevance to modern cataract surgery. For example, regarding outcome (i), it is unclear what, if any, type of IOL could reduce the risk of complication or trauma associated with cataract surgery, or what, if any, contemporary cataract surgery complication could be affected by a new type of IOL. As for outcome (ii), postoperative recovery is already rapid in uncomplicated cataract surgery; therefore, it is difficult to see how it could be significantly accelerated. Also, regarding outcome (iii), clinically significant induced astigmatism would be reflective of poor surgical technique and would not depend upon IOL design. Regarding outcome (iv), currently available IOLs provide such high quality postoperative visual acuity that it would be difficult to measure clinically significant improved postoperative visual acuity due to a new type of IOL. Finally, for outcome (v), postoperative vision is typically stable after uncomplicated cataract surgery, so again it would be difficult to improve upon this outcome.

The last of the listed improved outcomes is the nonspecific category described as ''other comparable clinical advantages.'' Given that present-day cataract surgery is such a successful procedure that results in significantly improved vision for almost all patients who undergo the procedure and who are appropriate candidates for cataract surgery, in the CY 2013 OPPS/ASC proposed rule (77 FR 45172), we solicited comments on what potential benefits associated with a new IOL could be considered to be a ''comparable clinical advantage'' as compared to the list of the five improved outcomes from the statute and regulation described above.

Comment: Several commenters supported retaining the ''comparable clinical advantage'' outcome as an open-ended category as necessary to accommodate future innovations. One commenter offered the following examples of potential comparable clinical advantages:

- Reduced incidence of posterior capsular opacity;
- Improved delivery to reduce error and minimize changes to the wound from insertion'
- Reduced inflammation;
- Reduced astigmatism;
- Improved vision;
- Improved vision stability; and
- Improved quality of life.

Response: It is important that companies consider all of the various possibilities for new clinical advantages, and we appreciate the range of potential issues that could be addressed through new IOL technology. However, some significant questions remain. For example, it could be that the incidence of some of these complications so low such that it would be impossible to design a study to measure any improvement due to a new IOL. It also could be that some surgical complications could be the result of surgical technique that could not be easily compensated for with a new IOL design. We also remind stakeholders that innovations that provide greater surgeon convenience, but no direct patient benefit, would not qualify for NTIOL status. Also, vision improvements cannot be merely improved optical performance but must relate to a meaningful improved outcome in visual performance.

The list of improved outcomes in the regulation is statutory and therefore we are not modifying it. After consideration of the public comments we received, we are adopting, without modification, our NTIOL proposals.

7. Announcement of CY 2013 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, 2014, 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 1, 2013. 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 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 2013 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 2012 OPPS/ASC final rule with comment period. These addenda can be found in a file labeled ''January 2012 ASC Approved HCPCS Code and Payment Rates'' 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 2013 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.

2. ASC Payment and Comment Indicators

In the CY 2013 OPPS/ASC proposed rule (77 FR 45172), we did not propose any changes to the definitions of the ASC payment and comment indicators for CY 2013. We referred readers to Addenda DD1 and DD2 to the CY 2013 OPPS/ASC proposed rule (which were available via the Internet on the CMS Web site) for the complete list of ASC payment and comment indicators proposed for the CY 2013 update.

We did not receive any public comments on the ASC payment and comment indicators. Addenda DD1 and DD2 to this final rule with comment period (which are available via the Internet on the CMS Web site) contain the complete list of payment and commenter indicators for the CY 2013 update.

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 2012 MedPAC ''Report to the Congress: Medicare Payment Policy'' included the following recommendations relating specifically to the ASC payment system for CY 2013:

Recommendation 5–1: ''The Congress should update the payment rates for ambulatory surgical centers by 0.5 percent for calendar year 2013. The Congress should also require ambulatory surgical centers to submit cost data.''

Regarding the ASC payment update for CY 2013, MedPAC further stated that: ''On the basis of our payment adequacy indicators, the lack of ASC cost data, and our concerns about the potential effect of ASC growth on overall program spending, we believe a moderate update of 0.5 percent is warranted for CY 2013.'' With regard to the collection of cost data, MedPAC indicated that cost data are needed to fully assess ASC payment adequacy under the revised ASC payment system and to 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 to annually update ASC payment rates.

CMS Response: We note that MedPAC's recommendation is for the Congress to increase ASC payment rates by 0.5 percent in CY 2013 and require ASCs to submit cost data. Congress has not yet acted on these recommendations. In the CY 2013 OPPS/ASC proposed rule (77 FR 45172), we proposed to continue our current policy to update the ASC conversion factor using the CPI–U, and we did not propose to require ASCs to submit cost data in the proposed rule. However, as discussed in section XIV.H.2.b. of the proposed rule (77 FR 45174), while we believe the CPI–U is appropriate to apply to update the ASC payment system, the CPI–U may not best reflect inflation for the goods and services provided by ASCs and, therefore, we sought public comment on the type of cost information that would be feasible to collect from ASCs that would assist us in determining possible alternatives to using the CPI–U to update ASC payment rates for inflation. In section XIV.H.2.b. of this final rule with comment period, we summarize and respond to the public comments we received regarding the ASC update and the feasibility of collecting ASC cost data.

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 the OPPS 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 adopted a policy to make the system budget neutral in subsequent calendar years (72 FR 42532 through 42533).

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 the OPPS, 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 XIV.D.2.b. of this final rule with comment period), the established policy is to set the payment rate at the lower of the MPFS unadjusted nonfacility PE RVU-based amount or the amount calculated using the ASC standard ratesetting methodology. 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 42517 through 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 period (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 recommendation that was made in the CY 2010 (74 FR 60625), CY 2011 (75 FR 72059), and CY 2012 (76 FR 74446) rulemakings—that is, that CMS adopt for the ASC payment system the same wage index values used for hospital payment under the OPPS.

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 continue to believe that the unadjusted hospital wage indices, which are updated yearly and are used by almost all Medicare payment systems, appropriately account for geographic variance in labor costs for ASCs. We refer readers to our response to this comment in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72059). We discuss our budget neutrality adjustment for changes to the wage indices below in section XIV.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 2013, 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 2013 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 42533). We note that, as

discussed in section II.A.2.f. of the CY 2013 OPPS/ASC proposed rule (45094 through 45098) and in this final rule with comment period, because we proposed to base the OPPS relative payment weights on geometric mean costs for CY 2013, the ASC system would shift to the use of geometric means to determine relative payment weights under the ASC standard ratesetting methodology. Consistent with our established policy, in the CY 2013 OPPS/ASC proposed rule (77 FR 45173), we proposed to scale the CY 2013 relative payment weights for ASCs according to the following method. Holding ASC utilization and the mix of services constant from CY 2011, we proposed to compare the total payment using the CY 2012 ASC relative payment weights with the total payment using the CY 2013 relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2012 and CY 2013. We proposed to use the ratio of CY 2012 to CY 2013 total payment (the weight scaler) to scale the ASC relative payment weights for CY 2013. The proposed CY 2013 ASC scaler was 0.9331 (77 FR 45174) 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 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 2013 proposed rule, we had available 98 percent of CY 2011 ASC claims data. For this final rule with comment period, we have approximately 99 percent of all ASC claims data for CY 2011.

To create an analytic file to support calculation of the weight scaler and budget neutrality adjustment for the wage index (discussed below), we summarized available CY 2011 ASC claims by ASC and by HCPCS code. We used the National Provider Identifier for the purpose of identifying unique ASCs within the CY 2011 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/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/ASCPaymentSystem.html*.

We did not receive any comments and, therefore, we are finalizing our CY 2013 ASC relative payment weight scaling methodology, without modification.

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 2013 scaler adjustment is 0.9324. This scaler adjustment is necessary to make the difference in aggregate ASC payments calculated using the CY 2012 ASC relative payment weights and the CY 2013 relative payment weights budget neutral. We calculated the difference in aggregate payments due to the change in relative payment weights holding constant the ASC conversion factor, the most recent CY 2011 ASC utilization from our claims data, and the CY 2012 wage index values. For this final CY 2013 calculation, we used the CY 2012 ASC conversion factor updated by the CY 2013 CPI–U, which is projected to be 1.4 percent, less the multifactor productivity adjustment of 0.8 percent, as discussed below in section XIV.H.2.b. of this final rule with comment period.

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 2013 ASC payment system, in the CY 2013 OPPS/ASC proposed rule (77 FR 45174), we proposed to calculate and apply a budget neutrality adjustment to the ASC conversion factor for supplier level changes in wage index values for the upcoming year, just as the OPPS wage index budget neutrality adjustment is calculated and applied to the OPPS conversion factor. For CY 2013, we calculated this proposed adjustment for the ASC payment system by using the most recent CY 2011 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2013 pre-floor and pre-reclassified hospital wage indices. Specifically, holding CY 2011 ASC utilization and service-mix and the proposed CY 2013 national payment rates after application of the weight scaler constant, we calculated the total adjusted payment using the CY 2012 pre-floor and pre-reclassified hospital wage indices and the total adjusted payment using the proposed CY 2013 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 2012 pre-floor and pre-reclassified hospital wage indices to the total adjusted payment calculated with the proposed CY 2013 pre-floor and pre-reclassified hospital wage indices and applied the resulting ratio of 1.0002 (the proposed CY 2013 ASC wage index budget neutrality adjustment) to the CY 2012 ASC conversion factor to calculate the proposed CY 2013 ASC conversion factor.

Section 1833(i)(2)(C)(i) of the Act requires that, ''if the Secretary has not updated amounts established'' under the revised ASC payment system 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.'' The statute, therefore, does not mandate the adoption of any particular update mechanism, but it requires the payment amounts to be increased by the CPI–U in the absence of any update. Because the Secretary updates the ASC payment amounts annually, we adopted a policy, which we codified at 42 CFR 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).

Stakeholders, as well as MedPAC, have commented throughout the years that the CPI–U may not adequately measure inflation for the goods and services provided by ASCs (for example, 76 FR 74444, 74448 through 74450; 73 FR 68757; and 72 FR 66859). While we believe the CPI–U is appropriate to apply to update the ASC payment

system, we are aware that the CPI–U is highly weighted for housing and transportation and may not best reflect inflation in the cost of providing ASC services. In developing the CY 2013 OPPS/ASC proposed rule, we considered possible alternatives to using the CPI–U to update ASC payment rates for inflation.

ASC stakeholders have urged us to adopt the hospital market basket to update ASC payment rates for inflation when commenting on each proposed rule since the beginning of the revised ASC payment system (72 FR 66859; 73 FR 68757; 74 FR 60628 through 60629; 75 FR 72063; and 76 FR 74449). We considered the hospital market basket as an alternative to the CPI–U and, while the items included in the hospital market basket seem reflective of the kinds of costs incurred by ASCs, as stated in the CY 2012 OPPS/ASC final rule with comment period, 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 reflective of costs associated with providing services in ASCs (76 FR 74450). As other possible alternatives to the CPI–U update, we considered using the physician's practice expense (PE) component of the Medicare Economic Index (MEI) update, as well as using an average of the hospital market basket update and the PE component of the MEI update. However, until we have more information regarding the cost inputs of ASCs, we are not confident that any of these alternatives are a better proxy for ASC costs than the CPI–U. Therefore, in the CY 2013 OPPS/ASC proposed rule (77 FR 45174), we proposed a continuation of the established policy of basing the ASC update on the CPI–U. In addition, we requested public comment on the type of cost information that would be feasible to collect from ASCs in the future in order to determine if one of these alternative updates or an ASC-specific market basket would be a better proxy for ASC cost inflation than the CPI–U.

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 effective with the calendar year beginning January 1, 2011. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the ''MFP adjustment''). Clause (iv) of section 1833(i)(2)(D) of the Act authorizes the Secretary to provide for a reduction in any annual update for failure to report on quality measures. Clause (v) of section 1833(i)(2)(D) of the Act 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 2012 OPPS/ASC final rule with comment period (76 FR 74516), we finalized a policy that ASCs begin submitting data on quality measures for services beginning on October 1, 2012 for the CY 2014 payment determination under the ASCQR Program. Section XVI.D. of the CY 2013 OPPS/ASC proposed rule (77 FR 45192 through 45193) provided a discussion of the proposed payment reduction to the annual update for ASCs that fail to meet the ASCQR Program requirements. In summary, we proposed to calculate reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements. The reduced rates would apply beginning in CY 2014. We proposed that application of the 2.0 percentage point reduction to the annual update factor, which currently is the CPI–U, may result in the update to the ASC payment system being less than zero for a year for ASCs that fail to meet the ASCQR Program requirements. We proposed changes to §§ 416.160(a)(1) and 416.171 to reflect this proposal. Comments to this proposal are addressed in section XVI.D.2 of this final rule with comment period.

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, we would hold the CPI–U update factor for the ASC payment system to zero. For the CY 2014 payment determination and subsequent payment determination years, under section 1833(i)(2)(D)(iv) of the Act, we would reduce the annual update by 2.0 percentage points for an ASC that fails to submit quality information under the rules established by the Secretary in accordance with section 1833(i)(7) of the Act. 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 annual update factor, after application of any quality reporting reduction 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 annual update factor after application of any quality reporting reduction would result in an MFP-adjusted update factor that is less than zero, the resulting 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 2013 OPPS/ASC proposed rule (77 FR 45175), for the 12-month period ending with the midpoint of CY 2013, the CPI–U update was projected to be 2.2 percent. Because the ASCQR Program does not affect payment rates until CY 2014, there would be no quality reporting reduction to the CPI–U for CY 2013. The MFP adjustment for the period ending with the midpoint of CY 2013 was projected to be 0.9 percent based on the methodology for calculating the MFP adjustment finalized in the CY 2011 MPFS final rule with comment period (75 FR 73394 through 73396) as revised in the CY 2012 MPFS final rule with comment period (76 FR 73300 through 73301). We proposed to reduce the CPI–U update of 2.2 percent by the MFP adjustment of 0.9 percent, resulting in an MFP-adjusted CPI–U update factor of 1.3 percent. Therefore, as stated in the CY 2013 OPPS/ASC proposed rule (77 FR 45175), we proposed to apply a 1.3 percent MFP-adjusted CPI–U update factor to the CY 2012 ASC conversion factor.

For CY 2013, we also proposed to adjust the CY 2012 ASC conversion factor ($42.627) by the wage adjustment for budget neutrality of 1.0002 in addition to the MFP-adjusted update factor of 1.3 percent discussed above, which resulted in a proposed CY 2013 ASC conversion factor of $43.190 (77 FR 45175). We invited public comments on these proposals.

Comment: Commenters expressed varied opinions regarding the feasibility of requiring ASCs to submit cost data to the Secretary. One commenter believes that CMS should require ASCs to submit

cost data so that an appropriate market basket for ASC annual updates can be identified and so that analysts can determine the costs of an efficient provider of ASC services. The commenter believes that reporting such data is feasible because businesses such as ASCs typically keep record of their costs for filing taxes and other purposes. In addition, this commenter pointed out that other small providers, including home health agencies and hospices, submit cost data to CMS.

Other commenters (predominantly commenters who represent ASCs) opposed a requirement that ASCs submit cost data to CMS. The commenters believed that a requirement to submit cost data would be both unnecessary and administratively burdensome for ASCs.

Further, some commenters stated that requiring ASCs to submit cost data that would not be directly tied to receipt of payment would likely result in the submission of data that is unreliable. These commenters also maintained that using cost data to develop an ASC-specific market basket would not provide a more accurate reflection of ASC cost growth. Commenters believed that creating a single set of cost weights that are representative of the industry average would relate to few ASCs as most centers are specialized and would have a cost structure that is specific to the procedures they provide. These commenters also stated that, by CMS' own description, the hospital market basket itself is an imperfect measure of hospital outpatient costs but CMS has rationalized use of the hospital market basket as the best available measure of costs in the hospital outpatient setting. The commenters believe that, likewise, the best available proxy to measure costs in the ASC setting is the hospital market basket. Commenters expressed frustration that CMS has not adopted the hospital market basket to update ASC payment rates and urged the agency to not waste precious resources collecting ASC cost data when this reasonable measure of input prices is readily available.

Response: We thank all of the commenters for their thoughts regarding the type of cost information that would be feasible to collect from ASCs in the future in order to determine if an alternative update or an ASC-specific market basket would be a better proxy for ASC cost inflation compared to the CPI–U. We will keep the commenters' perspectives about collecting cost information from ASCs in mind as we consider this issue further.

Comment: As in previous years, commenters requested that CMS adopt the hospital market basket to update the ASC payment system instead of using the CPI–U. The commenters explained that the CPI–U does not fairly represent the costs borne by the ASC industry because the prices measured in the basket of goods comprising the index reflect the types and weights of categories typical of an American household, rather than an outpatient surgical provider. Commenters believed that the hospital market basket more closely reflects the cost structure of ASCs than does the basket of goods included in the CPI–U. Commenters stated that adopting the hospital market basket to update ASC payment rates would minimize the divergence in CY 2013 payments in ASCs compared to HOPDs and would ensure continued beneficiary access to ASCs.

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. Commenters also requested that the 10-year MFP measurement period be uniform in ASCs and HOPDs so that there is no discrepancy in the estimates of the MFP that will provide additional divergence between the ASC and HOPD updates.

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. Hospitals provide a much wider range of services, such as room and board and emergency services, and the costs associated with providing these services are not part of the ASC cost structure. Therefore, at this time, we do not believe that it is appropriate to use the hospital market basket for the ASC annual update.

We recognize that the CPI–U is an output price index that accounts for productivity. However, section 1833(i)(2)(D)(v) of the Act requires the agency to reduce the annual update factor by the MFP adjustment. For the reasons stated above, we do not believe that the hospital market basket would appropriately reflect the cost structures of ASCs, and because we do not have cost data on ASCs, we are not able to recommend a more accurate update. Therefore, the CPI–U remains the most appropriate update. Regarding alignment of the MFP adjustment across payment systems, for reasons stated in the CY 2011 MPFS final rule with comment period (75 FR 73396), we believe that it is more appropriate to align the MFP adjustment with the update timeframes for each payment system rather than aligning the MFP adjustment across payment systems.

After consideration of the public comments we received, we are applying our established methodology for determining the final CY 2013 ASC conversion factor. Using more complete CY 2011 data for this final rule with comment period than was available for the proposed rule, we calculated a wage index budget neutrality adjustment of 1.0008. Based on updated data, the CPI–U for the 12-month period ending with the midpoint of CY 2013 is now projected to be 1.4 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 0.8 percent, resulting in an MFP-adjusted CPI–U update factor of 0.6 percent. The final ASC conversion factor of $42.917 is the product of the CY 2012 conversion factor of $42.627 multiplied by the wage index budget neutrality adjustment of 1.0008 and the MFP-adjusted CPI–U payment update of 0.6 percent. We also are finalizing proposed changes to §§ 416.160(a)(1) and 416.171, without modification, regarding the reduction to payment rates beginning in CY 2014 for ASCs that fail to meet the ASCQR Program requirements.

3. Display of CY 2013 ASC Payment Rates

Addenda AA and BB to this CY 2013 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 2013 for covered surgical procedures and covered ancillary services, respectively. These addenda contain several types of information related to the CY 2013 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 2013. 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 in this final rule with comment period.

The values displayed in the column titled ''CY 2013 Payment Weight'' are the relative payment weights for each of the listed services for CY 2013. 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 and brachytherapy sources that are separately paid under the OPPS, or services that are contractor-priced or paid at reasonable cost in ASCs.

To derive the CY 2013 payment rate displayed in the ''CY 2013 Payment'' column, each ASC payment weight in the ''CY 2013 Payment Weight'' column was multiplied by the CY 2013 conversion factor of $42.917. The conversion factor includes a budget neutrality adjustment for changes in the wage index values and the annual update factor as reduced by the productivity adjustment (as discussed in section XIV.H.2.b. of this final rule with comment period).

In Addendum BB, there are no relative payment weights displayed in the ''CY 2013 Payment Weight'' column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The ''CY 2013 Payment'' column displays the CY 2013 national unadjusted ASC payment rates for all items and services. The CY 2013 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 2012.

Addendum EE provides the HCPCS codes and short descriptors for surgical procedures that are to be excluded from payment in ASCs for CY 2013.

We did not receive any public comments regarding the continuation of our policy to provide CY 2013 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 2013 for covered surgical procedures and covered ancillary services, respectively, and provide additional information related to the CY 2013 rates.

XV. Hospital Outpatient Quality Reporting Program Updates

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 have financial incentives for the reporting of quality data to CMS.

CMS also has implemented quality reporting programs for long term care hospitals, inpatient rehabilitation hospitals, the hospice program, ambulatory surgical centers (the Ambulatory Surgical Center Quality Reporting (ASCQR) Program), as well as a program for physicians and other eligible professionals, known as the Physician Quality Reporting System (PQRS) (formerly known as the Physician Quality Reporting Initiative (PQRI)). CMS has recently finalized quality reporting programs for inpatient psychiatric facilities and PPS-exempt cancer hospitals.

Finally, CMS has implemented a Hospital Value-Based Purchasing Program and an end-stage renal disease (ESRD) Quality Incentive Program (76 FR 628 through 646) that link 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 national priorities for improved quality and efficiency of care for Medicare beneficiaries as reflected in the National Quality Strategy, as well as conditions for which wide cost and treatment variations have been reported, despite established clinical guidelines. Our ultimate goal is to align the clinical quality measure requirements of the Hospital OQR Program and various other programs, such as the Hospital IQR Program, the ASCQR Program, and the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs, authorized by the Health Information Technology for Economic and Clinical Health Act, so that the burden for reporting will be reduced. As appropriate, we will consider the adoption of measures with electronic specifications, to enable the collection of this information as part of care delivery. Establishing such an alignment will require interoperability between electronic health records (EHRs), and CMS data collection systems, with data being calculated and submitted via certified EHR technology; additional infrastructural development on the part of hospitals and CMS; and the adoption of standards for capturing, formatting, and transmitting the data elements that make up the measures. Once these activities are accomplished, the adoption of many measures that rely on data obtained directly from EHRs will enable us to expand the Hospital OQR Program measure set with less cost and burden to hospitals.

In implementing this and other quality reporting programs, we generally applied the same principles for the development and the use of measures, with some differences:

- Our overarching goal is to support the National Quality Strategy's goal of better health care for individuals, better health for populations, and lower costs for health care. The Hospital OQR Program will help achieve these goals by creating transparency around the quality of care at hospital outpatient departments to support patient decision-making and quality

improvement. Given the availability of well validated measures and the need to balance breadth with minimizing burden, measures should take into account and address, as fully as possible, the six domains of measurement that arise from the six priorities of the National Quality Strategy: Clinical care; Person- and caregiver-centered experience and outcomes; Safety; Efficiency and cost reduction; Care coordination; and Community/population health. More information regarding the National Quality Strategy can be found at: *http://www.healthcare.gov/law/resources/reports/*. HHS engaged a wide range of stakeholders to develop the National Quality Strategy, as required by the Affordable Care Act.

• Pay-for-reporting and public reporting should rely on a mix of standards, processes, outcomes, efficiency, and patient experience of care measures, including measures of care transitions and changes in patient functional status.

• To the extent possible and recognizing differences in payment system maturity and statutory authorities, measures should be aligned across Medicare and Medicaid public reporting and incentive payment systems to promote coordinated efforts to improve quality. 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.

• We weigh the relevance and the utility of measures compared to the burden on hospitals in submitting data under the Hospital OQR Program. The collection of information burden on providers should be minimized to the extent possible. To this end, we are working toward the eventual adoption of electronically-specified measures so that data can be calculated and submitted via certified EHR technology with minimal burden. We also seek to use measures based on alternative sources of data that do not require chart abstraction or that utilize data already being reported by many hospitals, such as data that hospitals report to clinical data registries, or all-payer claims databases. In recent years we have adopted measures that do not require chart abstraction, including structural measures and claims-based measures that we can calculate using other data sources.

• 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. We take into account the views of the Measure Application Partnership (MAP). The MAP is a public-private partnership convened by the National Quality Forum (NQF) for the primary purpose of providing input to HHS on selecting performance measures for quality reporting programs and pay for reporting programs. The MAP views patient safety as a high priority area and it strongly supports the use of NQF-endorsed safety measures. Accordingly, we consider the MAP's recommendations in selecting quality and efficiency measures. Information about the MAP can be found at *http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx*

• Measures should be developed with the input of providers, purchasers/payers, consumers, and other stakeholders. Measures should be aligned with best practices among other payers and the needs of the end users of the measures. We take into account widely accepted criteria established in medical literature.

• HHS Strategic Plan and Initiatives. HHS is the U.S. government's principal agency for protecting the health of all Americans. HHS accomplishes its mission through programs and initiatives. Every 4 years HHS updates its Strategic Plan and measures its progress in addressing specific national problems, needs, or mission-related challenges. The goals of the HHS Strategic Plan for Fiscal Years 2010 through 2015 are to: Transform Health Care; Advance Scientific Knowledge and Innovation; Advance the Health, Safety, and Well-Being of the American People; Increase Efficiency, Transparency, and Accountability of HHS Programs; and Strengthen the Nation's Health and Human Services Infrastructure and Workforce (*http://www.hhs.gov/about/FY2012budget/strategicplandetail.pdf*). HHS prioritizes policy and program interventions to address the leading causes of death and disability in the United States, including heart disease, cancer, stroke, chronic lower respiratory diseases, unintentional injuries and preventable behaviors. Initiatives such as the HHS Action Plan to Reduce Healthcare-associated Infections (HAIs) in clinical settings and the Partnership for Patients exemplify these programs.

• CMS Strategic Plan. We strive to ensure that measures for different Medicare and Medicaid programs are aligned with priority quality goals, that measure specifications are aligned across settings, that outcome measures are used whenever possible, and that quality measures are collected from EHRs as appropriate.

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74451 through 74452), we responded to public comment on many of these principles. In the CY 2013 OPPS/ASC proposed rulemaking, we generally applied the same principals for our considerations for future measures, with some differences.

Comment: Many commenters supported CMS' general principles of measure development, selection, and implementation, specifically, CMS' combined approach of using process and outcomes measures, as well as our intent to adopt NQF-endorsed measures whenever feasible, and to align measures across settings under different quality reporting programs. One commenter stated that CMS should only adopt measures that are useful for hospital outpatient departments to improve their quality performance.

A few commenters recommended that the Hospital OQR Program only adopt NQF-endorsed measures which undergo established sound, and timely measure maintenance and update procedures. Several commenters urged that CMS proceed cautiously when considering adopting non-NQF-endorsed measures, which in some cases may not have been rigorously field-tested and may end up in subsequent suspension or implementation deferral. Commenters requested that CMS delay adoption of measures in the future until specification problems are completely ironed out so that hospitals do not have to spend resources on preparing for incompletely specified or untested measures.

Response: As discussed, we usually focus on measures appropriate to the specific provider category that reflect the level of care and the most important areas of service and measures for that provider category. Section 1833(t)(17)(C)(i) of the Act requires the Secretary to ''develop measures that the Secretary determines to 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.'' This provision does not require that the measures we adopt for the Hospital OQR Program be endorsed by any particular entity, and we believe that consensus among affected parties can be achieved by means other than endorsement by a national consensus building entity, including through the

measure development process, through broad acceptance and use of the measure(s), and through public comment.

Generally, we prefer to adopt NQF-endorsed measures. We rely on NQF to endorse only those measures that have met the rigorous field testing requirement and we do not re-test these measures prior to adoption. However, in some circumstances, as with OP–19, when we find the specifications require revision after the measure has been adopted, CMS chooses to suspend a measure rather than requiring continued data collection to alleviate burden on hospitals.

We strive to field test each measure we use in our programs. However, on rare occasions, we adopt measures that were developed and tested by other measure stewards. With respect to the commenters who recommended that, in the future, we delay adoption of measures until specification problems are completely resolved so that hospitals would not have to spend resources on preparing for incompletely specified or untested measures, we believe the commenters may have been referring specifically to one measure—OP–24: Cardiac Rehabilitation Patient Referral from an Outpatient Setting. For that measure, we are delaying data collection until January 1, 2014, and its application toward a payment determination will be for CY 2015 rather than CY 2014. If our interpretation of the comment was correct, we understand the commenter's concerns. However, we clarify that because we have not added any OP–24 measure specifications to the Specification Manual yet, it is highly unlikely that hospitals would have spent resources in preparing for this measure.

In instances where we develop our measures, we do proceed with caution, employing a rigorous consensus-based measure development and field testing process that incorporates broad stakeholder input. Therefore, we believe it is reasonable to adopt measures developed in this manner whether or not they achieve NQF endorsement. For those measures that we have not developed, we strive to obtain testing information on the technical aspects from the developer and to work with the developer to create specifications that enable standardized collection in national programs. In the case of measures we do not develop, the above specification process may occur after adoption of the measure in a reporting program, but prior to implementing data collection.

Comment: Some commenters supported CMS' goal to align measures in the Hospital IQR, Hospital OQR, and Medicare and Medicaid EHR Incentive Programs. Commenters also commended CMS for striving for quality reporting that is based upon meaningful and comparable measures.

Response: We thank the commenters for supporting our strategy to align measures across settings and programs whenever feasible and to move toward more meaningful measures in our programs.

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. Measure Updates and Data Publication

a. Process for Updating Quality Measures

Technical specifications for the Hospital OQR Program measures are listed in the *Hospital OQR Specifications Manual,* which is posted on the CMS QualityNet Web site at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FSpecsManualTemplate&cid=1228772438492.*

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 an additional subregulatory process for making updates to the measures we have adopted for the Hospital OQR Program. This process is necessary so that the Hospital OQR measures are calculated based on the most up-to-date scientific and consensus standards. Under this process, when a national consensus building entity updates the specifications for a measure that we have adopted for the Hospital OQR Program, we update our specifications for that measure accordingly. For measures that are not endorsed by a national consensus building entity, the subregulatory process is based on scientific advances as determined necessary by CMS, in part, through our measure maintenance process involving Technical Expert Panels (73 FR 68767). We provide notice of the updates via the QualityNet Web site, *http://www.QualityNet.org,* and in the Hospital OQR Specifications Manual.

We generally release the Hospital OQR Specifications Manual every 6 months and release addenda as necessary. This release schedule provides at least 3 months of advance notice for nonsubstantive 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: One commenter believed that conversion of measures to use ICD–10–CM/PCS and eMeasure formats should be considered a substantial change and should warrant the proposed rulemaking process. One commenter asserted that there are shortcomings in the CMS subregulatory process. The commenter was concerned that this rapid subregulatory process may not include a field review of the measure. Secondly, the commenter stated that some measure changes affect data accuracy and completeness, such as change of diagnosis, procedure codes and changes to exclusions to the patient population and extended application of the measure to other hospital locations. The commenter believed that these are substantive changes rather than non-substantive changes as noted by CMS.

Response: We will be transitioning all of our billing and measurement systems from ICD–9 to ICD–10. We intend to solicit public comment on the ICD–10 versions of our measure specifications through future rulemaking prior to implementation. We normally incorporate coding updates for the measures using our established subregulatory process because such updates do not change the basic underlying concepts being measured. This is theoretically true of moving from ICD–9 to the ICD–10 coding system (or eMeasure format). However, we recognize that in moving to ICD–10 coding (or eMeasure format) there may be some nuances in the measures that when translated result in unanticipated differences in performance, rendering prior measure results untrendable with results for the same measures under the new coding system. We also intend to study this effect further once implementation has occurred and data are available to do so.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53504), we indicated that examples of what we might *generally* regard as nonsubstantive changes to measures might include updated

diagnosis or procedure codes, medication updates for categories of medications, or a broadening of age ranges. We believe that nonsubstantive changes may also include updates to NQF-endorsed measures based upon changes to guidelines upon which the measures are based. We note that the NQF process has already incorporated an opportunity for public comment and engagement in the measure maintenance process.

We will continue to use rulemaking to adopt substantive updates made by the NQF to the endorsed measures we have adopted for the Hospital OQR Program. Examples of changes that we might *generally* consider to be substantive would be those in which the changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent (for example, changes in acceptable timing of medication, NQF expansion of endorsement of a previously endorsed measure to a new setting, procedure/process, or test administration). However, these and other changes would need to be evaluated on a case-by-case basis to determine whether or not a change to a measure is in fact substantive.

Comment: A few commenters expressed concern that the CMS procedures for notifying providers of significant changes to quality measures and general changes to the Hospital OQR Program may be problematic at times, as email blasts, one of the CMS communication methods, do not always reach the appropriate quality measure personnel. The commenters requested consistency in transparency of CMS' communications to hospitals, vendors, and QIOs and requested sufficient notice be given to hospitals regarding the new start date of any measure changes.

Response: We thank these commenters for feedback on communication. We endeavor to communicate clearly to all Hospital OQR Program stakeholders. We offer email blasts to subscribers who sign up to receive them, indicating they prefer to receive information by email. The QualityNet Web site contains a full list of all email blasts sent, and it is available for any stakeholder to review at any time. We do not intend the listserv to replace QualityNet as the primary source for information and resources for the Hospital OQR Program.

We offer a helpline that is available weekdays to offer technical support and assistance to callers, in an effort to help any caller successfully comply with program requirements. Please find this helpline and program contact information by visiting the QualityNet Web site at *https://www.qualitynet.org*. From this page, choose ''Hospitals-Outpatient'' from the drop down menus across the top of the page, then click on ''Support Contact.''

Comment: A few commenters appreciated the 6-month advance notice of data elements and system changes but noted that the 6-month period for measure update and Specifications Manual release may not provide sufficient time for hospitals to make changes in data elements and system. Another commenter requested more detailed instructions on chart abstraction be provided because the training Qs and As posted on the QualityNet Web site are insufficient and appear to contradict the Specifications Manual at times.

Response: Our experience with this and other quality reporting programs indicates that 6 months' notice is sufficient for hospitals and their vendors to accommodate data element and system changes. We provide detailed abstraction instructions in our measure Specifications Manual, and provide additional guidance through Qs and As posted on the QualityNet Web site, and by offering periodic training.

We will take into consideration the recommendation to provide more detailed instructions on chart abstraction due to insufficient Qs and As posted on the QualityNet Web site. We are aware of a specific situation we corrected earlier this year. Under the ED Throughput topic, we had two contradictory answers posted within our Qs and As for a brief period. We have corrected the situation and we apologize for the confusion it may have caused.

We will address this comment by having our primary support contractor review the current and incoming Qs and As to look for opportunities to incorporate answers into the Specifications Manual where appropriate. We strive to maintain high quality Qs and As that stakeholders can use as a reference for chart abstraction and measure specifications.

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 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. To meet these requirements, data that a hospital has submitted for the Hospital OQR Program are typically provided to hospitals for a preview period via QualityNet, and then displayed on CMS Web sites such as the *Hospital Compare* Web site, *http://www.hospitalcompare.hhs.gov* following the preview period. The *Hospital Compare* Web site is an interactive Web tool that assists beneficiaries by providing information on hospital quality of care. We believe this information motivates beneficiaries to work with their doctors and hospitals to discuss the quality of care hospitals provide to patients, thus 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 CMS Certification Number (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. That is, in a situation in which a larger hospital has taken over ownership of a smaller hospital, the smaller hospital's CCN will be replaced by the larger hospital's CCN (the principal CCN). For data display purposes, we will only display data received under the principal CCN. If both hospitals are submitting data, those data are not distinguishable in the warehouse; and the data is calculated together as one hospital.

Consistent with our current policy, we make Hospital IQR and Hospital OQR data publicly available whether or not the data have been validated for payment purposes. The *Hospital Compare* Web site currently displays information covering process of care, structural, ED throughput timing, health IT, and imaging efficiency measure data under the Hospital OQR Program.

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, memoranda, Hospital Open Door Forums, national provider calls, and QualityNet announcements regarding the release of preview reports followed by the posting of data on a Web site other than *Hospital Compare.*

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: One commenter urged CMS to continue to use both stakeholders and focus groups to develop and evaluate terminology to present user-friendly measurement data on *Hospital Compare.* The commenter believed this procedure would help to decrease misinformation and unnecessary alarm to patients. Another commenter questioned the value of the ''old'' data and the ''outdated time-frame of data collection period'' presented in *Hospital Compare,* in facilitating health care decisions by Medicare beneficiaries.

Response: On *Hospital Compare,* we strive to provide consumers with meaningful information that they can use to help make healthcare decisions. When warranted, we use formative consumer testing to assure the language and display of information makes sense to consumers before posting. Formative testing allows CMS to adjust displays and language so that they are more meaningful to consumers based on consumer feedback. At the same time, we believe that it is critical to maintain the integrity of the measure intent, thereby not simplifying the data too much as to risk making the information so general that it is not meaningful.

The data we publicly report do not all have the same performance period. For example, the process-of-care measures are collected quarterly and are displayed as a rolling four quarters of data on *Hospital Compare.* We allow 4 to 4.5 months after the reporting quarter for hospitals to submit their complete data to the CMS clinical data warehouse. In contrast, the outcomes measures are calculated using 3 years of data from Medicare fee for service claims.

Comment: One commenter was concerned that the display of the acceptable quality range and benchmarks publicly reported for the Outpatient Imaging Efficiency (OIE) measures may cause unnecessary alarm to consumers.

Response: We appreciate the commenter's concerns. To provide meaningful performance benchmarks, we will emphasize the ''within range'' rates and facility outlier results in a facility's public reporting so as to minimize the potential for negatively affecting access to imaging services. In addition, we continue to use both stakeholder and focus groups for developing and evaluating terminology for presenting measurement data to the public, in order to avoid misleading or alarming patients unnecessarily.

B. Process for Retention of Hospital OQR Program Measures Adopted in Previous Payment Determinations

In past rulemakings, we have proposed to retain previously adopted measures for each payment determination on a year-by-year basis and invited public comments on the proposal to retain such measures for all future payment determinations unless otherwise specified. In the CY 2013 OPPS/ASC proposed rule (77 FR 45178), for the purpose of streamlining the rulemaking process, beginning with this rulemaking, we proposed that when we adopt measures for the Hospital OQR Program beginning with a payment determination and subsequent years, these measures are automatically adopted for all subsequent year payment determinations unless we propose to remove, suspend, or replace the measures. We invited public comment on this proposal.

Comment: Some commenters recognized the importance of stability and consistency in the Hospital OQR Program set and supported the proposed automatic retention of Hospital OQR Program measures adopted in a previous year for subsequent payment year determinations. One commenter stated that proposed rulemakings should be devoted to address new changes rather than repeating discussions of continuing measures previously adopted. However, the commenter urged CMS to publish the full list of measures to be continued, in the OPPS/ASC proposed rule each year. The commenter believed publishing the list of measures would provide the public the opportunity to comment and to share experience on current measures.

Response: We appreciate the commenters' recognition of the importance of our goal to streamline the administrative process in rulemaking. As suggested by the commenters, we will continue to publish the full list of measures to be continued in the OPPS proposed rules, for the public to provide input and share experience.

Comment: A few commenters urged that CMS continue to propose all Hospital OQR Program measures adopted, on an annual basis. Commenters were concerned that if measure retention occurs without going through the rulemaking process year by year, irrelevant and obsolete measures may not be removed timely, and the transparency of the rulemaking process will be compromised.

Response: We do not believe the proposed measure retention policy will compromise the transparency in rulemaking or slow down the removal or suspension of problematic measures. Rather, the measure retention policy would enhance administrative efficiency while providing clear expectations to hospital providers. Should we decide there is a need to remove or suspend a measure for concerns of patient safety, we will act expeditiously to remove or suspend the measure between rulemaking cycles. We will notify the public by using memoranda, email blasts distributed through QualityNet, and news postings on the ''Splash page'' on QualityNet. We will thereafter confirm the removal or suspension of the measure through rulemaking.

In the FY 2010 IPPS/LTCH PPS rulemaking, we adopted a process for the Hospital IQR Program for immediate measure removal based on evidence that the continued use of the measure as specified raises patient safety concerns. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60634), we adopted this same policy to be used in the Hospital OQR Program. Furthermore, should we determine that a measure is problematic based upon other criteria stated in the CY 2013 OPPS/ASC proposed rule (77 FR 45178), we will utilize rulemaking to propose the removal or suspension of the measure and obtain public comment prior to determining whether to remove or suspend the measure.

After consideration of the public comments we received, we are finalizing the automatic retention of Hospital OQR Program measures adopted in previous payment determinations for subsequent year payment determinations.

C. Removal or Suspension of Quality Measures From the Hospital OQR Program Measure Set

1. Considerations in Removing Quality Measures From the Hospital OQR Program

In the FY 2010 IPPS/LTCH PPS rulemaking, we finalized a process for immediate retirement of Hospital IQR Program measures based on evidence that the continued use of the measure as specified raises patient safety concerns (74 FR 43864 through 43865). We adopted this same immediate measure retirement policy for the Hospital OQR Program in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60634).

In previous Hospital IQR Program rulemakings, we have referred to the removal of measures from the Hospital IQR Program as ''retirement.'' We have used this term to indicate that Hospital IQR Program measures are no longer included in the Hospital IQR Program measure set for one or more indicated reasons. However, we note that this term may imply that other payers/purchasers/programs should cease using these measures that are no longer required for the Hospital IQR Program. In order to clarify that this is not our intent, we stated in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28034) that we will use the term ''remove'' rather than ''retire'' to refer to the action of no longer including a measure in the Hospital IQR Program. In the CY 2013 OPPS/ASC proposed rule (77 FR 45178), we proposed to adopt the same terminology of ''removal'' in the Hospital OQR Program to indicate our action of discontinuing a measure in the Hospital OQR Program.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50185), we finalized a set of criteria to use when determining whether to remove Hospital OQR Program measures. These criteria are: (1) Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped out'' measures); (2) performance or improvement on a measure does not result in better patient outcomes; (3) a measure does not align with current clinical guidelines or practice; (4) the availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic; (5) the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic; (6) the availability of a measure that is more strongly associated with desired patient outcomes for the particular topic; and (7) collection or public reporting of a measure leads to negative unintended consequences such as patient harm. These criteria were suggested by commenters during Hospital IQR Program rulemaking, and we determined that these criteria are also applicable in evaluating Hospital OQR Program quality measures for removal. In the CY 2013 OPPS/ASC proposed rule (77 FR 45178), we proposed to apply these measure removal criteria in the Hospital OQR Program as well, and we invited public comments on these proposals.

In addition to these criteria, we take into account the views of the Measure Application Partnership (MAP) in the evaluation of measure removal. The MAP is a public-private partnership convened by the NQF for the primary purpose of providing input to HHS on selecting performance measures for certain quality reporting programs and pay for performance programs. The MAP views patient safety as a high priority area and it strongly supports the use of NQF-endorsed measures. Furthermore, for efficiency and streamlining purposes, we strive to eliminate redundancy of similar measures.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45178), we did not propose to retire any measures from the Hospital OQR Program.

Comment: A few commenters agreed with CMS that the term ''removal'' is preferable to ''retirement'' as the measure at issue may still be relevant in other payers/purchasers/programs. The commenters supported all of the proposed measure removal criteria. One commenter noted that CMS should not always choose the availability of measures applicable to a broader patient population as a measure removal criterion, over focused measures targeted at subsets of patient population. The commenter asserted that in some instances, condition-specific measures are warranted.

Response: We thank the commenters for the support of the measure removal criteria. We are cognizant that some focused measures targeted at subsets of patient population are also relevant in the Hospital OQR Program. We want to clarify that before considering the removal of a measure in any given situation, we first assess whether the removal criteria are relevant. We would not be likely to propose the removal of a measure because there is a measure with broader applicability if what we seek to measure requires a more targeted, condition or patient-specific assessment. We might, on the other hand, consider removal of a measure based on the availability of a measure that is more strongly associated with desired patient outcomes for a particular topic, since this might result in a focused measure that is targeted to subsets of patient populations. In any given situation, we will focus only on removal criteria that are relevant to a particular set of circumstances. If more than one of the measure removal criteria appears to be relevant, we intend to take a balanced approach in assessing the value of each of the different criteria in a given situation before removing any measure.

Comment: One commenter requested that besides using CMS program data, CMS should also solicit input from developers and analyze data from EHRs and registries to identify topped-out measures. To avoid the unintended consequence of hospitals not spending resources on specific interventions due to measure removal, one commenter urged CMS to suspend the measures at issue rather than removing measures whenever feasible. In addition, the commenter requested that CMS solicit public input before suspending or removing a measure.

Response: We expect hospitals to always follow appropriate standard of care and clinical guidelines in exercising positive interventions, regardless of whether a measure is being suspended or removed. Should we propose to remove measures using the rulemaking process, we seek input from the public, including measure developers and entities using EHRs to collect the measures. However, in the case of suspension or removal due to patient safety concerns, action would need to be taken quickly and may not coincide with rulemaking cycles. Should this occur, we would seek to suspend measures in situations where we believe the measure can be re-specified in a manner that would not be overly prescriptive or overly burdensome to providers.

Comment: A few commenters urged CMS to closely align its measure removal with the MAP recommendations. The commenters cited as examples of measures that should be removed 7previously adopted Hospital OQR Program measures that are not NQF-endorsed and not recommended by the MAP.

Response: As we have already stated, we consider all of the MAP input we receive, including its recommendations for removal of measures, before making a decision about removing or keeping any particular measure. We did not include any proposals regarding the 7 measures that the commenters mentioned in the CY 2013 OPPS/ASC

proposed rule. As such, we are not making any revisions to these measures in this rulemaking. However, we thank the commenters for these measure removal suggestions and will take them into consideration for future measure removal.

We note that section 1833(t)(17)(C)(i) of the Act requires the Secretary to develop measures that the Secretary determines to be appropriate for the measurement of the quality of care furnished by hospitals in outpatient settings and that reflect consensus among affected parties and, to the extent feasible and practicable to include measures set forth by one or more national consensus building entities. The Act does not require that the measures we adopt for the Hospital OQR Program be endorsed by any particular entity, such as the NQF. In addition, we believe that consensus among affected parties can be reflected by means other than endorsement by a national consensus building entity, including consensus achieved during the measure development process, consensus shown through broad acceptance and use of measures, and consensus through public comment. Finally, the Act does not require us to do more than consider MAP input.

Comment: One commenter inquired about the criteria for resuming data collection for measures that are removed or temporarily suspended from the Hospital OQR Program.

Response: Measures that are removed must be proposed through rulemaking in order to be added back to the program prior to collecting data. For suspended measures, we will strive to align with the regular quarterly collection cycle that has been established for chart-abstracted measures, and we will provide sufficient notice (at least 3 months) prior to resuming collection of suspended measures. We will notify hospitals of resumed collection the same way we notify them of suspension—through QualityNet memoranda and email blasts. We also intend to issue addenda to Specifications Manual releases. However, should we determine that the re-specified measure is substantively changed; that is, changes have been made that affect the underlying quality concepts being measured, we would use rulemaking to formally propose to replace the suspended measure with the modified measure. As we have noted in an earlier response, examples of changes that we might generally consider to be substantive would be those in which the changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent.

After consideration of the public comments we received, we are finalizing the term ''removal'' to indicate future action of discontinuing a measure in the Hospital OQR Program. Also, we are finalizing the adoption of the measure removal criteria used in the Hospital IQR Program for the Hospital OQR Program. We also thank the commenters for the suggestions to keep, remove, or change the status of some of the measures we previously adopted. At this time, we intend to keep the measures as adopted.

2. Removal of One Chart-Abstracted Measure for the CY 2013 and Subsequent Years Payment Determinations

In the FY 2010 IPPS/LTCH PPS final rule (74 FR 43863), we established a precedent to immediately remove a measure from a measure set using a subregulatory notification process followed by subsequent confirmation in rulemaking in situations when there is a reason to believe that continued collection of the measure raises patient safety concerns, and the measure cannot be reasonably revised in a manner that would alleviate the concern without being overly complex. For CY 2013 and subsequent year payment determinations, we are confirming what we stated in our August 13, 2012, memorandum ''Removal of Hospital Outpatient Quality Reporting Measure (OQR) 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'' that we have removed measure OP–16. (To review this memorandum, visit *http://www.qualitynet.org;* from this page, choose ''Hospitals-Outpatient'' from the drop down menus across the top of the page, then click on ''Email-Notifications.'' Memoranda are listed by date of publication.)

We adopted measure OP–16 for the Hospital OQR Program for the CY 2013 payment determination with data collection beginning with January 1, 2012 encounters. However, we are removing OP–16 from the Hospital OQR measure set based on patient safety concerns. On July 11, 2012 the Food and Drug Administration (FDA) issued a Class I recall on several point of care (POC) testing kits, including those that provide Troponin results. The Class I recall was due to an increased frequency of false positive and false negative results. FDA defines a Class I recall as: ''a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.'' The FDA safety alert appears at the following Web site: *http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm311405.htm.*

While OP–16 did not specify which type of laboratory equipment should be used to obtain Troponin results, hospitals may be using these POC tests in order to expedite results. We understand that the FDA considers the size of this recent Class I recall to be large. Due to the magnitude of this recall, we became concerned that continued collection of the measure may potentially impact patient safety because of the high probability of false results associated with the equipment. We chose to remove the measure from the program rather than suspend the measure because revision of the measure to address this issue would result in an overly prescriptive and complex measure. On August 13, 2012, we released a memorandum ''Removal of Hospital Outpatient Quality Reporting Measure (OQR) 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.'' This memorandum notified the Hospital OQR Program stakeholder community to cease chart abstraction for the OP–16 measure immediately, and that CMS will not publically report, validate or use in the CY 2013 payment determination any data collected on this measure. The memorandum dated August 13, 2012 is available for review at the QualityNet Web site. To review this memorandum, access *http://www.qualitynet.org;* from this page, choose ''Hospitals-Outpatient'' from the drop down menus across the top of the page, then click on ''Email-Notifications.'' Memoranda are listed by date of publication.) Since the memorandum was issued, we have received two Congressional inquiries from POC device manufacturers indicating that our decision to remove the measure will impact them negatively. One commenter also indicated that the measure has encouraged increased communication in the Emergency Department and expressed concern that removal of the measure would result in reduced communication.

We emphasize that despite the removal of OP–16 from the Hospital OQR Program, we expect hospitals to continue the timely triage, diagnosis

and treatment of cardiac and other patients in the ED according to established clinical guidelines. We also expect that hospitals will continue their efforts to improve communication and throughput in the ED.

Although we have requested immediate discontinuation of chart abstraction for OP–16, CMS is unable to cease data collection in the system until January 1, 2013, when we have made certain system changes. In order to overcome CMS's system limitation, hospitals can choose to submit a meaningless value for this measure through December 31, 2012. We ask hospitals not to submit a blank value for OP–16, as a lack of a populated value for OP–16 will cause a case to be rejected. If a case is rejected due to lack of data, this could impact a hospital's ability to meet the Hospital OQR requirements. Some vendors may have the capability to provide a default value for OP–16. Hospitals are encouraged to work with their vendors to determine options to populate the OP–16 data field at submission.

Comment: A few commenters supported the removal of OP–16 and believed that there was insufficient evidence to link this process measure to patient outcomes. However, some commenters were concerned that the removal of OP–16 may undermine the importance of Troponin testing or the need to receive the results of Troponin testing in a timely manner. Commenters asserted that clinical guidelines for the diagnostic evaluation of patients with AMI or presumed cardiac chest pain still recommend receiving results from cardiac marker testing, including Troponin, within 60 minutes. The commenters urged that CMS either reconsider the removal of OP–16 or provide guidance on when the measure will be reinstated. Commenters added that currently, there are new and improved Troponin testing technologies available that would meet the intent of OP–16.

Response: We thank the commenter for the support of the removal of this measure. We also clarify that hospitals should not cease testing Troponin and other cardiac markers, nor should they cease following clinical guidelines for diagnosis and treatment of cardiac patients based on our decision to remove OP–16 from the Hospital OQR Program. We are considering initiating a call for measures for this program, and will consider suggestions for measures on this and other topics that are submitted through such a process for future rulemaking.

Comment: A few commenters perceived the CMS' instruction to submit a blank value for OP–16 to be burdensome and stated that hospitals or their vendors should not have to bear the responsibility of submitting meaningless data. Commenters urged CMS to work with contractors to derive a technical solution that would not require hospitals to submit meaningless data.

Response: As we stated in our memorandum, we urge hospitals to work with their data submission vendors on low-burden ways to populate fields for measures that are suspended or removed until such time as our system changes can be made. In the case of OP–16, this will be January 1, 2013. We have asked our systems developers to add functionality to remove a measure from the data collection system without any delay and this feature will be incorporated into a future release of our hospital reporting data collection system. In addition, we have added a business requirement for our contractor to fix this as soon as possible and it has been prioritized as high as possible given all the competing demands on contract programmers.

We are confirming the removal of measure 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 from the Hospital OQR Program in this final rule with comment period.

3. Suspension of One Chart-Abstracted Measure for the CY 2014 and Subsequent Years Payment Determinations

In April of this year, we took immediate action to suspend OP–19 because of patient safety concerns. We chose to suspend this measure rather than to immediately remove the measure from the program because the probability of harm occurring was relatively low, any potential harm that occurred would not be the direct result of patient care rendered at facilities, and the measure steward believed that the measure could be quickly re-specified in a manner that would mitigate the concerns raised by hospitals and stakeholders.

For CY 2014 and subsequent year payment determinations, we are confirming that we have suspended the collection of measure OP–19: Transition Record with Specified Elements Received by Discharged ED Patients, which specifies patients *or their caregivers* (emphasis added) receive a transition record at the time of ED discharge. We adopted measure OP–19 for the Hospital OQR Program for the CY 2013 payment determination with data collection beginning with January 1, 2012 encounters. Since data collection for this measure began, concerns have been raised about the current measure specifications, including potential privacy concerns related to releasing certain elements of the transition record to a patient who is being discharged from an emergency department or the patient's caregiver. Some examples provided by hospitals of this were the release of sensitive lab results or radiological findings to a parent, spouse, or guardian of a minor patient, or to the responsible party for a physically incapacitated patient.

In regard to the issue of patient safety, there is evidence that, in some cases, following the measure as currently specified could lead to patient harm especially when the medical results relate to pregnancy. During field testing of this measure, some women refused to accept transition records that documented pregnancy results. While it is unclear what motivated these particular women to decline to receive transition records, literature supports a rationale for why pregnant women may be reluctant to receive documentation of pregnancy results; under certain circumstances, pregnancy is associated with increased risk of physical violence from a current or former male partner (Richardson, J. et al., 2002. Identifying domestic violence: cross sectional study in primary care, British Medical Journal).

After consideration of these issues and internal review of the measure specifications, we decided to suspend data collection for OP–19 effective with January 1, 2012 encounters until further notice. On April 2, 2012 we released a memorandum ''Temporary Suspension of Hospital Outpatient Quality Reporting Measure OP–19: Transition Record with Specified Elements Received by Discharged Patients.'' This memorandum notified the Hospital OQR Program stakeholder community that we had suspended data collection for the OP–19 measure effective with January 1, 2012 encounters and until further notice.

On April 12, 2012, we released a memorandum, ''Revised: Temporary Suspension of Hospital Outpatient Quality Reporting Measure OP–19: Transition Record with Specified Elements Received by Discharged Patients'' to make clear our intent not to use any data submitted on this measure for payment determinations, public reporting, or in validation. The revised SDPS Memo is available for review at the QualityNet Web site (*http://www.qualitynet.org*) under the option

''Email Notifications'' within the ''Hospitals—Outpatient'' drop down menu found at the top of the page.

When NQF completes its maintenance review on this measure, and we have incorporated the necessary changes to the measure specifications in our measure manual, we anticipate being able to resume data collection, and will notify hospitals of changes in the suspension status of the measure for Hospital OQR via email blast.

Because CMS system constraints prevent immediate cessation of data collection, hospitals must continue to submit information for this measure during this temporary suspension. The data collection system currently requires a populated value for OP–19. During the period of time that the measure is suspended, hospitals may choose to populate their OP–19 submission field with a value that is not meaningful. Hospitals should not submit a null value because the lack of data for OP–19 will cause the submitted case to be rejected entirely from the data warehouse. In other words, failure to populate the OP–19 field could compromise reporting data for other measures for that same case because more than one measure can be reported within a single case.

Some vendors may have the capability to provide a default value for this measure to reduce data abstraction. Hospitals are encouraged to work with their vendors to determine options to reduce abstraction burden.

If a case is rejected from the data warehouse on the basis of a system error due to the current system's inability to accept a case without OP–19 data populated, in the event that the rejected case would have also fulfilled reporting requirements for one or more other measures, this rejection would could affect a hospital's ability to meet Hospital OQR Program requirements.

Therefore, we recommend continuing to submit a value for OP–19, although we will not use data submitted on OP–19 for payment determinations, will not publicly report these data, and will not validate these data until all concerns are resolved and measure specifications are refined as necessary.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45178), because the developer is working to revise the measure specifications to address the concerns raised by affected parties, and the measure is undergoing NQF maintenance review this year, we did not propose to remove the measure from the program at this time. After completion of the NQF maintenance process, we anticipate that normal program operations for this measure could resume once we have updated the Hospital OQR Specifications Manual and made any necessary changes to our data collection infrastructure. However, should we determine that these concerns cannot be addressed, we would propose to remove this measure in a future OPPS/ASC rule. We invited public comment on the suspension of OP–19 until further notice. We also invited public comment on whether the measure should be removed from the program at this time.

Comment: A few commenters strongly urged CMS to retain the OP–19 measure, with the ongoing revision of the measure specifications to address privacy concerns.

Some commenters advocated the removal of this measure on grounds that are completely different from CMS's rationale for removing this measure. Some commenters were concerned that many patients may not be able to comprehend most of the data elements (for example, lab tests and results, and procedures performed in the ED) required by the measure, which would be in the transition record. Many commenters believed that the provision of transition records by EDs would not enhance coordination between sites of care. Rather, the commenters stated it will increase the likelihood of confusion for the patients. Commenters were concerned that: (1) the transition records including instructions issued upon ED discharge are not final and may be changed subsequently by the observation unit staff, should the patient be put in the observation unit; and (2) the ED transition records may conflict with the subsequent transition record provided by the receiving provider, such as the home health care agency. In the commenters' view, the Emergency Medical Treatment and Labor Act (EMTALA) regulation already provides for the transfer of records that include communication between nurses and physicians. Some commenters suggested the provision of a simplified, user-friendly ED visit summary to patients would be a better alternative.

A few commenters requested clarification of the data elements specified in the Specifications Manual: major procedures and tests; patient instructions; follow up care; ED patient population; and medication types. Commenters stated that the data elements specified in the Specifications Manual are too vague and leave room for different interpretation. One commenter recommended creating individual measures to address each of the items that need to be included in the ED visit summary.

One commenter requested limiting the transition record information to include only diagnostic test procedures performed in the ED. One commenter did not view patients put on observation as ED patients and requested they be treated as exclusions in the measure specification. These commenters did not discuss their reasons for requesting these changes.

One commenter stated that currently, since hospitals are at different stages of implementing electronic health records technology, the time taken to generate electronic transition records will vary greatly. For some hospitals, this may potentially delay the discharge of patients from the ED.

Response: We appreciate the support and the recommendations from the commenters. As for the comments on clarification of data elements in the Specifications Manual, we note that there are no specific requirements related to what constitutes appropriate documentation that must be transferred to the next site of care.

We are aware of the concerns expressed by the commenters. Since the suspension of OP–19 on April 2, 2012, we have been actively working with the American Medical Association Physician Consortium for Performance Improvement (AMA–PCPI) (the measure stewards) to clarify the specifications of this measure. The intent of OP–19 is to require a transition record to patients discharged directly to home or home health, not those patients who would otherwise be transferred to an acute care facility, regardless of EMTALA status. It is our hope that the revised specifications will address the commenters' concerns prior to reinstatement of the measure in the Hospital OQR Program.

Comment: Many commenters perceived the submission of a blank value for OP–19, as requested by CMS, to be burdensome and stated that hospitals or their vendors should not have to bear the responsibility of submitting meaningless data. Commenters requested that CMS refine specifications so that hospitals do not have to submit meaningless data.

Response: As we stated in our April 12, 2012 revised memorandum, we urge hospitals to work with their data submission vendors on low-burden ways to populate fields for measures that are suspended or removed until such time as our system changes can be made.

We are confirming the suspension until further notice of measure OP–19: Transition Record with Specified Elements Received by Discharged ED Patients, effective with January 1, 2012

encounters. We are working with the measure steward, the AMA, to enhance OP–19 for future use. When the measure specifications have been updated and reviewed by the NQF, we will consider implementation of the revised measure.

4. Deferred Data Collection of OP–24: Cardiac Rehabilitation Measure: Patient Referral From an Outpatient Setting for the CY 2014 Payment Determination

In the CY 2012 OPPS/ASC final rule with comment period, we finalized OP–24: Cardiac Rehabilitation Measure: Patient Referral From an Outpatient Setting for the CY 2014 payment determination and indicated that the applicable quarters for data collection for this measure would be 1st quarter CY 2013 and 2nd quarter CY 2013 (76 FR 74464, 74481). In order for us to adhere to this data collection schedule, we would have needed to have published the measure specifications in the July 2012 release of the Hospital OQR Specifications Manual. While there are NQF-endorsed specifications for this measure, in order to implement standardized data collection on a national scale, we must include detailed abstraction instructions for chart-based measures in our Specifications Manual. These instructions were not completed and tested in time to include in the July 2012 release of the Specifications Manual, which includes collection instructions for measures beginning January 1, 2013. This was an unanticipated delay in implementation that we do not expect to be a regularly occurring issue for the Hospital OQR Program.

Therefore, in the CY 2013 OPPS/ASC proposed rule (77 FR 45179), we proposed to defer the data collection for this measure to January 1, 2014 encounters. We also proposed that the measure would no longer be used for the CY 2014 payment determination, and that its first application would be for the CY 2015 payment determination. The data collection deferral for this measure is detailed in the ''Form, Manner, and Timing'' section of this final rule with comment period. We invited public comments on these proposals.

Comment: Many commenters supported the proposed deferred data collection of this measure until detailed instructions for data collection are completed. Commenters believed the measure is beneficial for patients with cardiovascular diseases and they were hopeful that the measure could be included into the Hospital OQR program for implementation beginning with January 1, 2014 encounters.

Response: With the inclusion of the abstraction instructions for this chart-abstracted measure in our July 2013 release of the Specifications Manual, we anticipate that data collection can begin with January 1, 2014 encounters.

Comment: One commenter asked if the data for this measure could be collected through claims instead of chart-abstraction. Also, the commenter viewed this measure as merely documentation of a referral being offered as the patient could have refused the referral to enroll in a cardiac rehabilitation program.

Response: This measure cannot be collected via claims because patient referral is not captured in claims data. We recognize that this measure does not focus on whether the patient actually enrolls in a cardiac rehabilitation program. Rather, the measure focuses on the process of referring a patient to a cardiac rehabilitation or secondary prevention program.

Comment: One commenter requested clarification on: (1) What setting will be included in the denominator for the measure population; (2) definition of an outpatient practice; and (3) definition of an outpatient clinic practice. The commenter interpreted the measure specification developed by the American Association of Cardiovascular and Pulmonary Rehabilitation, American College of Cardiology Foundation, and the American Heart Association (AACVPR/AACF/AHA) Task Force to mean that the measure is intended for physicians providing follow-up care to patients after an acute event, and not for hospital outpatient department care. The commenter, therefore, suggested the removal of the current OP–24 measure and adoption of the measure ''Cardiac Rehabilitation Patient Referral from an Inpatient Setting'' for the Hospital OQR Program.

Response: We intend to operationalize the measure for patients seen for ongoing care at outpatient clinics affiliated with hospitals. The measure is designed for the outpatient setting and the denominator is intended to be the percentage of patients who had a qualifying event/diagnosis during the previous 12 months and have not participated in an outpatient cardiac rehabilitation program. Given the measure focus on the process of referring a hospital outpatient clinic patient to a cardiac rehabilitation program, we expect it will incentivize Hospital Outpatient Departments (HOPDs) to better coordinate the care that their patients receive. We agree that the measure could also be appropriate as a measurement for physicians' follow-up care. We are currently working on the definitions the commenter has requested, outpatient practices and outpatient clinic practices, in the context of the HOPD.

After consideration of the public comments we received, we are finalizing the deferred data collection for OP–24 from January 1, 2013 to January 1, 2014 encounters for the CY 2015 payment determination.

D. Quality Measures for the CY 2015 Payment Determination

We previously finalized 26 measures for the CY 2015 Hospital OQR Program measure set in the 2012 OPPS/ASC rulemaking (76 FR 74472 through 74474).

In the CY 2013 OPPS/ASC proposed rule (77 FR 45179), taking into consideration the time and effort for CMS to develop, align, and implement the infrastructure necessary to collect data on the Hospital OQR Program measures and make payment determinations, as well as the time and effort on the part of hospital outpatient departments to plan and prepare for reporting additional measures, we did not propose any additional quality measures for CY 2015 and subsequent years payment determinations in this rulemaking.

As discussed above, we have removed OP–16 as of August 2012, we suspended measure OP–19 and deferred data collection for OP–24 until the measure specifications can be further refined.

In summary, in this final rule with comment period, we are not adopting additional measures for the CY 2015 payment determination, and we are retaining 25 of the 26 measures previously adopted for the CY 2014 payment determination for CY 2015 and subsequent year payment determinations.

Set out below are the previously adopted measures which we are retaining for the CY 2014, CY 2015, and subsequent years payment determinations under the Hospital OQR Program.

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Hospital OQR Program Measures for the CY 2014, CY 2015 and Subsequent Year 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-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 ED 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

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

Hospital OQR Program Measures for the CY 2014, CY 2015 and Subsequent Year Payment Determinations

Procedure Category	Corresponding HCPCS Codes
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

*Information for OP-15 will not be reported in Hospital Compare in 2012. Public reporting for this measure would occur in July 2013 at the earliest.
**Data collection for OP-19 was suspended effective with January 1, 2012 encounters until further notice.
***Data collection for OP-24 would begin on January 1, 2014, and its first application toward a payment determination will be for CY 2015 rather than CY 2014.

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Comment: Many commenters commended CMS' pausing in the expansion of the Hospital OQR Program by not proposing any new measures for the CY 2014 and CY 2015 payment determinations. Commenters appreciated CMS' recognition of burden from quality reporting on providers.

Response: We thank the commenters for supporting our decision not to add any new measures. We plan to continue to find ways to strike a balance between quality reporting and burden reduction for providers.

We received comments on some of the previously finalized measures that we have proposed to continue using under the Hospital OQR Program.

Comment: Commenters expressed support and opposition to the adopted measures from previous rulemakings. Commenters also provided suggestions on these measures, regarding measure implementation, adding exceptions, and revising measure specifications.

Response: We thank the commenters for their comments; those supporting our previously finalized proposals as well as those in opposition. We will consider all of these views for future rulemaking and Hospital OQR Program development.

E. Possible Quality Measures Under Consideration for Future Inclusion in the Hospital OQR Program

The current measure set for the Hospital OQR Program includes measures that assess process of care, imaging efficiency patterns, care transitions, ED throughput efficiency, the use of HIT care coordination, patient safety, and volume. We anticipate that as EHR technology evolves and more infrastructure is put into place, we will have the capacity to accept electronic reporting of many clinical chart-abstracted measures that are currently part of the Hospital OQR Program using certified EHR technology. We work diligently toward this goal. We believe that this future progress at a future date, such as FY 2015, would significantly reduce the administrative burden on hospitals under the Hospital OQR Program to report chart-abstracted measures. We recognize that considerable work needs to be done by measure owners and developers to make this possible with respect to the clinical quality measures targeted for e-specifications. This includes completing electronic specifications for measures, pilot testing, reliability and validity testing, and implementing such specifications into certified EHR technology to capture and calculate the results, and implementing the systems.

We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the hospital outpatient setting. Therefore, through future rulemaking, we intend to propose new measures that help us further our goal of achieving better health care and improved health for Medicare beneficiaries who receive health care in hospital outpatient settings. In addition, we are considering initiating a call for input to assess the following measure domains: clinical quality of care; care coordination; patient safety; patient and caregiver experience of care; population/community health; and efficiency. We believe this approach will promote better care while bringing the Hospital OQR Program in line with other established quality reporting and pay for performance programs such as the Hospital IQR Program.

We invited public comment on this approach and on our suggestions and rationale for possible quality measures for future inclusion in the Hospital OQR Program.

Comment: One commenter noted that it is important to address the priority areas in the National Quality Strategy; however, the commenter also suggested that measure selection should not be limited to only those that fall inside the six domains, as this would hinder improvement in other areas in HOPDs.

Response: We note that the six domains of measurement that arise from the six priorities of the National Quality Strategy are some of our considerations in measure selection. We also weigh other aspects of measures as delineated in our measure selection criteria.

Comment: A few commenters strongly supported CMS in considering whether to initiate a call to get input to assess the measure domains. One commenter requested that CMS use the same process used in past rulemakings by providing a list of measures under consideration for future years for public input.

Response: In the past, we have solicited comments on a list of measures in the rule that are under consideration for future years of the program. Although we did not provide a list in this year's rulemaking, we will take this comment under consideration in future years.

In addition, we will consider hosting a call for measures for the Hospital OQR Program in the future.

Comment: Commenters suggested that CMS add the following measures to the Hospital OQR Program: a comprehensive ''medication

management'' measure set; a system of care metric that looks at the overall median time to PCI in transferred patients to capture the entire process of care; a stroke measure set for outpatients; measures for diabetes care, congestive heart failure, heart attack, breast cancer detection rate, central-line associated blood stream infection, chronic obstructive pulmonary disease, coronary artery disease, and depression screening.

Response: We thank the commenters for the input on future measures and will take them into consideration in future measure selections.

Comment: One commenter strongly encouraged CMS to adopt registry-based measures for which providers submit quality data directly to a registry instead of to CMS.

Response: We thank the commenter for the recommendation for registry reporting. We intend to continue considering how registry reporting may be leveraged as a reporting mechanism for this and other quality programs.

Comment: A few commenters recommended that for burden reduction, CMS should harmonize measures in the Medicare and Medicaid EHR Incentive Programs and the Hospital OQR Program as well as limiting adopting future measures to e-specified measures only.

Response: As we stated previously, coordinated efforts to align measures in the Medicare and Medicaid public reporting programs and incentive payment systems have been ongoing, and we are working toward the eventual adoption of electronically-specified measures so that data can be calculated and submitted via certified EHR technology with minimal burden.

Comment: One commenter recommended that CMS refrain from adopting claims-based measures which the commenter believed are purely administrative in nature and yield little value in measuring quality of care.

Response: While we recognize the merits of chart-abstracted measures, we also believe that claims may still be needed to identify prior events and diagnosis for measures that require look-back periods, involving the matching of data for a single patient over a long period of time (for example, 1 year of prior history) across multiple settings. Claims-based measurement facilitates the use of historical and longitudinal information on Medicare beneficiaries across providers.

Comment: Commenters also expressed views and provided suggestions regarding additional topics and previously finalized proposals including:

- Topped-out measures;
- ED measures;
- Outpatient imaging efficiency measures; and
- Removal of additional adopted measures.

Response: We appreciate the commenters' views on these additional topics or our previously finalized measures. However, these additional topics were not the subject of our proposed rule. It is our policy to retain previously adopted measures unless we specifically propose to remove or suspend measures, or take action outside of rulemaking to do so for patient safety reasons. We will consider these suggestions in future Hospital OQR Program development.

F. Payment Reduction for Hospitals That Fail To Meet the Hospital OQR Program Requirements for the CY 2013 Payment Update

1. Background

Section 1833(t)(17) of the Act, which applies to subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act), states 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 will incur a 2.0 percentage point reduction to their Outpatient Department (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 that meet the reporting requirement 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 found in Addendum B of 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, OPPS outlier payments made for high cost and complex procedures 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), in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72099), and in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74478). 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 2013

In the CY 2013 OPPS/ASC proposed rule (77 FR 45182), 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 2013 annual payment update factor. For the CY 2013 OPPS, the reporting ratio is 0.980, calculated by dividing the reduced conversion factor of $69.887 by the full conversion factor of $71.313. We proposed to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. For the CY 2013 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,'' ''V,'' ''U,'' 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 2013 proposal to apply the Hospital OQR Program reduction in the manner described above and, therefore, are finalizing our proposal, without modification.

Therefore, for the CY 2013 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 Hospital OQR Program 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 Hospital OQR Program 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.

G. Requirements for Reporting of Hospital OQR Data for the CY 2014 Payment Determination and Subsequent Years

1. Administrative Requirements for the CY 2014 Payment Determination and Subsequent Years

In order 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 administrative requirements for the payment determination requirements for the CY 2013 and subsequent years' payment updates in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74479 through 74487).

In the CY 2013 OPPS/ASC proposed rule (77 FR 45182), with respect to the payment determinations for CY 2014 and subsequent years, we proposed one modification to these requirements. Under current requirements, CMS deadlines for hospitals to submit notice of participation forms are based on the date identified as a hospital's Medicare acceptance date on the CMS Certification and Survey Provider Enhanced Reporting (CASPER) system. Deadlines are based on whether a hospital's Medicare acceptance date falls before January 1 of the year prior to the annual payment update, or on or after January 1 of the year prior to the annual payment update (for example, 2013 would be the year prior to the affected CY 2014 annual payment update). Currently, for a hospital whose Medicare acceptance date is before January 1 of the year prior to the affected payment update affected, the notice of participation form is due by March 31 of the year prior to the affected annual payment update (76 FR 74479 through 74480). We proposed to extend this deadline for hospitals, as described below.

Hospitals with Medicare acceptance dates before January 1 of the year prior to the affected annual payment update: For the CY 2014 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, 2013 would be the year prior to the affected CY 2014 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 July 31, rather than March 31, of the year prior to the affected annual payment update. We proposed a deadline of July 31 to give hospitals the maximum amount of 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 chart-abstracted data for the first quarter of the year's services which are due August 1.

We invited public comment on this proposed modification to Hospital OQR Program administrative requirements for the CY 2014 and subsequent years' payment determinations.

Comment: Several commenters supported the proposal to extend the deadline to submit a participation form for a hospital that is not currently participating in Hospital OQR and wishes to participate in OQR to July 31, rather than March 31, of the year prior to the affected annual payment update.

Response: We thank these commenters for supporting our proposal to extend the deadline for submitting a participation form for a hospital that is not currently participating in Hospital OQR and wishes to participate.

After consideration of the public comments received, we are finalizing our proposal to extend the deadline for a hospital that is not currently participating in the Hospital OQR Program and wishes to participate in the Program to submit a participation form by July 31, rather than March 31, of the year prior to the affected annual payment update.

2. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program for the CY 2014 Payment Determination and Subsequent Years

a. Background

In the CY 2013 OPPS/ASC proposed rule (77 FR 45182), we did not propose any additional measures for the CY 2014 payment determination year. 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 finalized for the CY 2011 payment determination (74 FR 60637); 15 measures finalized for the CY 2012 payment determination (75 FR 72083 through 72084); 23 measures finalized for the CY 2013 payment determination (75 FR 72090); and 26 measures finalized for the CY 2014 and CY 2015 payment determinations (76 FR 74469 and 74473).

Because of the clarification in the measure table in section XV.D above that public reporting for OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache is not planned until July 2013 at the earliest, we confirm this measure will not be used in the CY 2014 payment determination. We will confirm our intent to include or exclude this measure in the CY 2015 payment determination in future rulemaking.

We refer readers to section XV.C.2 of this final rule with comment period for a discussion of measure 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. Due to a patient safety concern, this measure has been removed from the OQR Program measure set.

We refer readers to section XV.C.3. of this final rule with comment period for a discussion of measure OP–19: Transition Record with Specified Elements Received by Discharged ED Patients. Because the data collection for this measure is currently suspended, this measure will not be used in the CY 2014 payment determination. We will indicate whether data collection for this measure will resume in time for the CY 2015 payment determination in future rulemaking.

We refer readers to section XV.C.4. of this final rule with comment period for a discussion of measure OP–24: Cardiac Rehabilitation Patient Referral From an Outpatient Setting. We proposed not to use this measure in the CY 2014 payment determination and deferred data collection for this measure until the CY 2015 payment determination.

b. General Requirements

In the CY 2013 OPPS/ASC proposed rule (77 FR 45183), we proposed to continue the policy 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. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74480 through 74482) for a discussion of these requirements.

c. Chart-Abstracted Measure Requirements for CY 2014 and Subsequent Payment Determination Years

The table in section XV.D. of this final rule with comment period includes measures that are collected by abstracting the information from patient charts. In this final rule with comment period, we are confirming removal of one chart-abstracted measure from the program, OP–16: Troponin Results for Emergency Department acute myocardial infarction (AMI) patients or chest pain patients (with Probable Cardiac Chest Pain) Received Within 30 minutes of Arrival. For a full discussion of this removal, please refer to section XV.C.2. of this final rule with comment period.

Comment: Several commenters supported the proposal not to collect data for measures that CMS proposed to exclude from the CY 2014 payment determination.

Response: We thank the commenters for supporting our proposal regarding collection of data for measures which are to be excluded from the CY 2014 payment determination. A discussion of measures that are under review or have been removed from the program is found in section XV.C. above.

After consideration of the public comments received, we are finalizing our proposal to exclude chart abstracted measures OP–19 and OP–24, from the CY 2014 payment determination. In addition, in this final rule with comment period, we are confirming the removal of chart-abstracted measure OP–16. Thus, the following chart-abstracted measures remain in the Hospital OQR Program and data for these measures is required for the CY 2014 payment determination:

- 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–18: Median Time from ED Arrival to ED Departure for Discharged ED 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

Of those measures for which we proposed to collect data for in CY 2014, the form and manner for submission of one of these measures, OP–22: ED Patient Left Without Being Seen, is unique, and the form and manner for this measure is detailed in section XV.G.2.f. of this final rule with comment period.

For the chart-abstracted measures for which we have finalized that we will collect data for the CY 2014 payment determination, we proposed that the applicable quarters for data collection would be as follows: 3rd quarter CY 2012, 4th quarter CY 2012, 1st quarter CY 2013, and 2nd quarter CY 2013 for hospitals that are continuing participants; newly participating hospitals would follow reporting requirements as outlined in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74480) and in section XV.G.1. of this final rule with comment period.

In general, submission deadlines would be approximately 4 months after the last day of each calendar quarter. Thus, for example, the submission deadline for data for services furnished during the first quarter of CY 2013 (January–March 2013) would be on or around August 1, 2013. We proposed to post actual submission deadlines on the *http://www.QualityNet.org* Web site.

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 previously adopted measures which we are retaining for the CY 2014 payment determination, found in the table in section XV.D above. 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.

For the CY 2015 payment determination, we proposed that the applicable quarters for previously finalized chart-abstracted measures would be as follows: 3rd quarter CY 2013, 4th quarter CY 2013, 1st quarter CY 2014, and 2nd quarter CY 2014.

Hospitals that did not participate in the CY 2014 Hospital OQR Program, but would like to participate in the CY 2015 Hospital OQR Program, and that have a Medicare acceptance date on the CASPER system before January 1, 2014, would begin data submission with respect to 1st quarter CY 2014 encounters using the previously adopted measures which we are retaining for the CY 2015 payment determination, found in the table in section XV.D above. For those hospitals with Medicare acceptance dates on or after January 1, 2014, data submission must begin with the first full quarter following the submission of a completed online participation form. We invited public comments on these proposals.

Comment: Some commenters encouraged CMS to improve alignment among CMS quality reporting programs; specifically, they would like to see alignment of data submission deadlines and encounter/discharge periods. These commenters urged CMS to review its programs for opportunities to harmonize program design. These commenters stated their belief that aligning program design and measures supports stakeholders in fulfilling CMS' requirements, whereas lack of alignment results in stakeholders competing for resources to fulfill requirements.

Response: We thank these commenters for their suggestions. We agree that end users and stakeholders, especially those that fulfill reporting requirements for multiple programs, would benefit from standardized program requirements.

Besides the Hospital OQR Program, we have a significant number of quality data reporting or incentive programs. Currently, we are working on integrating the Hospital OQR, Hospital Inpatient Quality Reporting (IQR) Program, and the Hospital Value-Based Purchasing (VBP) Program more fully to meet the requirements of the Health Information Technology for Economic and Clinical Health Act. This statute promotes driving transformation through the adoption and use of health information technology (HIT), electronic health records (EHR) and health information organizations (HIOs)

We agree with commenters that alignment is important to reduce stakeholder burden, and we will also continue to consider opportunities to align program requirements for programs outside of the Hospital OQR, IQR, and VBP Programs.

Comment: Many commenters supported the proposed data submission deadlines for chart-abstracted measures.

Response: We thank these commenters for supporting the proposed deadlines.

After consideration of the public comments we received, we are finalizing our proposals for the applicable quarters for chart abstracted measures for the CY 2014 and CY 2015 payment determinations and for subsequent years. We are finalizing our proposals for submission deadlines for chart abstracted data for the CY 2014 payment determination and for subsequent years, and for posting these deadlines on the QualityNet Web site. We are finalizing our proposals for hospitals who are newly participating or who are resuming participation in the OQR program to submit a notice of participation and begin submitting data to the OQR Program.

d. Claims-Based Measure Data Requirements for the CY 2014 and CY 2015 Payment Determinations

The table in section XV.D. of this final rule with comment period includes

measures that the Hospital OQR Program collects by accessing electronic claims data submitted by hospitals for reimbursement.

OP–15 is a claims-based measure that has not been implemented for public reporting through rulemaking (76 FR 74456), and it is not required for the CY 2014 payment determination.

Therefore, the 6 remaining claims-based measures set out below will be included for the CY 2014 payment determination:

- 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–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)

We will continue our policy of calculating the measures using the hospital's Medicare claims data as specified in the Hospital OQR Specifications Manual; therefore, no additional data submission is required for hospitals. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74483), we stated that for the CY 2013 and CY 2014 payment updates, we will use paid Medicare FFS claims for services furnished from January 1, 2010 to December 31, 2010 and January 1, 2011 to December 31, 2011, respectively.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45184), for the CY 2015 Hospital OQR payment determination, we proposed to use paid Medicare FFS claims for services from a 12-month period from July 1, 2012 through June 30, 2013 for the calculation of the claims-based measures. While this would be a departure from the traditional 12-month calendar year period we have used for these measures, we proposed this period in order to align the data period for inpatient and outpatient claims based measures reported on the *Hospital Compare* Web site, and also to be able to post more recent data for the outpatient imaging efficiency on the Web site. We invited public comment on this proposal.

Comment: Some commenters supported the proposal to move away from the traditional 12-month data period to align the data period for inpatient and outpatient claims based measures reported on the *Hospital Compare* Web site, and also to be able to post more recent data for the outpatient imaging efficiency on the Web Site.

Response: We thank these commenters for supporting our efforts to align the data collection period for the Hospital OQR Program with that of the Hospital IQR Program.

Comment: One commenter questioned why CMS needs such a long delay in claims utilization. This commenter believed that CY 2011 claims are not appropriate to use in the CY 2014 payment determination.

Response: We have proposed to adjust the time period of when services are furnished; doing so moves the period away from the traditional January–December time period to make it six months more current. Regarding the data lag for claims based data, for the CY 2015 payment determination year, we proposed using paid, FFS claims for services during the time period from July 1, 2012 through June 30, 2013. Calculations based on this time period would be publicly reported on *Hospital Compare* in July 2014, and we would make actual payment determinations for the CY 2015 payment year on or around December 1, 2014.

For claims from the period July 1, 2012 through June 30, 2013, the data lag, or time elapsed until payment determination is made, is approximately 17 months at the longest (for data from July 1, 2012) to 5 months at shortest (for data from June 30, 2013). This is due to several factors. First, we allow three months after the last date of service to pass before pulling the data extract for claims based measures in order to ensure that we are capturing most of the final paid claims through the last date of service (in this example, the last date of service is June 30, 2012). Second, it takes three to six months to build our analytic files for the measures, generate calculations, and ensure their accuracy. For some claims-based measures, we generate and deliver detailed confidential reports for hospitals. About two months prior to public reporting, we allow 30 days for hospitals to preview their data, after which we deliver final public reporting files for the *Hospital Compare* Web site.

With our proposal, we believe we have adequately balanced the need for current data with the need to have a stable set of FFS claims data for a payment determination and a preview process that takes into account the needs of hospital stakeholders.

Comment: One commenter believed that there is an inconsistency in the use of Medicare claims versus data from all patients. According to the commenter, CMS stated that it will use only Medicare FFS claims for structural measures, but proposes to use data from all patients (for example, including non-Medicare patients) for other measures.

Response: We do not use Medicare FFS claims for structural measures. For structural measures, hospitals currently review the time period covered in the reporting period to answer questions about registry use, safe surgery checklist use, etc. The structural measures in the Hospital OQR Program apply to the hospital outpatient department setting.

For clarification, the Hospital OQR chart-abstracted 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 FFS claims. The structural measures apply to the hospital outpatient department.

We 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 us to publicly report the quality measure data submitted under the Hospital OQR Program, including measures that we calculate using Medicare claims and all other submitted data, including non-Medicare data.

After consideration of the public comments we received, we are finalizing our proposals for the data periods we will use for claims-based measures for the CY 2014 and CY 2015 payment determinations.

e. Structural Measure Data Requirements for the CY 2014 Payment Determination and Subsequent Years

A summary of the previously finalized structural measures that we require for the CY 2014 and subsequent years payment determinations is set out below:

- 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–17: Tracking Clinical Results Between Visits
- OP 25: Safe Surgery Check List Use
- OP 26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures

We previously finalized that for the CY 2014 payment determination, hospitals will 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. In the CY 2013 OPPS/ASC proposed rule (77 FR 45184), we proposed to extend this submission deadline. Under this

proposed change, for the CY 2014 payment determination, hospitals would be required to submit data on all structural measures between July 1, 2013 and November 1, 2013 with respect to the time period from January 1, 2012 to December 31, 2012. In section XV.G.2.f. of this final rule with comment period, we describe how this proposal would likewise extend the deadline to submit data for OP–22: ED Patient Left Without Being Seen. We proposed to continue this schedule so that, for the CY 2015 payment determination, hospitals would be required to submit data on all structural measures between July 1, 2014 and November 1, 2014 with respect to the time period from January 1, 2013 to December 31, 2013. We invited public comments on these proposals.

Comment: Two commenters supported the change in the 12-month period because it better aligns the reporting period with that of other claims based measures displayed on *Hospital Compare.*

Response: We agree that this alignment is beneficial and we seek to align programs to the extent possible. We are finalizing this policy as proposed.

After consideration of the public comments we received, we are finalizing the proposal that, for the CY 2014 payment determination, hospitals would be required to submit data on all structural measures between July 1, 2013 and November 1, 2013 with respect to the time period from January 1, 2012 to December 31, 2012, and for the CY 2015 payment determination, hospitals would be required to submit data on all structural measures between July 1, 2014 and November 1, 2014 with respect to the time period from January 1, 2013 to December 31, 2013.

f. Data Submission Requirements for OP–22: ED Patient Left Without Being Seen for the CY 2015 Payment Determination

OP–22: ED Patient Left Without Being Seen is a chart-abstracted measure for which aggregate data is collected via a Web-based tool, as previously finalized. In other words, for purposes of data collection, this measure is treated like a structural measure. For this reason, it is collected on the same schedule as the structural measures described above, and, in the CY 2013 OPPS/ASC proposed rule (77 FR 45184) we proposed to extend the submission window for all structural measures, including OP–22. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485), with respect to OP–22, we stated that hospitals would be required to submit data once for the CY 2014 payment determination via a Web-based tool located on the QualityNet Web site. For the CY 2014 payment determination, we proposed that hospitals would be required to submit data, including numerator and denominator counts, between July 1, 2013 and November 1, 2013 (comparable to the submission window that we proposed for the structural measures data collection in the section above) with respect to the time period of January 1, 2012 to December 31, 2012.

For the CY 2015 payment determination, we proposed to continue this policy. Hospitals would be required to submit data between July 1, 2014 and November 1, 2014 with respect to the time period of January 1, 2013 to December 31, 2013. We invited public comment on these proposals.

Comment: Some commenters opposed data collection for OP–22: ED Patient Left Without Being Seen. These commenters noted that OP–22 is not NQF-endorsed and believed it is not a clear measure of quality of care for a variety of reasons: Because there are credible reasons why a patient might choose to leave an ER prior to treatment; the measure disadvantages ED's in areas where an ED is used as a primary care facility; and there are no underlying patient records to validate this data.

Response: We thank the commenters for their feedback. Please refer to section XV.C.1 of this final rule with comment period for a discussion of measure OP–22.

After consideration of the public comments we received, we are finalizing our proposal to extend the data submission window for OP–22.

g. Population and Sampling Data Requirements for the CY 2014 Payment Determination and Subsequent Years

In the CY 2013 OPPS/ASC proposed rule (77 FR 45184), for the CY 2014 payment determination and subsequent years, we proposed to continue our policy that hospitals may submit voluntarily 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, but they will not be required to do so. Where hospitals do choose to submit this data, the deadlines for submission are the same as those for reporting data for chart-abstracted measures, and hospitals may also choose to submit data prior to these deadlines. The deadline schedule is available on the QualityNet Web site. We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72101 through 72103) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74482 through 74483) for discussions of these policies. We invited public comments on these proposals.

Comment: One commenter appreciated the policy that program participants can continue to submit population and sampling data voluntarily.

Response: We believe there is no need to require the submission of population and sampling data due to the high level of voluntary submission of these data.

After consideration of the public comments we received, we are finalizing our policies for population and sampling data requirements for the CY 2014 payment determination and subsequent years.

3. Hospital OQR Program Validation Requirements for Chart-Abstracted Measure Data Submitted Directly to CMS for the CY 2014 Payment Determination and Subsequent Years

a. Random Selection of Hospitals for Data Validation of Chart-Abstracted Measures for the CY 2014 Payment Determination and Subsequent Years

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74484 through 74485), similar to our approach for the CY 2012 payment determination (75 FR 72103 through 72106), we adopted a policy to validate chart-abstracted patient-level data submitted directly to CMS from randomly selected hospitals for the CY 2013 payment determination.

For the CY 2013 payment determination, we reduced the number of randomly selected hospitals from 800 to 450.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45184), we proposed to continue this policy for the CY 2014 payment determination and for subsequent years. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74484) for a discussion of sample size, eligibility for validation selection, and encounter minimums for chart abstracted data submitted directly to CMS from randomly selected hospitals. We invited public comment on this proposal.

Comment: One commenter was pleased that the number of hospitals selected dropped from 800 to 450 for the CY 2013 payment determination.

Response: We thank this commenter for supporting our proposal to maintain the sample size for hospitals selected for validation. We note that in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53552)

the total base sample size of hospitals included in the annual validation random sample has recently been reduced from 800 to 400, to reduce overall burden. For both the Hospital IQR and Hospital OQR Programs, we believe we can reduce the annual random sample size without adversely affecting our ability to infer reliability of the chart-abstracted clinical data submitted to the programs.

After consideration of the public comments we received, we are finalizing our proposal to retain our sample size for hospitals randomly selected for data validation of chart-abstracted measures for the CY 2014 payment determination and subsequent years.

b. Targeting and Targeting Criteria for Data Validation Selection for the CY 2014 Payment Determination and Subsequent Years

In the CY 2011 OPPS/ASC proposed rule (75 FR 46380) we discussed applying, to CY 2013 and subsequent years' data submission, criteria to determine whether a hospital would be included in our validation selection based on abnormal data patterns or a specific situation. At that time we provided, for public comment, specific examples of what we thought could be appropriate criteria.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72106) we stated our belief that the targeting criteria we shared for comment were reasonable. We considered one commenter's concern that we should use targeting criteria to ensure we do not over-select a hospital for validation. We reiterated our intent to propose the specific targeting criteria in the upcoming CY 2012 OPPS/ASC proposed rule (76 FR 42332), in order to finalize and apply it to 2012 encounter data collected for the CY 2013 validation process year. We did so, and finalized our proposal without modification in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485).

In summary, we finalized our intent to select a random sample of hospitals for validation purposes, and to select an additional 50 hospitals based on specific criteria designed to measure whether the data these hospitals have reported raises a concern regarding data accuracy.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45185), for the CY 2014 payment determination and subsequent years, we proposed to continue these policies and to continue to use the targeting criteria finalized previously. Specifically, a hospital will be preliminarily selected for validation based on targeting criteria if it:

- Fails the validation requirement that applies to the previous year's payment determination. For example, if a hospital was selected for validation for the CY 2013 payment determination year, either on a random or targeted basis, and the hospital did not meet the 75 percent validation score for the designated time period, based upon our validation process, for the designated time period, the hospital would be included in the targeted sample pool for the CY 2014 payment determination); or
- Has an outlier value for a measure based on the data it submitted, based on finalized criteria from the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485).

In the CY 2012 OPPS/ASC proposed rule (76 FR 42333) and CY 2012 OPPS/ASC final rule with comment period (76 FR 74486) we describe additional data validation conditions under consideration for the CY 2014 payment determination and subsequent years. We thank those who commented on the CY 2012 proposed additional data validation targeting conditions and will take their views under consideration as we develop any future proposals on these issues. In the CY 2013 OPPS/ASC proposed rule (77 FR 45185), we did not propose any additional targeting criteria to use in selecting the additional 50 hospitals we include in the validation process for CY 2014 payment determination or in subsequent years. We invited public comment on this proposal.

Comment: One commenter believed that CMS quality measures should be based strictly on data derived either through claims or data abstracting on the Medicare population, not on all patients who are treated in the outpatient setting.

Response: Data submitted to the Hospital OQR Program are intended to provide the public with information on as many patients treated in the outpatient hospital setting as possible, including both Medicare and non-Medicare patients. As noted above, however, claims-based data collection is limited to Medicare FFS patients.

The Hospital OQR Program requires this data to be submitted under section 1833(t)(17)(A) of the Act, which applies to hospitals as defined under section 1886(d)(1)(B) of the Act. That provision states that subsection (d) hospitals that do not report data required for the quality measures selected by the Secretary in the form and manner required by the Secretary will not receive the full payment rate update. We modeled the Hospital OQR Program after the Hospital IQR Program.

In order for us to evaluate the care of the Medicare population which is a subset of the entire population, we look at data of the whole population, to ensure Medicare beneficiaries are receiving the same level of care as non-Medicare beneficiaries receive. Because we collect chart-abstracted quality measure data on both Medicare and non-Medicare patients, we believe it is appropriate to establish sampling criteria that apply to the same populations, which include both Medicare and non-Medicare patients.

Comment: One commenter advocated selecting a valid sample based on local practice patterns, desiring inter-rater reliability. This commenter suggested that CMS select all 450 hospitals using criteria that measure whether the data hospitals have reported raises a concern regarding accuracy.

Response: We interpret the commenter to be suggesting that sampling criteria should be refined in order to reflect local practice patterns. Because we use quality measures reflecting national consensus, we do not believe that such further refinement is necessary. Regarding inter-rater reliability, this should not be affected by the criteria used for sample selection.

Comment: One commenter believed that our sample sizes would be acceptable if they were the only Federal data submission requirement. This commenter believed that the records requested by the Hospital OQR Program are in addition to those that are already established as part of the Federal integrity audit processes (for example, RAC, Medicaid Integrity, ZPIC, and MAC). The commenter encourages CMS to review the validation process with respect to other CMS data requirements.

Response: We understand the commenter's concern regarding multiple Federal medical record requests. For Hospital OQR Program validation, we have worked to limit overall burden by reducing the number of hospitals participating annually in validation through our random sampling of hospitals. In addition, hospitals are reimbursed for photocopying and mailing costs. We agree that efforts should be made to keep record requests for validation purposes at the minimum necessary to ensure accuracy of submitted data.

We refer readers to section XV.J. Electronic Health Records (EHRs), below, for a discussion of how Hospital IQR and Hospital OQR Programs are transitioning to the use of certified EHR technology, for measures that otherwise require information from the clinical

record. We look forward to the adoption of EHR technology as a means to reduce burden, allowing us to collect data for measures without the need for manual chart abstraction, and we will explore validating these data in ways that likewise reduce burden to providers.

Comment: One commenter would like CMS to clearly identify whether a record has been requested as a result of random selection or targeted selection.

Response: We interpret this commenter's suggestion to mean that we should indicate whether we selected a hospital for validation as a result of random or targeted selection.

For example, because all hospitals are eligible for random selection, a hospital that failed validation in one payment determination year would not know whether it was selected for validation in the subsequent payment determination year based on random or targeted selection. The hospital might have been selected in either of these categories.

We have refrained from noting on what basis a hospital is selected on public Web sites, since our targeting criteria are based on possible data quality issues.

However, we do have that information available. If a hospital would like to understand why it was selected for validation, the hospital may call the support contractor and request that information. Contact information for the Hospital OQR support contractor is available at *https://qualitynet.org*.

After consideration of the public comments we received, we are finalizing our proposal not to include any additional targeting criteria to use in selecting the additional 50 hospitals we include in the validation process for the CY 2014 payment determination or in subsequent years.

c. Methodology for Encounter Selection for the CY 2014 Payment Determination and Subsequent Years

In the CY 2013 OPPS/ASC proposed rule (77 FR 45185), for each selected hospital (random or targeted), we proposed to continue the approach we adopted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485 through 74486) for the CY 2014 payment determination and subsequent years. For the CY 2014 payment determination, for each selected hospital (random or targeted), we would continue 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 complete supporting medical record documentation that corresponds to the encounter. We refer readers to 42 CFR 482.24(c)(2) for a definition of what is expected in a medical record submitted for validation. The validation process requires full supporting medical documentation, including ECG tapes and/or other pieces of a medical record that may not be stored in a single location. The hospital must ensure a full medical record goes to the contractor for accurate validation.

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 of hospitals per year will be 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 would be validating data from April 1 to March 31 of the year preceding the payment determination year. This provides validation results data in time to use to make the payment determination. For example, encounter data from April 1, 2012 to March 31, 2013 provides a full year of the most recent data possible to validate in time to make the CY 2014 payment determination. We invited public comment on our proposal to continue to use our established methodology for encounter selection and to continue to use our annual schedule for encounters to be validated and used in payment determinations.

We did not receive any public comments regarding our proposal to continue to use our established methodology for encounter selection and our annual schedule for encounters to be validated and used in payment determinations. As a result, we are finalizing our proposal to continue to use our established methodology for encounter selection and our annual schedule for encounters to be validated and used in payment determinations.

d. Validation Score Calculation for the CY 2014 Payment Determination and Subsequent Years

In the CY 2013 OPPS/ASC proposed rule (77 FR 45185) we proposed to retain the medical record return policy that we finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72104) for the CY 2014 payment determination and subsequent years. For the CY 2014 payment determination, we proposed to continue the validation score policies we adopted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74486), for the CY 2013 payment determination. We proposed to use the validation calculation approach finalized for the CY 2012 and CY 2013 payment determinations 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.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45185), for the CY 2014 payment determination and subsequent years, we proposed to use the medical record validation procedure we finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72105). A designated CMS contractor would, for each quarter that applies to the validation, ask each of the selected hospitals to submit medical documentation for up to 12 randomly selected cases submitted to and accepted by the OPPS Clinical Warehouse. The CMS contractor would request paper copies of medical documentation corresponding to selected cases from each hospital via certified mail or another trackable method that requires a hospital representative to sign for the request letter. A trackable method would be used so that we would be assured that the hospital received the request. The hospital would have 45 calendar days from the date of the request as documented in the request letter to submit the requested documentation and have the documentation received by the CMS contractor. If the hospital does

not comply within 30 calendar days of receipt of the initial medical documentation request, the CMS contractor would send a second letter by certified mail or other trackable method to the hospital, reminding the hospital that paper copies of the requested documentation must be submitted and received within 45 calendar days following the date of the initial CMS contractor request. If the hospital does not submit the requested documentation and the documentation is not received by the CMS contractor within the 45 calendar days, then the CMS contractor would assign a ''zero'' score to each data element for each selected case and the case would fail for all measures in the same topic (for example, OP–6 and OP–7 measures for a Surgical Care case).

We proposed that the letter from the designated CMS contractor would be addressed to the hospital's medical record staff identified by the hospital for the submission of records under the Hospital IQR Program (that is, the hospital's medical records staff identified by the hospital to its State QIO). If CMS has evidence that the hospital received both letters requesting medical records, the hospital would be deemed responsible for not returning the requested medical record documentation and the hospital would not be allowed to submit such medical documentation as part of its reconsideration request so that information not utilized in making a payment determination is not included in any reconsideration request.

Once the CMS contractor receives the requested medical documentation, the contractor would independently reabstract the same quality measure data elements that the hospital previously abstracted and submitted, and the CMS contractor would then compare the two sets of data to determine whether the two sets of data match. Specifically, the CMS contractor would conduct a measures level validation by calculating each measure within a submitted case using the independently reabstracted data and then comparing this to the measure reported by the hospital; a percent agreement would then be calculated. The validation score for a hospital would equal the total number of measure matches divided by the total number of measures multiplied by 100 percent.

We invited public comment on our proposals regarding the medical record request policy for the CY 2014 payment determination and subsequent payment determination years.

Comment: Many commenters supported our proposal to continue the 45 day time period for medical record submission. These commenters noted that they appreciated the Hospital OQR Program's consistency with the RAC auditing.

Response: We thank these commenters for their support. We agree that the 45 day time period to submit medical record documentation for validation is reasonable and has the additional benefit of being consistent with RAC medical documentation requests.

To receive the full OPPS OPD fee schedule increase factor for CY 2014, 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 and CY 2013 payment determinations (75 FR 72105 and 76 FR 74486). We also proposed to use the same medical record documentation submission procedures that we also finalized for the CY 2012 and CY 2013 payment determinations (75 FR 72104 and 76 FR 74486). We invited public comments on these proposals.

Comment: One commenter expressed concerns regarding the strict validation of ED throughput measures, and recommended that CMS adopt the 5 minute allowance for the Hospital OQR Program, which was previously adopted for the Hospital IQR Program.

Response: We thank this commenter for expressing this concern. We believe the commenter is referring to our policy requiring validation of measures requiring time values. The commenter is referring to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53549).

We agree with the commenter that requiring time values to match exactly is not realistic based on our historical experience with clinical data abstraction, the recognition that hospital clocks may vary from system to system such that the same time may be recorded differently depending on the source, and the limited clinical significance of small deviations in time. We note that this particular concern affects the validation score for the CY 2014 payment determination as well as for future years.

Accordingly, we are finalizing that, for the CY 2014 payment determination and for subsequent years, we will not require, when scoring the following chart-abstracted measures, that these measures have matching numerator and denominator states:

- OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
- OP–19: Transition Record with Specified Elements Received by Discharged ED Patients (this measure is currently suspended and will not be used in the CY 2014 payment determination. We intend to confirm whether this measure will be included in future payment determinations in future rulemaking).
- 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

Instead, for scoring of these measures, we will allow a 5 minute variance between the time abstracted by the hospital and that abstracted by the Clinical Data Abstraction Center (CDAC).

After consideration of the public comments we received, we are finalizing our proposals as modified regarding the validation score calculation methodology and timeframe for submission of medical record documentation requested for validation.

H. Hospital OQR Reconsideration and Appeals Procedures for the CY 2014 Payment Determination 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 could 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. This process required that a hospital's CEO sign any request for a reconsideration.

In the CY 2011 and CY 2012 OPPS/ASC final rules with comment periods (75 FR 72106 through 72108 and 76 FR 74486 through 75587), we continued this process for the CY 2012 and CY 2013 payment updates with some modification. In the CY 2011 OPPS/ASC final rule with comment period(75 FR 72107), we finalized that the CEO was not required to sign the reconsideration request form.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45186), we proposed to continue this process, with additional modifications, for the CY 2014 payment determination and subsequent years' payment determinations. We have now realized that, in eliminating the requirement that a CEO sign a request form, we did not include any requirement for a signature on the reconsideration request form. To increase accountability, we proposed for the CY 2014 payment determination and subsequent years' payment determinations, that the hospital designate a contact on its reconsideration request form, who may or may not be the CEO. We would communicate with this designee. We also proposed that the hospital's designee must sign its reconsideration request form. This process is consistent with our recently adopted proposals for reconsideration requests under the ASCQR Program (77 FR 53643 through 53644).

Under this 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 2014 payment determination, the request must be submitted by February 3, 2014) 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.
  - Designated hospital personnel contact information, including name, email address, telephone number, and mailing address (must include physical address, not just a post office box). We proposed that the designee, who may or may not be the hospital's CEO, must sign the form submitted to request reconsideration.
  - 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). Hospitals submit this documentation to a designated CMS contractor which has authority to review patient level information. We 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 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 proposed these requirements for the CY 2014 payment determination year program and for subsequent years. We invited public comment on these proposed changes.

Comment: Many commenters supported the proposal that the CEO or designee be able to sign the reconsideration request form.

Response: We thank these commenters for their support.

Following receipt of a request for reconsideration, CMS—

- Provides an email acknowledgement, using the contact information provided in the reconsideration request, to the designated hospital personnel notifying them that the hospital's request has been received.
- Provides a formal response to the hospital-designated personnel, using the contact information provided in the reconsideration request, notifying the hospital of the outcome of the reconsideration process.
- Applies policies that we finalized for the CY 2012 and CY 2013 payment determinations 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 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 of the complete 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 of the complete 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 is initially limited. We would review only to determine whether the medical documentation submitted in response to the designated CMS contractor's request was the correct and complete documentation. If we determine that the hospital did submit the correct and complete medical documentation, we abstract the data elements and compute a new validation score for the encounter. If we conclude that the hospital did not submit the correct and complete medical record documentation, we do 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 45 calendar day timeframe (which we are finalizing in this final rule with comment period), our review is initially limited to determining whether the CMS contractor received the requested medical record documentation within 45 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 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 45 calendar day period, we do not further consider the hospital's request.

If a hospital is dissatisfied with the result of a Hospital OQR reconsideration decision, the hospital is able to file an appeal under 42 CFR Part 405, Subpart R (PRRB appeal).

We invited public comment on the modifications we proposed to the Hospital OQR Program reconsideration and appeals procedures.

Comment: One commenter thanked CMS for fully describing the process for making a reconsideration request.

Response: We thank the commenter and appreciate the support. We agree that the program process for reconsiderations should be clear and fully described.

After consideration of the public comments we received, we are finalizing our proposals to the Hospital OQR Program reconsideration and appeals procedures.

I. Extraordinary Circumstances Extension or Waiver for the CY 2013 Payment Determination 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 a modification to eliminate redundancy in the information a hospital must provide in the request. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74478 through 74479), for CY 2012 and subsequent years, we retained these procedures with one modification. The CY 2012 modification allowed that the original procedures for requesting an extension or waiver of quality data submission would thereafter also extend to include medical record documentation submission for purposes of complying with our validation requirement for the Hospital OQR Program. In the CY 2013 OPPS/ASC proposed rule (77 FR 45187), we proposed to retain these procedures with a modification for CY 2013 and subsequent years.

We proposed to modify one element of the information required on the CMS request form. Under the procedures set out in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74479), hospitals were required to submit ''CEO *and* any other designated personnel contact information'' (emphasis added), the CEO was required to sign the form, and CMS was required to respond to the CEO and additional designated hospital personnel. The information required in CY 2013 and subsequent years would include ''CEO *or* other hospital-designated personnel contact information'' (emphasis added). This proposed change would allow the hospital to designate an appropriate, non-CEO, contact at its discretion. This individual would be responsible for the submission, and would be the one signing the form. Therefore, the hospital's designated-contact may or may not hold the title of CEO. We invited public comment on this proposed modification to the process for granting extraordinary circumstances extensions or waivers for the Hospital OQR Program.

Comment: Many commenters supported the proposal that the hospital should designate its own most appropriate contact for the signing and submission of the extraordinary circumstance extension and waiver form.

Response: We appreciate these commenters' support.

Thus, we proposed that, 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 or other hospital-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 designated contact, whether or not that individual is the 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 an email acknowledgement using the contact information provided in the request notifying the designated contact that the hospital's request has been received;

(2) Provide a formal response to the hospital's designated contact using the contact information provided in the request notifying them of our decision; and

(3) Complete our review of any CY 2013 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. We invited public comments on these proposals.

Comment: One commenter thanked CMS for fully describing the process for making a request for an extension or waiver of program requirements.

Response: We thank this commenter for supporting our efforts.

After consideration of the public comments we received, we are finalizing our proposed modifications to the procedures for requesting an extension or waiver of Hospital OQR Program requirements.

J. 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 electronic clinical quality measures (eCQMs), as they are referred to in the EHR Incentive Program), by sponsoring the creation of electronic specifications for eCQMs under consideration for the Hospital IQR Program. Through the Medicare and Medicaid 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, eCQMs via hospital EHRs for Hospital IQR Program and Hospital OQR Program measures. We expect the Hospital IQR and Hospital OQR Programs to transition to the use of electronic specifications for eCQMs that otherwise require information from the clinical record. This would allow us to collect data for eCQMs 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 for the Hospital IQR Program. We also anticipate such a transition for hospital outpatient measures, although likely somewhat after the transition for hospital inpatient measures. This is because we hope to first align the eCQMs in the Medicare EHR Incentive Program with the Hospital IQR Program measures. 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 many eCQMs based on clinical record data.

As noted below, the Medicare and Medicaid EHR Incentive Programs—Stage 2 final rule (77 FR 54088) requires electronic reporting of eCQMs beginning in 2014 for eligible hospitals and CAHs that are beyond the first year of Stage 1 of meaningful use. Under our timeline for EHR-based submission under the Hospital OQR Program, some eligible hospitals would be in their second year of Stage 2 reporting and these eligible hospitals could be using two methods to report similar information for the Medicare and Medicaid EHR Incentive Programs and the Hospital OQR Program. In the CY 2013 OPPS/ASC proposed rule (77 FR 45188), we stated that we had considered allowing, but not requiring, EHR-based submission at the earliest possible date, so as to reduce the burden of hospitals. We did not propose this approach because we believe that it would not be consistent with our goal that measure results that must be publicly reported should be based on consistent, comparable results among reporting hospitals and because our first priority is the align EHR-based submissions under the Hospital IQR Program. We invited public comment on this issue.

Comment: A few commenters pointed out that the transition from manual to electronic submission is a huge task and could be very labor intensive. Another commenter stated that the timeline to transition to electronic reporting is too aggressive. Some commenters urged CMS to immediately allow data submission via chart abstraction or electronically to ease the burden of quality reporting. Another commenter agreed with CMS's consideration for a full migration to electronic quality measurement and reporting. The commenter stated it is inappropriate to report data using chart-abstraction and electronic submission concurrently in the interim.

Response: We understand the transition to electronic submission is an immense undertaking that requires intense collaboration among stakeholders. As stated earlier, we still believe that public reporting should be consistent and comparable among reporting hospitals. We intend to move toward a full migration to electronic quality measurement and reporting. In addition, the EHR Incentive Program has incorporated eCQMs that are part of various hospital reporting programs, including the Hospital IQR and Hospital OQR Programs, in order to maximize financial incentives to help with this transition.

Comment: One commenter urged CMS to lay out its vision for electronic reporting, stating that it is overly burdensome for hospitals to collect and report data via chart abstraction and electronically.

Response: We have previously stated our vision, including in the Medicare and Medicaid EHR Incentive Programs—Stage 2 final rule (77 FR 54053). We noted that our alignment efforts focus on several fronts including using the same eCQMs for different programs, standardizing the measure development and electronic specification processes across our programs, coordinating quality measurement stakeholder involvement efforts, and identifying ways to minimize multiple submission requirements and mechanisms. We gave the example that we are working toward allowing eCQM data submitted via certified EHR technology (CEHRT) by eligible professionals (EPs), eligible hospitals and CAHs to apply to other CMS quality reporting programs. A longer-term vision would be hospitals and clinicians reporting through a single, aligned mechanism for multiple CMS programs. For EPs, we have finalized such an alignment between the PQRS and the EHR Incentive Program, and we expect hospital reporting programs such as Hospital IQR and Hospital OQR Programs to follow.

In order to properly transition to electronic reporting, it is imperative that we take a staggered approach to electronic reporting in order to allow for careful review of the infrastructure and data integrity during the process. We have and will continue to look for ways to reduce reporting burden. We note that providers could collect data in EHRs even if the submission of the data is not done electronically for all quality reporting programs.

Comment: One commenter strongly recommended that all eCQMs should be field-tested and validated prior to implementation.

Response: We agree with the commenter that eCQMs should be tested and validated prior to implementation. We are collaborating with the NQF, measure stewards, and the ONC to develop accurate, and medical-record compatible electronic specifications while maintaining the integrity of the measures as endorsed.

We thank the commenters for submitting comments on the use of EHRs in the Hospital OQR Program and will take these comments into consideration as we develop future policies on this issue.

K. 2013 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs

In the CY 2012 OPPS/ASC final rule with comment period, we finalized the voluntary 2012 Electronic Reporting Pilot for eligible hospitals and CAHs participating in the Medicare EHR Incentive Program for FY 2012 and also revised our regulations at § 495.8(b)(2) accordingly. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74489 through 74492) for detailed discussion of the 2012 Electronic Reporting Pilot.

We proposed to continue the Electronic Reporting Pilot for FY 2013 as finalized for FY 2012. We proposed to revise our regulations at § 495.8(b)(2)(vi) to reflect the continuation of the Electronic Reporting Pilot for FY 2013, and also to remove the reference to § 495.6(f)(9) in order to conform with the proposed changes to § 495.6(f) that were included in the Medicare and Medicaid EHR Incentive Programs—Stage 2 proposed rule (77 FR 13817). (We note we recently published the Medicare and Medicaid EHR Incentive Programs—Stage 2 final rule

(77 FR 53968).)We invited public comments on these proposals.

We noted in the proposed rule that we finalized reporting clinical quality measures for the Medicare EHR Incentive Program by attestation of clinical quality measure results in the CY 2012 OPPS/ASC final rule with comment period for FY 2012 and subsequent years, such as FY 2013 (76 FR 74489). Thus, eligible hospitals and CAHs may continue to report clinical quality measure results as calculated by CEHRT by attestation for FY 2013, as they did for FYs 2011 and 2012. We also noted the intent of CMS to move to electronic reporting. In the Medicare and Medicaid EHR Incentive Programs—Stage 2 final rule, we finalized that the Medicare EHR Incentive Program would require electronic reporting of clinical quality measures beginning in FY 2014 for eligible hospitals and CAHs that are beyond the first year of Stage 1 of meaningful use (77 FR 54088).

Comment: A few commenters stated that some eCQMs have not been sufficiently validated. One commenter also stated that not enough clinical quality measures in the Hospital IQR and Hospital OQR Programs are electronically specified, noting that some data elements are not always captured in CEHRT and still require manual review and input. A few commenters stated that electronic specifications have not undergone field testing.

Response: The clinical quality measures finalized in the Medicare and Medicaid EHR Incentive Programs—Stage 2 final rule (77 FR 53968) for reporting beginning with FY 2014 have either undergone feasibility testing in EHR systems and clinical settings or were finalized in the Stage 1 final rule for reporting in FYs 2011 and 2012, and specifications have been and will continue to be updated based on experiences with reporting those clinical quality measures in the EHR Incentive Program.

In addition, the Office of the National Coordinator for Health Information Technology's (ONC) 2014 Edition EHR certification criteria explicitly requires that EHR technology presented for certification must be able to capture the requisite data for each and every clinical quality measure to which the EHR technology is requested to be certified (see 45 CFR 170.314(c)(1) and 77 FR 54226 through 54232). Therefore EHR technology that is certified to the 2014 Edition EHR certification criteria should include all of the data elements needed for each and every clinical quality measure to which an EHR technology is certified for the purposes of the EHR Incentive Program (for a list of these measures, including other quality measure programs that use the same measure, please refer to Table 10 of the Medicare and Medicaid EHR Incentive Programs—Stage 2 final rule at 77 FR 54083 through 54087). Finally, we do not believe that many of the issues experienced by providers with eCQMs in 2011 and 2012 of the EHR Incentive Program would continue.

We expect that eCQMs that will be electronically reported in hospital reporting programs such as the Hospital OQR Program would have undergone the same or similar processes as the eCQMs in the EHR Incentive Program (for more information, please refer to the Medicare and Medicaid EHR Incentive Programs—Stage 2 final rule 77 FR 54053 through 54056, section B.3. Criteria for Selecting CQMs and section B.4. CQM Specification). As the transition to electronic reporting becomes more ubiquitous in the hospital reporting programs, we expect that more eCQMs would be created *de novo* based on data that is readily available in EHR systems rather than retooled from paper-based specifications.

Comment: Several commenters stated that CMS should establish a process for updating specifications for eCQMs. These commenters also suggested that we establish a mechanism through which vendors and providers can offer feedback on problematic or unclear measures.

Response: The Electronic Reporting Pilot, which began in FY 2012 and is being finalized to continue in FY 2013, is used in part as a mechanism for testing the entire infrastructure for reporting eCQMs, including the ability to accurately abstract clinical quality data from EHRs, transmit them to CMS, and for CMS to receive the data. The EHR Incentive Program is currently the only CMS quality reporting program using electronic clinical quality measures for hospitals. The process of updating specifications regularly is expected to continue in order to maintain alignment with current clinical guidelines and ensure that the measure remains relevant and actionable within the clinical care setting.

In addition, we expect to make updates based on experiences of vendors, providers, and CMS during the process of reporting clinical quality data. We currently have various forums in which vendors and providers can provide feedback, such as the joint CMS and the Joint Commission ePilot vendor conference call, national partners' calls and open door forums. We continue to engage with the vendor and provider communities to keep an open dialogue for feedback and continuous improvement in electronic quality measurement.

Comment: One commenter did not support CMS having direct access to a facility's EHR for data abstraction.

Response: We have not proposed nor do we intend to directly access a facility's EHR for data abstraction. The Electronic Reporting Pilot for the Medicare EHR Incentive Program (established in the CY 2012 OPPS/ASC final rule with comment period and being finalized to continue in FY 2013 in this final rule with comment period) is expected to be the basis for electronic reporting of clinical quality data in Hospital IQR and Hospital OQR Programs, as well as potentially in other hospital reporting programs.

Comment: Several commenters were concerned about participation levels in the Electronic Reporting Pilot and suggested flexibility with data transmission standards, such as using standards that EHR vendors already use. One commenter urged CMS to perform a comprehensive assessment of the pilot.

Response: The submission period for the first Electronic Reporting Pilot (that is, the pilot established for FY 2012) is October 1, 2012 through November 30, 2012. Therefore, when this final rule with comment period is published, the submission period for the first Electronic Reporting Pilot for hospitals would not yet be completed and a comprehensive assessment would not yet be possible. The data transmission standard used in the Electronic Reporting Pilot (Quality Reporting Data Architecture category I, or QRDA–I) has also been finalized in the Medicare and Medicaid EHR Incentive Programs—Stage 2 final rule as a standard that we will accept beginning with FY 2014 (77 FR 54088). ONC has also included QRDA–I in its 2014 Edition EHR certification criteria, which means that CEHRT should be capable of transmitting data using this standard if certified to the 2014 Edition EHR certification criteria. Therefore, it is a standard that we believe will continue to be used more widely for electronic reporting of clinical quality measures. As stated previously, we have and will continue to engage with the vendor community in order to continue to improve the ease and accuracy of electronic transmission of clinical quality data.

Comment: One commenter provided suggestions on development and selection of future electronic clinical

quality measures, including considerations such as measure validity, quality improvement potential, reporting burden, and the National Quality Strategy described in the Medicare and Medicaid EHR Incentive Programs—Stage 2 final rule (77 FR 54054).

Response: We appreciate the suggestions on development and selection of future electronic clinical quality measures; however, this is outside the scope of this rulemaking. We will consider these suggestions when developing new electronic clinical quality measures and in future rulemaking when selecting new measures in our quality reporting programs.

Comment: One commenter stated that it is inconsistent for the Electronic Reporting Pilot to collect only Medicare data when reporting of all payer data is instrumental to meeting the goals of national initiatives as well as needed for *Hospital Compare.* This commenter was concerned that submission of patient-level data is inconsistent with the requirement in the EHR Incentive Program to report summary-level data and could have adverse consequences for patient privacy.

Response: In order to work towards the goal of transitioning our quality reporting programs to electronic reporting, we are piloting the electronic submission of patient-level data, which is the data level required in the hospital reporting programs, such as the Hospital IQR and Hospital OQR Programs. Whether the data are submitted to us through a manual process or electronically, all parties are expected to comply with HIPAA as applicable in order to maintain patient confidentiality and secure data transmission. Since this is a pilot, we limited the data submission to Medicare patients only in order to limit the reporting burden on participating hospitals during the pilot phase.

Comment: One commenter suggested piloting both the QRDA–I (patient-level) and QRDA–III (aggregate-level) transmission formats in 2013.

Response: We proposed to continue the Electronic Reporting Pilot for FY 2013 exactly as adopted for FY 2012, which only included the QRDA–I transmission format. The QRDA–III format is currently being finalized and is not ready for full implementation in FY 2013.

Comment: Several commenters supported continuing the Electronic Reporting Pilot through the EHR Incentive Program. One of these commenters specifically supported the electronic reporting of clinical quality measures under the terms in the EHR Incentive Program.

Response: We thank the commenters for the support to continue the Electronic Reporting Pilot and for electronically-reported clinical quality measures.

After consideration of the public comments we received, we are finalizing our proposal to continue the Electronic Reporting Pilot for FY 2013, as finalized for FY 2012. We are revising our regulations as proposed at § 495.8(b)(2)(vi) to reflect the continuation of the Electronic Reporting Pilot for FY 2013 and to remove the reference to § 495.6(f)(9).

XVI. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

A. Background

1. Overview

We refer readers to section XV.A.1. of this final rule with comment period for a general overview of our quality reporting programs.

2. Statutory History of the ASC Quality Reporting (ASCQR) Program

We refer readers to section XIV.K.1. of the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74493) for a detailed discussion of the statutory history of the ASCQR Program.

3. History of the ASCQR Program

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 quality reporting requirements. However, in these rules, we indicated that we intended to implement a quality reporting program for ASCs in the future.

In preparation for proposing a quality reporting program for ASCs, in the CY 2011 OPPS/ASC proposed rule (75 FR 46383), we solicited public comments on 10 measures. In addition to preparing to propose implementation of a quality reporting program for ASCs, HHS developed a plan to implement a value-based purchasing (VBP) program for payments 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 details this plan. This report is found on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/Downloads/C_ASC_RTC–2011.pdf.* Currently, we do not have express statutory authority to implement an ASC VBP program. If and when legislation is enacted that authorizes CMS to implement an ASC VBP program, we will develop the program and propose its implementation through notice-and-comment rulemaking.

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74517), we finalized our proposal to implement the ASCQR Program beginning with the CY 2014 payment determination. We adopted quality measures for the CY 2014, CY 2015, and CY 2016 payment determination years and finalized some data collection and reporting timeframes for these measures. We also adopted policies with respect to the maintenance of technical specifications and updating of measures, publication of ASCQR Program data, and, for the CY 2014 payment determination, data collection and submission requirements for the claims-based measures. For a discussion of these final policies, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74517).

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74515), we indicated our intent to issue proposals for administrative requirements, data validation and completeness requirements, and reconsideration and appeals processes in the FY 2013 IPPS/LTCH PPS proposed rule, rather than in the CY 2013 OPPS/ASC proposed rule, because the FY 2013 IPPS/LTCH PPS proposed rule was scheduled to be finalized earlier and prior to data collection for the CY 2014 payment determination, which is to begin with services furnished on October 1, 2012. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53636 through 53644), we issued final policies for administrative requirements, data completeness requirements, extraordinary circumstances waiver or extension requests, and a reconsideration process. For a complete discussion of these policies, we refer readers to the FY 2013 IPPS/LTCH PPS final rule.

Because we included proposals for the ASCQR Program in the FY 2013

IPPS/LTCH PPS proposed rule, we limited the number of proposals in the CY 2013 OPPS/ASC proposed rule. In addition, in an effort to prevent confusion regarding what we proposed in the CY 2013 OPPS/ASC proposed rule and what we proposed in the FY 2013 IPPS/LTCH PPS proposed rule, in the CY 2013 OPPS/ASC proposed rule, we limited our discussion of the proposals contained in the FY 2013 IPPS/LTCH PPS proposed rule primarily to background related to the proposals in the CY 2013 OPPS/ASC proposed rule.

Comment: Two commenters supported the implementation of a pay-for-performance program (that is, an ASC Value-Based Purchasing (VBP) Program) by CY 2016 to reward high performing facilities and penalize low performing facilities. The commenters also recommended that the measure set for such a program focus not only on clinical outcomes and include clinical process, structural, and patient experience of care measures, but also minimize burden.

Response: Currently, we do not have the statutory authority to implement an ASC VBP Program. If legislation is enacted that authorizes CMS to implement such a program for ASCs, we will consider these recommendations.

B. ASCQR Program Quality Measures

1. Considerations in the Selection of ASCQR Program Quality Measures

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 under section 1833(t)(17)(C)(i) of the Act state that measures developed shall ''be appropriate for the measurement of 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 addition to following the statutory requirements, in selecting measures for the ASCQR 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 the ASCQR Program 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, 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 discussed above, the Hospital OQR Program statute only requires that we adopt measures that are appropriate for the measurement of the quality of care furnished by hospitals in outpatient settings, reflect consensus among affected parties, and, to the extent feasible and practicable, include measures set forth by one or more national consensus building entities. Therefore, measures are not required to be endorsed by the NQF or any other national consensus building entity and, as we have noted in a 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. Further, the Secretary has broader authority under the ASCQR Program statute, as discussed above, to adopt non-endorsed measures or measures that do not reflect consensus for the ASCQR Program because, under the ASCQR Program statute, these Hospital OQR Program provisions apply ''except as the Secretary may otherwise provide.''

In developing the ASCQR Program, we applied the principles set forth in the CY 2011 OPPS/ASC proposed rule and final rule with comment period (76 FR 42337 through 42338 and 74494 through 74495, respectively). Although we did not propose any new measures for the ASCQR Program in the CY 2013 OPPS/ASC proposed rule as discussed below, we stated that we plan to apply the following principles in future measure selection and development for the ASCQR Program. These principles were applied in developing other quality reporting programs and many are the same principles applied in developing the ASCQR Program last year.

- Our overarching goal is to support the National Quality Strategy's goal of better health care for individuals, better health for populations, and lower costs for health care. The ASCQR Program will help achieve these goals by creating transparency around the quality of care provided by ASCs to support patient decision-making and quality improvement. More information regarding the National Quality Strategy can be found at: *http://www.healthcare.gov/law/resources/reports/quality03212011a.html*. HHS engaged a wide range of stakeholders to develop the National Quality Strategy, as required by the Affordable Care Act.
- Pay-for-reporting and public reporting programs should rely on a mix of standards, process, outcomes, and patient experience of care measures. 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 the 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.
- We weigh the relevance and the utility of measures compared to the burden on ASCs for submitting data under the ASCQR Program. The collection of information burden on providers and suppliers should be minimized to the extent possible. To this end, we continuously seek to adopt electronic-specified measures so that data can be calculated and submitted via certified EHR technology with minimal burden. We also seek to use measures based on alternative sources of data that do not require chart abstraction or that use data already being reported by ASCs.
- We take into account the views of the Measure Application Partnership (MAP). The MAP is a public-private partnership convened by the NQF for the primary purpose of providing input to HHS on selecting performance measures for quality reporting programs and pay-for-reporting programs. The MAP views patient safety as a high priority area and it strongly supports the use of NQF-endorsed safety measures. Accordingly, we consider the MAP's recommendations in selecting quality and efficiency measures (we refer readers to the Web sites at: *http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx,* and *http://*

www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=69885).

• Measures should be developed with the input of providers/suppliers, purchasers/payers and other stakeholders. Measures should be aligned with best practices among other payers and the needs of the end users of the measures. We take into account widely accepted criteria established in medical literature.

• HHS' Strategic Plan and Initiatives. HHS is the U.S. Government's principal agency for protecting the health of all Americans. HHS accomplishes its mission through programs and initiatives. Every 4 years, HHS updates its Strategic Plan and measures its progress in addressing specific national problems, needs, or mission-related challenges. The current goals of the HHS Strategic Plan can be located on the Web site at: *http://www.hhs.gov/secretary/about/priorities/strategicplan2010-2015.pdf*.

• CMS Strategic Plan. We strive to ensure that measures for different Medicare and Medicaid programs are aligned with priority quality goals, that measure specifications are aligned across settings, that outcome measures are used whenever possible, and that quality measures are collected from EHRs as appropriate.

We believe that ASCs are similar to HOPDs, insofar as the delivery of surgical and related nonsurgical services. Similar standards and guidelines can be applied between HOPDs and ASCs with respect to surgical care improvement because many of the same surgical procedures are provided in both settings. Measure harmonization assures that comparable care in these 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.

We invited public comment on this approach for future measure selection and development for the ASCQR Program.

Comment: Some commenters supported CMS' efforts to establish the ASCQR Program. One commenter emphasized that ASCQR Program measures should reflect ASC facility-level accountability rather than physician-level accountability.

Response: We appreciate the commenters' support for the implementation of the ASCQR Program. The measures we adopted for the ASCQR Program are directly attributable to ASCs. The quality data are submitted by ASCs and are reported at a facility-level and not at a physician-level. We finalized a policy to publish ASC quality data by CMS Certification Number (CCN) in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74514 through 74515), which is a facility-level identifier.

Comment: A few commenters asserted that ASCs are small entities and the utilization of EHR technology in the ASC industry is limited. Nonetheless, commenters requested that CMS consider electronic submission as an option for ASCs that have implemented EHR technology.

Response: We recognize that many ASCs are small entities and some may have limited EHR technology. We are still in the beginning stages of implementing the ASCQR Program, and we will need to assess the readiness of ASCs prior to considering an option of allowing electronic submission of measures for the ASCQR Program.

Comment: One commenter encouraged the adoption of NQF-endorsed measures to ensure that field testing and the consensus process are rigorous. Another commenter urged CMS to facilitate direct representation from the ASC industry on either the National Priorities Partnership (NPP) or the MAP to formulate priorities for outpatient settings and coordinate efforts across inpatient and outpatient settings.

Response: 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, sections 1833(i)(7)(B) and 1833(t)(17)(C)(i) of the Act, read together, require that the Secretary develop measures that the Secretary determines to be appropriate for the measurement of quality of care (including medication errors) furnished by ASCs 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. Therefore, measures are not required to be endorsed by the NQF or any other national consensus building entity and, as we have noted in a previous rulemaking (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. Further, section 1833(i)(7)(B) of the Act states that these provisions shall apply to the ASCQR Program ''except as the Secretary may otherwise provide.'' Thus, the Secretary has broad authority under the ASCQR Program statute to adopt non-endorsed measures or measures that do not reflect consensus.

As required by section 1890A of the Act, as added by section 3014 of the Affordable Care Act, we submit measures under consideration for this Program (and other programs utilizing quality measures) to the MAP by December 1 of each year, at the same time that we make the list of measures available to the public. We consider the recommendations issued by the MAP prior to proposing measures for the ASCQR Program.

We encourage stakeholders interested in direct representation on either the NPP or the MAP to submit nominations to the NQF for consideration. The NQF holds open calls for membership nominations annually for both the NPP and the MAP, followed by a public comment period for vetting of balanced stakeholder groups.

Comment: A few commenters strongly supported CMS' measure selection criteria for ASCs. Commenters also commended CMS' effort to align some of the measures for the ASCQR Program with the Hospital OQR Program measures, and encouraged greater alignment of the measures so that Medicare beneficiaries can compare ASC and HOPD quality data.

Response: We appreciate the commenters' support for CMS' measure selection criteria. We believe that ASCs are similar to HOPDs, insofar as they deliver similar surgical and related nonsurgical services. Therefore, many of the measures may be applicable across these two settings. We agree with the commenters that greater harmonization of measures across these programs would allow beneficiaries to compare quality of care for similar services across these settings, and we will seek greater alignment in future program years.

After consideration of the public comments we received, we are finalizing our approach for future measure selection and development for the ASCQR Program.

2. ASCQR Program Quality Measures

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74517), we finalized our proposal to implement the ASCQR Program beginning with the CY 2014 payment determination and adopted measures for the CY 2014, CY 2015, and CY 2016 payment determinations. We also finalized our policy to retain measures from one calendar year payment determination to the next so

that measures adopted for a previous payment determination year would be retained for subsequent payment determination years (76 FR 74504, 74509, and 74510).

We adopted the following five claims-based measures for the CY 2014 payment determination for services furnished between October 1, 2012 and December 31, 2012: (1) Patient Burns (NQF #0263); (2) Patient Fall (NQF #0266); (3) Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267); (4) Hospital Transfer/Admission (NQF #0265); and (5) Prophylactic Intravenous (IV) Antibiotic Timing (NQF #0264).

For the CY 2015 payment determination, we retained the five claims-based measures we adopted for the CY 2014 payment determination and adopted the following two structural measures: (1) Safe Surgery Checklist Use; and (2) ASC Facility Volume Data on Selected ASC Surgical Procedures. We specified that reporting for the structural measures would be between July 1, 2013 and August 15, 2013 for services furnished between January 1, 2012 and December 31, 2012, using an online measure submission Web page available at: *https://www.QualityNet.org.* We did not specify the data collection period for the five claims-based measures for the CY 2015 payment determination.

For the CY 2016 payment determination, we finalized the retention of the seven measures from the CY 2015 payment determination (five claims-based measures and two structural measures) and adopted Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431), a process of care, healthcare-associated infection measure (HAI). We specified that data collection for the influenza vaccination measure would be via the National Healthcare Safety Network (NHSN) from October 1, 2014 through March 31, 2015. We did not specify the data collection period for the claims-based or structural measures.

We stated that, to the extent we finalize some or all of the measures for future payment determination years, we would not be precluded from adopting additional measures or changing the list of measures for future payment determination years through annual rulemaking cycles so that we may address changes in program needs arising from new legislation or from changes in HHS' and CMS' priorities.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45191), considering the time and effort required for us to develop, align, and implement the infrastructure necessary to collect data on the ASCQR Program quality measures and make payment determinations, and likewise the time and effort required on the part of ASCs to plan and prepare for quality reporting, we did not propose to delete or add any quality measures for the ASCQR Program for the CY 2014, CY 2015, and CY 2016 payment determination years, or to adopt quality measures for subsequent payment determination years. For readers' reference, the following table lists the ASCQR Program quality measures that were previously finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74504 through 74511).

ASC Program Measurement Set Adopted in Previous Rulemaking	
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, and 0170T
Eye	65000 through 68999, G0186, 0124T, 0099T, 0017T, 0016T, 0123T, 0100T, 0176T, 0177T, 0186T, 0190T, 0191T, 0192T, 76510, and 0099T
Nervous System	61000 through 64999, G0260, 0027T, 0213T, 0214T, 0215T, 0216T, 0217T, 0218T, and 0062T
Musculoskeletal	20000 through 29999, 0101T, 0102T, 0062T, 0200T, and 0201T
Skin	10000 through 19999, G0247, 0046T, 0268T, G0127, C9726, and C9727
Genitourinary	50000 through 58999, 0193T, and 58805
ASC- 8: Influenza Vaccination Coverage among Healthcare Personnel ***	

*New measure for the CY 2014 payment determination.
** New measure for the CY 2015 payment determination.
***New measure for the CY 2016 payment determination.

Comment: Many commenters applauded CMS' plan of not adding new measures to the ASCQR Program at this time because it would allow ASCs adequate time to adapt to reporting requirements for the initial measure set for the CY 2014 payment determination.

Response: We appreciate the commenters' support.

3. ASC Measure Topics for Future Consideration

We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the ASC setting. Therefore, in the CY 2013 OPPS/ASC proposed rule (77 FR 45191), we stated that, through future rulemaking, we intend to propose new measures consistent with the principles discussed in section XVI.B.1. of the proposed rule, in order to select quality measures that address clinical quality of care, patient safety, and patient and caregiver experience of care. We invited public comment specifically on the inclusion of procedure-specific measures for cataract surgery, colonoscopy, endoscopy, and for anesthesia-related complications in the ASCQR Program measure set.

Comment: Commenters either supported or suggested the inclusion of the following measure topics under the ASCQR Program:

- Patient Experience of Care
- Surgical Site Infection
- Surgical Complications
- Anesthesia-Related Complications
- Otolaryngology
- Gastroenterology
- Equipment Reprocessing
- Adverse Events after Discharge

Response: We appreciate the commenters' suggestions for future measure topics for the ASCQR Program.

4. Clarification Regarding the Process for Updating ASCQR Program Quality Measures

In the CY 2012 OPPS/ASC final rule with comment period, we finalized our proposal to follow the same process for updating the ASCQR Program measures that we adopted for the Hospital OQR Program's measures (76 FR 74513 through 74514). This process includes the same subregulatory process for the ASCQR Program as used for the Hospital OQR Program for updating measures, including issuing regular manual releases at 6-month intervals, providing addenda as necessary, and providing at least 3 months of advance notice for nonsubstantive changes such as changes to ICD–9–CM, CPT, NUBC, and HCPCS codes, and at least 6 months' notice for substantive changes to data elements that would require significant systems changes. We provided a citation to the CY 2009 OPPS/ASC final rule with comment period where the final Hospital OQR Program policies are discussed (73 FR 68766 through 68767).

In examining last year's finalized policy for the ASCQR Program, we recognize that we may need to provide

additional clarification of the ASCQR Program policy in the context of the previously finalized Hospital OQR Program policy in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766 through 68767). Therefore, in the CY 2013 OPPS/ASC proposed rule (77 FR 45191), we sought to more clearly articulate the policy that we adopted for the ASCQR Program, which is the same policy that has been adopted for the Hospital OQR Program.

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 measures we have adopted for the Hospital OQR Program. This process is necessary so that the Hospital OQR measures are calculated based on the most up-to-date scientific evidence and consensus standards. Under this process, when a national consensus building entity updates the specifications for a measure that we have adopted for the Hospital OQR Program, we update our specifications for that measure accordingly and provide notice as described above and in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74514). An example of such an entity is the NQF. For measures that are not endorsed by a national consensus building entity, the subregulatory process is based on scientific advances as determined necessary by CMS, in part, through our measure maintenance process involving Technical Expert Panels (73 FR 68767). We invited public comment on this clarification of the finalized ASCQR Program policy of using a subregulatory process to update measures.

Comment: A few commenters requested that CMS consider the measure changes made by measure developers and stewards of measures, as these can occur at any time based on a change in evidence, consensus standards, or other factors that merit an update. With respect to measures that are not endorsed by a national entity, the commenters recommended that CMS consult with ASC clinical and operational experts. Further, the commenters suggested that the Technical Expert Panels (TEPs), which are charged with maintenance of the ASCQR Program measures, include substantial representation from the ASC community and relevant surgical specialty societies.

Response: We regularly monitor changes to measures adopted for the ASCQR Program and other quality programs that are made by measure stewards, as well as the evidence upon which the measures are based. The current ASCQR Program measure set has been implemented with input by ASC stakeholders, including the measure stewards, as well as other affected parties.

For NQF-endorsed measures, measure developers and stewards are expected to present these changes to the NQF for review annually. We would incorporate these changes based upon the NQF's acceptance. For non-NQF-endorsed measures, we evaluate changes to measures recommended by our contractors' surgical TEP, which includes outpatient ASC surgical representatives.

In summary, we clarified that we adopted the Hospital OQR Program's process for updating the ASCQR Program measures that was finalized in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766 through 68767), which is explained above.

C. Requirements for Reporting of ASC Quality Data

1. Form, Manner, and Timing for Claims-Based Measures for the CY 2014 Payment Determination and Subsequent Payment Determination Years

a. Background

In the CY 2012 OPPS/ASC final rule with comment period, we adopted claims-based measures for the CY 2014, CY 2015, and CY 2016 payment determination years (76 FR 74504 through 74511). We also finalized 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 (76 FR 74515 through 74516). As stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74516), ASCs will add the appropriate QDCs on their Medicare Part B claims forms, the Form CMS–1500s submitted for payment, to submit the applicable quality data. A listing of the QDCs with long and short descriptors is available in Transmittal 2425, Change Request 7754 released March 16, 2012 (*http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Transmittals-Items/ASC-CR7754-R2425CP.html*). Details on how to use these codes for submitting numerator and denominator information are available in the ASCQR Program Specifications Manual located on the QualityNet Web site (*https://www.QualityNet.org*). We also finalized the data collection period for the CY 2014 payment determination, as the Medicare fee-for-service ASC claims submitted for services furnished between October 1, 2012 and December 31, 2012. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53640), we adopted a policy that claims for services furnished between October 1, 2012 and December 31, 2012, would have to be paid by the Medicare administrative contractor (MAC) by April 30, 2013, to be included in the data used for the CY 2014 payment determination. We believe that this claim paid date will allow ASCs sufficient time to submit claims while allowing CMS sufficient time to complete required data analysis and processing to make payment determinations and to supply this information to administrative contractors.

b. Form, Manner, and Timing for Claims-Based Measures for the CY 2015 Payment Determination and Subsequent Payment Determination Years

In the CY 2013 OPPS/ASC proposed rule (77 FR 45192) we proposed that, for the CY 2015 payment determination and subsequent payment determination years, an ASC must submit complete data on individual claims-based quality measures through a claims-based reporting mechanism by submitting the appropriate QDCs on the ASC's Medicare claims. We proposed that the data collection period for the claims-based quality measures would be for the calendar year 2 years prior to a payment determination. We also proposed that the claims for services furnished in each calendar year would have to be paid by the MAC by April 30 of the following year of the ending data collection time period to be included in the data used for the payment determination. Thus, for example, for the CY 2015 payment determination, we proposed the data collection period to be claims for services furnished in CY 2013 (January 1, 2013 through December 31, 2013) which are paid by the MAC by April 30, 2014. We believe that this claim paid date would allow ASCs sufficient time to submit claims while allowing CMS sufficient time to complete required data analysis and processing to make payment determinations and to supply this information to administrative contractors. We invited public comment on these proposals.

Comment: Some commenters agreed with CMS' proposals to begin the data collection period for claims-based measures in the calendar year 2 years prior to a payment determination, and to establish the policy that the claims for services furnished in each calendar year would have to be paid by the MAC by April 30 of the following year of the ending data collection time period to be included in the data used for the

payment determination. The commenters stated that they believed the April 30 deadline would allow sufficient time for claims processing.

However, other commenters believed the proposed period for the collection of claims data may be too abbreviated to capture all pertinent data. Because ASCs have up to 1 year to submit claims for services furnished, some commenters suggested that the period for the collection of claims data be as close to 1 year from the date the service was furnished to be included in a payment determination. Some commenters suggested that CMS establish a longer time period for the claims payment deadline in order to include all available claims data in the data used for payment determinations; one commenter suggested a June 30 deadline rather than April 30 deadline.

Response: We appreciate the commenters' support of our proposals regarding the period for the collection of claims data and the time allowed for data processing to be included in payment determinations. We agree that sufficient time should be allowed for claims processing to obtain complete data. We have conducted an internal analysis of claims submission by ASCs and have found that over 90 percent of the ASC claims are submitted and paid within the proposed timeframe. Therefore, we believe at this time that the proposed April 30 claims paid date is the latest date that would allow CMS to acquire and analyze the claims data, make payment determinations, and importantly, provide sufficient time for the MACs to program their systems. However, as we gain more experience and our systems become established, we will explore whether allowing more time for claims processing may be possible; if so, we will propose such changes through notice-and-comment rulemaking.

Comment: One commenter expressed concern with the lag between the quality data reporting period and the payment reductions under the ASCQR Program by basing payment adjustments on participation a full 2 years before the results of a payment determination take effect.

Response: We understand the commenter's concern with the lag between when data are reported and when payment is affected, and we will strive to reduce this lag without significant adverse effects on data completeness and quality. However, we note that with the data collection period ending December 31 for the payment determinations becoming effective beginning January 1, the lag basically is 1 year past the end of the data collection period. Based upon our current experience, we believe the timeline we are finalizing provides a balance between data completeness and expediency.

Comment: One commenter stated that the ASCQR Program's use of the term ''claims-based'' is not consistent with the Hospital IQR Program's use and does generate additional costs to the organization. The commenter stated that claims-based measures under the Hospital IQR Program truly means that CMS can obtain the data solely based on coding data without the organization taking additional steps of manually applying quality coding and having a clinician review the record for inclusion/exclusion criteria. The commenter further stated that for process measures, it is not accurate to label them as ''claims-based'' and state that this process is not time consuming and costly.

Response: We understand the commenter's concerns. However, we are clarifying that we have used the term ''claims-based'' to indicate the data source and mechanism for data submission as well as to differentiate claims-based measures from measures based on manual chart-abstracted data. We believe that a claims-based mechanism for data collection is less time consuming and less costly than such chart-abstracted quality measures. In addition, the use of the term ''claims-based'' for the claims-based ASCQR Program quality measures is consistent with the Physician Quality Reporting Program (PQRS), which also uses QDCs for the reporting of quality data via claims.

After consideration of the public comments we received, we are finalizing our proposals without modification that, for the CY 2015 payment determination and subsequent payment determination years, an ASC must submit complete data on individual claims-based quality measures through a claims-based reporting mechanism by submitting the appropriate QDCs on the ASC's Medicare claims. We also are finalizing that the data collection period for such claims-based quality measures will be for the calendar year 2 years prior to a payment determination and that the claims for services furnished in each calendar year will have to be paid by the MAC by April 30 of the following year of the ending data collection time period to be included in the data used for the payment determination.

2. Data Completeness and Minimum Threshold for Claims-Based Measures Using QDCs

a. Background

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74516), we finalized our proposal that data completeness for claims-based measures for the CY 2014 payment determination 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 claims. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53641), we finalized our policy for the CY 2014 and CY 2015 payment determination years that the minimum threshold for successful reporting be that at least 50 percent of claims meeting measure specifications contain QDCs. We believe that 50 percent is a reasonable minimum threshold based upon the considerations discussed above for the initial implementation years of the ASCQR Program. We stated in that final rule that we intend to propose to increase this percentage for subsequent payment determination years as ASCs become more familiar with reporting requirements for the ASCQR Program.

Comment: One commenter asked what method CMS would use to assess when to raise the required threshold for the level of completeness.

Response: We plan to monitor the level of completeness for submitting QDCs and to monitor the ASCQR Program for issues as they arise. Based upon program experience, we will assess what level of completeness should be required. Any changes in the threshold level for completeness of reporting for ASCQR Program claims-based measures will be proposed through notice-and-comment rulemaking.

b. Data Completeness Requirements for the CY 2015 Payment Determination and Subsequent Payment Determination Years

After publication of the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28101 through 28105), we realized that we did not propose a methodology for determining data completeness for the CY 2015 payment determination and subsequent payment determination years. Therefore, in the CY 2013 OPPS/ASC proposed rule (77 FR 45192), we proposed that data completeness for claims-based measures for the CY 2015 payment determination and subsequent payment determination years be

determined by comparing the number of Medicare claims (where Medicare is the primary or secondary payer) meeting measure specifications that contain the appropriate QDCs with the number of Medicare claims (where Medicare is the primary or secondary payer) that would meet measure specifications, but did not have the appropriate QDCs on the submitted claims for the CY 2015 payment determination and subsequent payment determination years. We stated that this method is the same method for determining data completeness for claims-based measures that was finalized in the CY 2012 OPPS/ASC final rule with comment period for the CY 2014 payment determination (76 FR 74516).

However, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53641), we stated that, because private payers would not have QDCs in their required HCPCS data files until January 1, 2013, claims with QDCs received prior to January 1, 2013 could be rejected for invalid codes. Because it is not possible for ASCs to submit differing codes on primary versus secondary payer claims for at least some payers, we specified that only claims where Medicare is the primary payer—not the secondary payer—will be used in the calculation of data completeness for the CY 2014 payment determination.

We invited public comment on this proposal.

Comment: One commenter asked how ASCs would be notified of their claim completeness percentages and encouraged CMS to post claim completeness percentages on the QualityNet Web site (*http://www.QualityNet.org*).

Response: We appreciate the commenter's suggestion. We intend to supply preliminary completeness percentages and other data submission information to ASCs prior to the closing of the data submission deadline in April 2013 either electronically or by the mailing of a facility-specific report so ASCs can assess their data completeness levels. In addition, ASCs can use their remittance information to assess if QDCs have been successfully processed by MACs.

We did not receive any public comments regarding our proposal that data completeness for claims-based quality measures for the CY 2015 payment determination and subsequent payment determination years be determined by comparing the number of Medicare claims (where Medicare is the primary or secondary payer) meeting measure specifications that contain the appropriate QDCs with the number of Medicare claims (where Medicare is the primary or secondary payer) that would meet measure specifications, but did not have the appropriate QDCs on the submitted claims for the CY 2015 payment determination and subsequent payment determination years. Therefore, we are finalizing this proposal without modification.

3. Other Comments on the ASCQR Program

Comment: Commenters expressed views and provided suggestions regarding additional topics and previously finalized policies for which we did not make proposals in the CY 2013 OPPS/ASC proposed rule, including comments and suggestions on the following:

- The NHSN infrastructure;
- Retention of quality measures from one calendar year to the next;
- Case thresholds for determining completeness of reporting;
- Alternative methods of data collection for certain finalized measures;
- The utility of certain finalized measures;
- Public reporting of data, including previewing data prior to public display;
- Patient exclusions for specific measures;
- Data collection and submission time periods for finalized measures;
- Validation;
- Mechanisms for opting out of reporting due to lack of cases meeting measure specifications;
- The use of alternatives to claims-based reporting such as registries and EHRs;
- The use of administrative claims data for the identification of HAIs;
- ASCQR Program implementation date; and
- Educational outreach to ASCs regarding the ASCQR Program.

Response: We greatly appreciate the commenters' views on these new topics and our previously finalized policies. Although we did not make proposals in the CY 2013 OPPS/ASC proposed rule on these topics or finalized policies, we will consider all of these views for future rulemaking and program development. For information on the ASCQR program, we refer readers to the information posted on the QualityNet Web site (*http://www.QualityNet.org*) and the CMS Web site (*http://www.cms.hhs.gov*) under the Quality Initiatives and ASC sections.

D. Payment Reduction for ASCs That Fail To Meet the ASCQR Program Requirements

1. Statutory Background

Section 1833(i)(2)(D)(iv) of the Act states that the Secretary may 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).'' Paragraph (7) contains subparagraphs (A) and (B). Subparagraph (A) of paragraph (7) states the Secretary may provide that an ASC that does not submit ''data required to be submitted on measures selected under this paragraph with respect to a year'' to the Secretary in accordance with this paragraph 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 this reduction applies only with respect to the year involved and will not be taken into account in computing any annual increase factor for a subsequent year. Subparagraph (B) of paragraph (7) makes many of the provisions of the Hospital OQR Program applicable to the ASCQR Program ''[e]xcept as the Secretary may otherwise provide.'' Finally, section 1833(i)(2)(D)(v) of the Act states that, in implementing the revised ASC payment system for 2011 and each subsequent year, ''any annual update under such system for the year, after application of clause (iv) [regarding the reduction in the annual update for failure to report on quality measures] shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II).'' Section 1833(i)(2)(D)(v) of the Act also states that the ''application of the preceding sentence may result in such update being less than 0.0 for a year, and may result in payment rates under the [revised ASC payment system] for a year being less than such payment rates for the preceding year.''

2. Reduction to the ASC Payment Rates for ASCs That Fail To Meet the ASCQR Program Requirements for the CY 2014 Payment Determination and Subsequent Payment Determination Years

The national unadjusted payment rates for many services paid under the ASC payment system equal the product of the ASC conversion factor and the scaled relative payment weight for the APC to which the service is assigned. Currently, the ASC conversion factor is equal to the conversion factor calculated for the previous year updated by the MFP-adjusted CPI–U update factor,

which is the adjustment set forth in section 1833(i)(2)(D)(v) of the Act. The MFP-adjusted CPI–U update factor is the Consumer Price Index for all urban consumers (CPI–U), which currently is the annual update for the ASC payment system, minus the MFP adjustment. As discussed in the CY 2011 MPFS final rule with comment period (75 FR 73397), if the CPI–U is a negative number, the CPI–U would be held to zero. Under the ASCQR Program, any annual update would be reduced by 2.0 percentage points for ASCs that fail to meet the reporting requirements of the ASCQR Program. This reduction would apply beginning with the CY 2014 payment rates. For a complete discussion of the calculation of the ASC conversion factor, we refer readers to section XIV.H. of this final rule with comment period.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45193), in order to implement the requirement to reduce the annual update for ASCs that fail to meet the ASCQR Program requirements, we proposed that we would calculate two conversion factors: a full update conversion factor and an ASCQR Program reduced update conversion factor. We proposed to calculate the reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for that calendar year payment determination. We proposed that application of the 2.0 percentage point reduction to the annual update may result in the update to the ASC payment system being less than zero prior to the application of the MFP adjustment.

The ASC conversion factor is used to calculate the ASC payment rate for services with the following payment indicators (listed in Addenda AA and BB to this final rule with comment period, which are available via the Internet on the CMS Web site): ''A2,'' ''G2,'' ''P2,'' ''R2,'' ''Z2,'' as well as the service portion of device-intensive procedures identified by ''J8.'' We proposed that payment for all services assigned the payment indicators listed above would be subject to the reduction of the national unadjusted payment rates for applicable ASCs using the ASCQR Program reduced update conversion factor.

The conversion factor is not used to calculate the ASC payment rates for separately payable services that are assigned status indicators other than payment indicators ''A2,'' ''G2,'' ''J8,'' ''P2,'' ''R2,'' and ''Z2.'' These services include separately payable drugs and biologicals, pass-through devices that are contractor-priced, brachytherapy sources that are paid based on the OPPS payment rates, and certain office-based procedures and radiology services where payment is based on the MPFS PE RVU amount and a few other specific services that receive cost-based payment. As a result, we also proposed that the ASC payment rates for these services would not be reduced for failure to meet the ASCQR Program requirements because the payment rates for these services are not calculated using the ASC conversion factor and, therefore, not affected by reductions to the annual update.

Office-based surgical procedures (performed more than 50 percent of the time in physicians' offices) and separately paid radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents, as discussed in section XIV.D.2.b. of this final rule with comment period) are paid at the lesser of the MPFS non-facility PE RVU-based amounts and the standard ASC ratesetting methodology. We proposed that the standard ASC ratesetting methodology for this comparison would use the ASC conversion factor that has been calculated using the full ASC update adjusted for productivity. This is necessary so that the resulting ASC payment indicator, based on the comparison, assigned to an office-based or radiology procedure is consistent for each HCPCS code regardless of whether payment is based on the full update conversion factor or the reduced update conversion factor.

For ASCs that receive the reduced ASC payment for failure to meet the ASCQR Program requirements, we believe that it is both equitable and appropriate that a reduction in the payment for a service should result in proportionately reduced copayment liability for beneficiaries. Therefore, we proposed that the Medicare beneficiary's national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would be based on the reduced national unadjusted payment rate.

We proposed that all other applicable adjustments to the ASC national unadjusted payment rates would apply in those cases when the annual update is reduced for ASCs that fail to meet the requirements of the ASCQR Program. For example, the following standard adjustments would apply to the reduced national unadjusted payment rates: the wage index adjustment, the multiple procedure adjustment, the interrupted procedure 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 payment for ASCs that do not meet the ASCQR Program requirements.

We invited public comment on these proposals but did not receive any public comments. Therefore, we are finalizing our proposals without modification regarding the process for reducing ASC payment rates for ASCs that fail to meet the ASCQR Program requirements for the CY 2014 payment determination and subsequent payment determination years.

XVII. Inpatient Rehabilitation Facility (IRF) Quality Reporting Program Updates

A. Overview

In accordance with section 1886(j)(7) of the Act, as added by section 3004 of the Affordable Care Act, the Secretary established a quality reporting program (QRP) for Inpatient Rehabilitation Facilities (IRFs). The IRF Quality Reporting Program (IRF QRP) was implemented in the FY 2012 IRF PPS final rule (76 FR 47836). We refer readers to the FY 2012 IRF PPS final rule (76 FR 47873 through 47883) for a detailed discussion on the background and statutory authority for the IRF QRP.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45193 through 45196), we proposed to: (1) Adopt updates to a previously adopted measure for the IRF QRP that will affect the annual prospective payment amounts in FY 2014; (2) adopt a policy that would provide that any measure that has been adopted for use in the IRF QRP will remain in effect until the measure is actively removed, suspended, or replaced; and (3) adopt policies regarding when rulemaking will be used to update existing IRF QRP measures.

While we generally would expect to publish IRF QRP proposals in the annual IRF PPS rule, there are no proposals for substantive changes to the IRF PPS this year; therefore, we published only an IRF PPS payment update notice for FY 2013.[2] Because full notice-and-comment rulemaking is required for the proposals mentioned above in regard to the IRF QRP, we needed to identify an appropriate rulemaking vehicle in which we could insert our IRF QRP proposals. Because the CY 2013 OPPS/ASC proposed rule was already scheduled to include

[2] The FY 2013 IRF PPS Payment Update Notice was published in the **Federal Register** on July 30, 2012 (77 FR 44618). We refer readers to: *http://www.gpo.gov/fdsys/pkg/FR-2012-07-30/pdf/2012-18433.pdf.*

additional pay-for-reporting proposals for the Hospital OQR Program and quality reporting requirements for the ASCQR Program, it offered an opportunity to allow the public to review all three quality programs' proposals in concert with one another in a timeframe that would be appropriate for implementing the IRF QRP proposals in time for the FY 2014 IRF PPS payment cycle. Therefore, we elected to include the IRF QRP proposals in the CY 2013 OPPS/ASC proposed rule.

B. Updates to IRF QRP Measures Which Are Made as a Result of Review by the National Quality Forum (NQF) Process

Section 1886(j)(7) of the Act generally requires the Secretary to adopt measures that have been endorsed by the entity with a contract under section 1890(a) of the Act. This contract is currently held by the National Quality Forum (NQF). The NQF is a voluntary consensus standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other health care stakeholder organizations. The NQF was established to standardize health care quality measurement and reporting through its consensus development process.[3]

The NQF's responsibilities include: (1) Reviewing new quality measures and national consensus standards for measuring and publicly reporting on performance; (2) providing annual measure maintenance updates to be submitted by the measure steward for endorsed quality measures; (3) providing measure maintenance endorsement on a 3-year cycle; (4) conducting required follow-up reviews of measures with time-limited endorsement for consideration of full endorsement; and (5) conducting ad hoc reviews of endorsed quality measures, practices, consensus standards, or events when there is adequate justification for a review.[4] In the normal course of measure maintenance, the NQF solicits information from measure stewards for annual reviews and in order to review measures for continued endorsement in a specific 3-year cycle. In this measure maintenance process, the measure steward is responsible for updating and maintaining the currency and relevance of the measure and for confirming existing specifications to the NQF on an annual basis.[5] As part of the ad hoc review process, the ad hoc review requester and the measure steward are responsible for submitting evidence to be reviewed by a NQF technical expert panel (TEP) which, in turn, provides input to the Consensus Standards Approval Committee (CSAC). This committee then makes a recommendation to the NQF Board on endorsement status and/or specification changes for the measure, practice, or event.

Through the NQF's measure maintenance process, the NQF-endorsed measures are sometimes updated to incorporate changes that we believe do not substantially change the nature of the measure. Examples of such changes that we gave in the CY 2013 OPPS/ASC proposed rule (77 FR 45194) included updated diagnosis or procedure codes, changes to exclusions to the patient population, definitions, or extension of the measure's endorsement to apply to other settings. We stated in the proposed rule that we believed these types of maintenance changes are distinct from more substantive changes to measures that result in what can be considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act.

In the CY 2013 OPPS/ASC proposed rule, we proposed that if the NQF updates an endorsed measure that we have adopted for the IRF QRP in a manner that we consider to not substantially change the nature of the measure, we would use a subregulatory process to incorporate those updates to the measure specifications that apply to the program. Specifically, we would revise the information that is posted on the CMS IRF QRP Web site at: *http://www.cms.gov/IRF-Quality-Reporting/* so that it clearly identifies the updates and provides links to where additional information on the updates can be found. In addition, we would refer IRFs to the NQF Web site for the most up-to-date information about the quality measures (*http://www.qualityforum.org/*). We would provide sufficient lead time for IRFs to implement the changes where changes to the data collection systems would be necessary.

We proposed to continue to use the rulemaking process to adopt changes to measures that we consider to substantially change the nature of the measure. We believe that our proposal adequately balances our need to incorporate NQF updates to NQF-endorsed IRF QRP measures in the most expeditious manner possible, while preserving the public's ability to comment on updates to measures that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We noted that, in the FY 2013 IPPS/LTCH PPS proposed rule, we proposed a similar policy for the Long-Term Care Hospital Quality Reporting (LTCHQR) Program (77 FR 53652 through 53653). CMS finalized a modified version of this policy for the LTCHQR Program, as discussed below.

Comment: Many of the commenters supported the use of the subregulatory process to incorporate NQF updates to measures that do not substantially change the nature of the measure. One commenter believed that this approach would be reasonable, as long as the use of the subregulatory process does not create any additional burden for IRFs. Another commenter stated that not all NQF updates need to be subject to a formal rulemaking process before the update can be implemented.

Response: We appreciate the commenters' support of our proposal. However, in response to some of the concerns expressed by other commenters below, and to be consistent with the policy that we have adopted for other quality reporting programs, we are finalizing this proposal with the modifications discussed below.

Comment: Several commenters supported the proposal to use the subregulatory process to incorporate non-substantial NQF updates to quality measures that are made between rulemaking cycles. However, the commenters expressed concern regarding how CMS would define substantial and non-substantial changes. The commenters were concerned that even slight changes to a measure's specifications will cause them to incur significant burden. The commenters urged CMS to use great caution in making decisions about what should be classified as a substantial change and a non-substantial change. One commenter expressed concern regarding the lack of specificity in the definition of a substantial change to a measure. One commenter suggested that the decision on whether a change to a measure rises to the level of substantial should be made by giving consideration not only to the measure itself, but also to what data the provider is required to report on the changed measure and how it would impact providers. Another commenter expressed concern that there was a lack of specificity by both CMS and the NQF regarding the definition of

[3] For more information about the NQF Consensus Development Process, we refer readers to the Web site at: *http://www.qualityforum.org/Measuring_Performance/Maintenance_of_NQF-Endorsed%C2%AE_Performance_Measures.aspx*).

[4] For more information about the NFQ Ad Hoc Review process, we refer readers to the Web site at: *http://www.qualityforum.org/Projects/ab/Ad_Hoc_Reviews/CMS/Ad_Hoc_Reviews-CMS.aspx*).

[5] For more information about the NQF Measure Maintenance process, we refer readers to the NQF Web site at: *http://www.qualityforum.org/Measuring_Performance/Improving_NQF_Process/Process_Assessment_Measure_Maintenance.aspx*.

a substantive change in a measure. Several commenters disagreed with the examples of substantial and non-substantial changes to a measure that were presented in the CY 2013 OPPS/ASC proposed rule. Another commenter urged CMS to consider any update to a measure that requires any additional data collection as a substantial change and thus subject to the more formal rulemaking process.

Response: The NQF regularly maintains its endorsed measures through annual and triennial reviews, which may result in the NQF making updates to the NQF-endorsed measures. We believe that it is important to have a subregulatory process in place, which we can use to incorporate non-substantive changes made by the NQF to measures we have adopted for use in the IRF QRP. Such a policy would allow for IRF QRP measures to be updated quickly and with a minimum amount of burden to IRF providers. However, we do recognize that some changes the NQF might make to its endorsed measures are substantive in nature and, therefore, it might not be appropriate for CMS to adopt these changes to the measures used in the IRF QRP using a subregulatory process.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45194), we proposed a policy to use a subregulatory process to adopt changes made to quality measures by the NQF that we consider to be non-substantial in nature. We further proposed to continue using the rulemaking process to adopt changes made by the NQF if we consider them to substantially change the nature of a measure. We have recently reconsidered these proposals in light of modified policies that were finalized in other quality reporting programs, such as the LTCHQR Program and the Hospital IQR Program. We have also reconsidered our proposals regarding this policy in light of the public comments we received. We believe that consistency and harmonization among the Medicare quality reporting programs is vitally important and helps to reduce provider burden.

In the FY 2013 IPPS/LTCH final rule (77 FR 53504) we indicated examples of what we might *generally* regard as non-substantive changes to measures might include, but are not limited to, updated diagnosis or procedure codes, medication updates for categories of medications, or a broadening of age ranges. We believe that non-substantive changes may also include updates to NQF-endorsed measures based upon changes to guidelines upon which the measures are based. We noted that the NQF process has already incorporated an opportunity for public comment and engagement in the measure maintenance process.

We stated that we will continue to use rulemaking to adopt substantive updates made by the NQF to the endorsed measures we have adopted for the IRF Quality Reporting Program. Examples of changes that we might *generally* consider to be substantive would include, but are not limited to, those circumstances in which the changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent (for example, changes in acceptable timing of medication, NQF expansion of endorsement of a previously endorsed measure to a new setting, procedure/process, or test administration). However, these and other changes would need to be evaluated on a case-by-case basis to determine whether or not a change to a measure is in fact substantive. We intend to follow this modified policy when making changes to all IRF QRP measures.

Comment: One commenter recommended that CMS clearly identify subregulatory updates, provide links to where additional information about the updates can be found, and provide sufficient lead time for IRFs to implement any changes related to the NQF's updates. Another commenter recommended that CMS confer with a sufficient number of stakeholders in the rehabilitation hospital community to apprise them of the impending change and to seek informal feedback and input prior to adopting the measure's change. Further, the commenter recommended that CMS conduct testing of the change to determine its effectiveness before implementation.

Response: In the event that any measure that has been previously adopted for use in the IRF QRP is updated in a manner that we deem to be non-substantive in nature, we will use the subregulatory process to incorporate those changes. We will ensure that stakeholders are fully informed about these changes and that they have been afforded adequate lead time to make any necessary changes. Some of the methods that we will use to keep our stakeholders informed include: posting of information on the IRF QRP Web page [6]; holding special open door forums, posting information in the CMS weekly E-News publication, and responding to provider questions that we receive through the IRF QRP helpdesk.[7] While we expect to provide notice to stakeholders when we intend to seek NQF's review of measures, the NQF process incorporates an opportunity for public comment and engagement in the measure maintenance process.[8]

After consideration of the public comments we received, we are adopting as final a policy to: (a) Utilize a subregulatory process to incorporate updates to the IRF QRP quality measures that are not substantive in nature; and (b) continue use of the rulemaking process to adopt changes to measures that we consider to be substantive in nature.

C. Process for Retention of IRF Quality Measures Adopted in Previous Fiscal Year Rulemaking Cycles

We expect that the measures that we adopt for purposes of the IRF QRP will remain current and useful for a number of years after their initial adoption. While we could elect to adopt measures for each fiscal year's payment determinations, we believe that it would be easier for all parties concerned if we adopt the measures in perpetuity with an expectation that we will propose to remove, suspend or replace measures through future rulemaking, if necessary. Therefore, for the purpose of streamlining the rulemaking process, in the CY 2013 OPPS/ASC proposed rule (77 FR 45194), we proposed that when we initially adopt a measure for the IRF QRP for a payment determination, that measure will be automatically adopted for all subsequent fiscal year's payment determinations or until such time as we might propose and finalize the measure's removal, suspension, or replacement.

Quality measures may be considered for removal by CMS if: (1) Measure performance among IRFs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made; (2) performance or improvement on a measure does not result in better patient outcomes; (3) a measure does not align with current clinical guidelines or practice; (4) a more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available; (5) a measure that is more proximal in time to desired patient outcomes for the particular topic is

[6] *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html?redirect=/IRF-Quality-Reporting/.*

[7] *IRF.questions@cms.hhs.gov.*

[8] For information about the NQF consensus development process, we refer readers to the NQF Web site at: *http://www.qualityforum.org/Measuring_Performance/Consensus_Development_Process%e2%80%99s_Principle/Public_and_Member_Comment.aspx.*

available; (6) a measure that is more strongly associated with desired patient outcomes for the particular topic becomes available; or (7) collection or public reporting of a measure leads to negative unintended consequences.

For any such removal, the public will be given an opportunity to comment through the next annual rulemaking process. However, if there is reason to believe that continued data collection of a measure raises potential safety concerns, we will take immediate action to remove the measure from the IRF QRP and not wait for the annual rulemaking cycle. Such measures will be promptly removed with IRFs and the public being immediately notified of such a decision through the usual IRF QRP communication channels, including listening sessions, memos, email notifications, and Web site postings. In such instances, the immediate removal of a measure will also be formally confirmed in the next annual rulemaking cycle. We invited public comment on our proposal that once a quality measure is adopted, it is retained for use in the subsequent fiscal year's payment determinations unless otherwise stated.

Comment: One commenter suggested that CMS should be required to re-propose quality measures each year so that stakeholders have the opportunity to submit comments before measures are finalized for use. The commenter stated that there needs to be a continuing opportunity for the public to comment each year on not only measures that are being proposed, but also on measures that were previously adopted. Further, the commenter expressed concern that this policy would result in a scenario in which stakeholder comments about previously adopted measures would not be given proper consideration.

Response: Our proposal to retain previously finalized IRF QRP measures for future years aligns with our policy to retain measures for future years in other Medicare quality reporting programs such as the LTCHQR Program and the Hospital IQR Program. We plan to review quality measures that have been adopted for use in the IRF QRP on at least an annual basis to make sure that each measure remains relevant, valid and reliable. The optimum time to perform this review would be at the time when we review and analyze the quality measure data received from IRFs for any given reporting period or data reporting cycle. Some of the IRF QRP measures may be reviewed more often, depending upon the frequency with which we receive data for these measures or whether other circumstances prompt review. We will perform ad hoc reviews of IRF QRP quality measures if we find any indication that a measure is no longer valid, reliable or that continued collection of data for this measure leads to negative unintended consequences. Regardless of the type of review performed, if our analysis of these data reveals that a quality measure meets any of the above-stated enumerated criteria for removal (for reasons other than patient safety) we will propose to remove that measure in the next rulemaking cycle. If, at any time, we discover that an IRF quality measure poses a potential safety concern, we will take immediate action to remove that measure from the IRF QRP.

We have provided IRFs with a mechanism by which to submit comments regarding quality measures that have previously been adopted for use in the IRF QRP. IRFs may submit comments regarding quality measures that are already being used in the IRF QRP through the IRF QRP helpdesk email box.[9] We will give full consideration to any comments that we receive.

Finally, we also plan to solicit input in regard to the quality measures that are already being used in the IRF QRP from technical experts, as well as the public, through venues such as listening sessions, special open door forums, and national provider calls. These venues will provide IRFs with several ways to provide us with input on quality measures that are currently in use under the IRF QRP. We will give equal consideration to comments that we receive in regard to measures, whether they are being proposed or have previously been finalized for use under the IRF QRP. This will help to ensure that each of the adopted measures remains appropriate for continued inclusion in the IRF QRP.

After consideration of the public comments we received, we are finalizing our proposal to retain adopted quality measures for subsequent reporting periods (and the associated annual payment determinations) unless we propose to remove, suspend, or replace these measures.

We proposed to apply this principle to the two measures that were selected for use in the IRF QRP beginning on October 1, 2012. These adopted measures are: (1)) An application of the NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome measure (NQF #0138),[10] and (2) An application of the Percent of Residents with Pressure Ulcers that Are New or Worsened measure (NQF #0678). We also invited public comment on our proposal to apply the principle of retention to the two above-stated quality measures that were adopted for use under the IRF QRP in the FY 2012 IRF PPS final rule (76 FR 47874 through 47878) for the second and all subsequent reporting periods (and associated payment determinations).

Likewise, we invited public comment on our proposed use of the process, as stated above, for retention of any additional future quality measures that may be adopted for use in the IRF QRP.

Comment: Two commenters supported CMS' proposal for retention of the two quality measures that were previously finalized for use under the IRF QRP.

Response: We appreciate the commenters' support of our proposed approach for retention of the two quality measures adopted for use under the IRF QRP.

After consideration of the public comments we received, for the reasons set forth above, we are finalizing our proposal to apply this policy of retention of IRF QRP quality measures to the two measures that were finalized in the FY 2012 IRF PPS final rule. These measures are (1) An application of the NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138) (previously titled ''CAUTI rate per 1,000 urinary catheter days, for Intensive Care Unit Patients''); and (2) An application of the Percent of Residents with Pressure Ulcers that Are New or Worsened measure (NQF #0678).[11] Although we are retaining these measures for the IRF QRP, we discuss below certain updates that we are making with respect to each of them.

[9] *IRF.questions@cms.hhs.gov.*

[10] The CAUTI measure that was adopted in the FY 2012 IRF PPS final rule (76 FR 47836 through 47915) was titled ''Urinary Catheter-Associated Urinary Tract Infection [CAUTI] Rate Per 1,000 Urinary Catheter Days for ICU patients.'' However, this measure was submitted by the CDC (measure steward) to the NQF for a measure maintenance review. As part of their NQF submission, the CDC asked for changes to the measure, including expansion of the scope of the measure to non-ICU settings, including IRFs. The NQF approved the CDC's request on January 12, 2012. Due to the changes that were made to the measure, the CDC believed that it was appropriate that the measure title be changed. This measure is now titled ''National Health Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure.''

[11] This measure was recently reviewed by the NQF and the scope of the measure was expanded to include post-acute care settings such as IRFs. Patients in post-acute care settings are referred to as ''patients'' as opposed to ''residents'', which is a term used in the nursing home setting. To reflect the expansion in the scope of this measure, the title was changed to ''Percent of *Patients/Residents* with Pressure Ulcers that Are New or Worsened (NQF #0678)'' (emphasis added).

D. Measures for the FY 2014 Payment Determination

We have previously identified the measurement of pressure ulcers and the prevalence of urinary tract infections (UTI) as two critical areas for quality measurement under the IRF QRP. While section 1886(j)(7) of the Act generally requires the adoption of endorsed measures, there were no NQF-endorsed measures for the two desired areas in the IRF context at the time CMS was conducting its rulemaking. As section 1886(j)(7)(D)(ii) of the Act authorizes the use of measures that are not endorsed when there are no feasible and practicable endorsed options, in the FY 2012 IRF PPS final rule (76 FR 47874 through 47878), we adopted applications of an NQF-endorsed pressure ulcer measure that had been endorsed for use in skilled nursing facilities (NQF #0678) and a CDC measure, the CDC's Urinary Catheter Associated Urinary Tract Infection [CAUTI] rate per 1, 000 urinary catheter days, for Intensive Care Unit [ICU] Patients (NQF #0138), that had NQF endorsement for use in intensive care settings of hospitals.

1. Clarification Regarding Existing IRF Quality Measures That Have Undergone Changes During NQF Measure Maintenance Processes

In the FY 2012 IRF PPS final rule (76 FR 47874 through 47876), we used the endorsement exception authority under section 1886(j)(7)(D)(ii) of the Act. This authority permitted us to adopt the Urinary Catheter-Associated Urinary Tract Infection [CAUTI] rate per 1,000 urinary catheter days, for Intensive Care Unit [ICU] Patients measure (NQF #0138). We chose to adopt this measure because there was no NQF-endorsed CAUTI measure available to assess the prevalence of urinary CAUTI rates in the IRF setting.

As stated in section XVII.C. of this final rule with comment period, the CAUTI measure steward, the CDC, submitted the CAUTI measure to the NQF for a scheduled measure maintenance review in late 2011. At that time, the CDC also filed a request to expand the CAUTI measure to non-ICU settings, including IRFs. The NQF granted the CDC's request for an expansion of the scope of endorsement of the CAUTI measure to additional non-ICU care settings, including ''rehabilitation hospitals.'' The NQF defined the term ''rehabilitation hospitals'' as including both freestanding IRFs, as well as IRF units that are located within an acute care facility. Despite the expansion in the scope of endorsement of the CAUTI measure, the original NQF endorsement number (NQF #0138) was retained. However, the measure was re-titled ''National Health Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure.'' [12]

As amended, the expanded CAUTI measure includes a different data calculation method, which is referred to as the standardized infection ratio (SIR).[13] The change in the data calculation method does not, however, change the way in which IRFs will submit CAUTI data to the CDC. IRFs will still be required to submit their CAUTI data to the CDC via the National Healthcare Safety Network (NHSN) online system.

Under the originally endorsed version of the CAUTI measure, the CDC calculated an infection rate per 1,000 urinary catheter days. Under the new method, CDC will use a SIR calculation method, which is comprised of the observed number of infections over the expected number of infections.[14] The SIR calculation consists of an ''observed'' rate of CAUTI infections over the ''expected rate'' of CAUTI infections for that particular healthcare location. The CDC calculates the ''expected rate'' of CAUTI infections from CAUTI data that is reported to them by healthcare facilities. According to the epidemiologists at the CDC, they will need to analyze approximately 12 months of CAUTI data in order to calculate the ''expected rate'' of CAUTI infections for any given healthcare facility.

We believe that the SIR calculation method is a more accurate way to calculate the CAUTI measure results for comparative purposes because it takes into account an IRF's case mix. In addition, use of the SIR calculation does not require any change to the type of data required to be submitted by IRFs or the method of data submission that IRFs must use in order to comply with the CAUTI measure reporting requirements.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45196), we made the following proposals in regards to the CAUTI measure: (1) We proposed to adopt the changes made to the NQF #0138 CAUTI measure, which will apply to the FY 2014 annual payment update determination; (2) we proposed to adopt the CAUTI measure, as revised by the NQF on January 12, 2012, for the FY 2015 payment determination and all subsequent fiscal year's payment determinations; and (3) we proposed to incorporate, for use under the IRF QRP, any future changes to the CAUTI measure to the extent these changes are consistent with our proposal in section XVII.B. of the CY 2013 OPPS/ASC proposed rule to update measures.

Comment: Several commenters supported our proposal to adopt the changes made by the NQF to the CAUTI measure. Several commenters also supported use of the SIR calculation. The commenters also supported the delay in the implementation of the SIR calculation by the CDC. One commenter agreed that CMS should delay public reporting of the CAUTI measure data until after the CDC has collected enough data to calculate the expected CAUTI infection rate that will be used in the SIR calculations.

Response: We agree that use of the SIR calculation will be a more accurate method for risk stratified calculation of the CAUTI measure data. We also agree that public reporting of the CAUTI measure data should not take place until sufficient baseline data has been collected by the CDC.

Comment: One commenter expressed concern regarding CMS being able to properly risk adjust the CAUTI data results using the SIR calculation. The commenter was concerned that IRFs caring for more complicated patients will appear to have worse quality outcomes than other IRFs that care for less specialized patients, unless CMS can make the proper type of risk adjustments. The commenter further expressed concern that the SIR calculation method will be unable to provide adequate risk adjustment when comparing IRFs that have a specialized patient population to other IRFs that tend to have a more general patient population.

Response: After the IRF QRP begins, the CDC will take time to collect and analyze the CAUTI measure data in an amount that is sufficient to calculate an ''expected rate'' of CAUTI infection for IRF locations/units. The CDC needs up to 12 months of CAUTI data from various IRF's in order to calculate the ''expected'' CAUTI rates for the IRFs locations and units. These expected CAUTI infection rates can then be used to calculate a SIR for each IRF that includes adjustment for the patient population mix. The CDC and their subject matter experts, will make a determination with regard to how the

[12] *http://www.qualityforum.org/MeasureDetails.aspx?actid=0&SubmissionId=1121#k=0138&e=0&st=&sd=&s=n&so=a&p=1&mt=&cs=&ss=.*

[13] Centers for Disease Control and Prevention (2012, January), Catheter Associated Urinary Tract Infection Event. Retrieved from: *http://www.cdc.gov/nhsn/PDFs/pscManual/7pscCAUTIcurrent.pdf.*

[14] *http://www.cdc.gov/nhsn/pdfs/pscmanual/7psccauticurrent.pdf.*

patient population mix will be used in the risk adjustment for the SIR.

Comment: One commenter expressed concern regarding IRFs being held accountable for CAUTI infections that a patient acquired prior to an admission or transfer into that IRF.

Response: To help determine where the CAUTI infection may have developed, the CAUTI measure specifications incorporate a ''transfer rule.'' The ''transfer rule'' provides that if a patient develops a CAUTI within 48 hours of transfer from another location, the CAUTI is attributed back to the transferring location (*http://www.cdc.gov/nhsn/pdfs/pscmanual/7psccauticurrent.pdf*). We believe that the use of the transfer rule to the CAUTI measure calculations will help ensure that CAUTI infections are properly attributed to the facility where they originated.

Comment: One commenter suggested that pediatric patients should be excluded from the CAUTI measure because it has not been NQF-endorsed for the pediatric population due to low frequency of catheter use and difficulty in attributing UTIs.

Response: We disagree with the commenter's suggestion that pediatric patients should be excluded from this measure for the reasons stated below. The measure specifications for the NQF #0138 CAUTI measure exclude patients in a neonatal ICU, but otherwise have no other age based exclusions. The target population age range for the NQF #0138 CAUTI measure is described in the measure specifications as follows: ''*Patients of all ages* are eligible except patients in Levels I, II, II/III and III nurseries, and in locations where patients do not reside overnight.'' (Emphasis added)

Second, we believe that it is important to gather and analyze CAUTI measure data from patients of all age groups so that we can study the rate of CAUTI infections in not only adults and the elderly, but also in children. There are several IRFs that specialize in the rehabilitation of pediatric patients. Many other IRFs also treat pediatric patients. We would be remiss in our duty to measure the quality of care in the IRF setting if we did not gather CAUTI measure data from these IRFs on their pediatric patients.

After consideration of the public comments we received, we are finalizing our proposals to: (1) Adopt the changes made to the NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138) as applicable to the FY 2014 annual payment update determination; and (2) adopt the NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138) measure for the FY 2015 payment determination and all subsequent fiscal year payment determinations thereafter.

2. Updates to the ''Percent of Residents Who Have Pressure Ulcers That Are New or Worsened'' Measure

In the FY 2012 IRF PPS final rule (76 FR 47876 through 47878), we again used the endorsement exception authority under section 1886(j)(7)(D)(ii) of the Act to adopt an application of the ''Percent of Residents with Pressure Ulcers that Are New or Worsened'' measure (NQF #0678). We selected this measure because there was no other NQF-endorsed measure available to assess the percentage of patients with pressure ulcers that are new or worsened in the IRF setting at that time. We recognized that the NQF endorsement of this measure was, at that time, limited to short-stay nursing home patients, but we noted our belief that this measure was highly relevant to patients in any setting who are at risk of pressure ulcer development and a high priority quality issue in the care of IRF patients. Therefore, in the FY 2012 IRF PPS final rule, we finalized the adoption of an application of the NQF-endorsed #0678 pressure ulcer measure. We also stated that we would request that the NQF extend its endorsement of this short-stay nursing home pressure ulcer measure to the IRF setting (76 FR 47876 through 47878).

In April 2012, CMS filed an ad hoc request for review of the NQF #0678 short-stay pressure ulcer measure with the NQF. As part of that request, we asked the NQF to expand its endorsement of the measure to several other care settings, including IRFs. As we noted in the FY 2012 IRF PPS final rule, we believe this measure is highly applicable to all post acute care settings, including IRFs (76 FR 47876). We stated in the proposed rule that if the pressure ulcer measure was revised by the NQF, we anticipated that it would be re-titled ''Percent of *Patients or Residents* with Pressure Ulcers That Are New or Worsened'' (NQF #0678) (emphasis added) so as to reflect the expansion in the scope of the applicable patient population.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45196), we noted that, as of the publication of that proposed rule, the NQF review process for the NQF #0678 pressure ulcer measure expansion request was still in progress. We proposed that if the NQF expands the scope of endorsement for this measure to the IRF setting, without any substantive changes, we would adopt and use the NQF-endorsed pressure ulcer measure in the IRF QRP, in accordance with the policy set forth above in section XVII.B. of that proposed rule. We believed that, in this anticipated scenario, the pressure ulcer measure, as revised, would be substantively the same measure, although broader in scope, than the current NQF-endorsed #0678 pressure ulcer measure. We invited public comments on our proposed use of this policy. For the reasons stated below, we have decided not to finalize this proposal.

In the meantime, in the CY 2013 OPPS/ASC proposed rule (77 FR 45196), we proposed to proceed with our plan, as finalized in the FY 2012 IRF PPS final rule, to use an application of the Percent of Residents With Pressure Ulcers that Are New or Worsened (NQF #0678) measure for the FY 2014 payment determination and all subsequent fiscal year payment determinations. For the reasons stated below, we will collect only part of the pressure ulcer measure data as part of the pressure ulcer measure that we adopted last year. We have decided to adopt a non-risk-adjusted version of the NQF #0678 short-stay pressure ulcer measure, and will not publicly report the measure data until such time that we are able to collect data on the IRF–PAI necessary to calculate risk-adjusted measure rates.

Comment: Many commenters supported the use of the ''Percent of Residents with Pressure Ulcers That Are New or Worsened'' (NQF #0678) measure in the IRF QRP. The commenters also supported CMS' request to expand this measure to the IRF setting. One commenter expressed support for the use of the updated pressure ulcer measure, but recommended adding the term ''patients'' to the title of this measure.

Response: We appreciate the commenters' support and agree that adding the word ''patients'' to the title of the revised pressure ulcer measure will help to distinguish the IRF population from patients in nursing homes who are typically referred to as ''residents.'' However, for the reasons discussed below, at this time, we are adopting a non-risk-adjusted version of the NQF-endorsed pressure ulcer measure (NQF #0678).

Comment: One commenter expressed doubt regarding the applicability of the pressure ulcer measure to the IRF setting.

Response: We believe that pressure ulcer development and worsening is an issue that is highly relevant to the IRF

setting. Pressure ulcers are high-volume and high-cost adverse events across the spectrum of health care settings from acute hospitals to home health. Patients in the IRF setting may have medically complex conditions and severe functional limitations, and are, therefore, at high risk for the development, or worsening, of pressure ulcers. Pressure ulcers are serious medical conditions and an important measure of quality. Pressure ulcers can lead to serious, life threatening infections, which substantially increase the total cost of care. Even if the proportion of patients in IRFs with new or worsening pressure ulcers is small, any such cases are particularly troubling.

Comment: One commenter urged CMS to remove this measure from the IRF QRP until such time as the issues that have been raised in stakeholder calls regarding the measure specifications and definitions can be resolved. The commenter stated that CMS has given conflicting guidance on how to stage pressure ulcers and document pressure ulcer data on the Inpatient Rehabilitation Facility—Patient Assessment Instrument (IRF–PAI) during several different provider outreach activities. The commenter opposed ''back-staging'' of pressure ulcers, and suggested that the IRF–PAI does not allow for the documentation of unstageable pressure ulcers that develop after the patient is admitted. Another commenter expressed concern that the modifications to the ''Quality Indicator'' section of the IRF–PAI are confusing. The commenter stated that the pressure ulcer questions that were added to the IRF–PAI do not account for all categories of pressure ulcers, such as unstageable pressure ulcers and suspected deep tissue injuries. Two commenters suggested that CMS delay implementation of the pressure ulcer measure and take time to work with IRFs and the National Pressure Ulcer Advisory Panel (NPUAP) to develop a standardized approach to reporting pressure ulcers.

Response: We have made several different types of training opportunities available to the IRF provider community. We held special open door forums on November, 29, 2011, and April 19, 2012. We also provided a full day in-person provider training on May 2, 2012. Most recently, we initiated a four-part series of special open door forums held on July 26, 2012; August 16, 2012; September 20, 2012; and October 18, 2012. PowerPoint slides used at the IRF Open Door Forums are available on the IRF QRP Web page. (*http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html?redirect=/IRF-Quality-Reporting/*). Documentation of the collection of pressure ulcer data is contained in Section 4 of the IRF–PAI training manual. This manual is available on the CMS Web site (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Downloads/IRFPAI-manual-2012.pdf*).

During each of these training/outreach activities, we provided individuals with information regarding the IRF quality reporting program, including information about CAUTI and pressure ulcer data reporting. The information that we have offered to providers at each of the outreach activities noted above has been consistent.

We have also engaged the help of two widely known experts in the area of skin conditions and wound care. These experts have served as consultants to CMS and have taught our outreach activities. These experts have given presentations on how to stage and report pressure ulcer data. One of these experts was a guest lecturer at our provider training, which took place on May 2, 2012. Our pressure ulcer experts also attended the open door forums held on July 26, 2011, August 16, 2012, and October 18, 2012. At three of the open door forums held, these experts were available to answer questions from providers.

In addition, we held an open door forum on September 20, 2012, that dealt exclusively with the issue of pressure ulcer staging and documentation on the IRF–PAI. We also presented answers to questions that had been previously raised as well as a copy of a properly completed ''Quality Indicator'' section (questions 48A to 50C) of the IRF–PAI, which corresponded to the scenarios presented in each question. We believed that showing examples of a properly completed IRF–PAI for each question would help to reduce the confusion that IRFs were experiencing regarding the coding of pressure ulcer data on the IRF–PAI. We also discussed during this open door forum the issue of ''back-staging'' pressure ulcers, and explained that we do not, nor have we ever recommended, ''back-staging'' pressure ulcers in the IRF QRP.

We have provided IRFs with written guidance related to the staging of pressure ulcers, collection of pressure ulcer data, and documentation of pressure ulcer data in the ''Quality Indicator'' section of the IRF–PAI. This written guidance is contained in Section 4 of the IRF–PAI training manual. This manual is available on the CMS Web site (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Downloads/IRFPAI-manual-2012.pdf*).

We recognize that the format and structure of the pressure ulcer questions, which are located in the ''Quality Indicator'' section of the revised IRF–PAI has resulted in some unintended limitations in the type and amount of pressure ulcer data that can be collected. We will continue to work with stakeholders to address their concerns and make the appropriate modifications to the data collection instrument over time. In the meantime, we will continue with the collection of the pressure ulcer measure data using the questions contained in the ''Quality Indicator'' section of the IRF–PAI.

We do not believe that it would be in the best interest of many of the IRF providers if we were to delay the use of the pressure ulcer measure in the IRF QRP until such time as the IRF–PAI is modified. We recognize that IRFs have incurred a significant financial burden preparing their EHR systems and staff to report pressure ulcer measure data beginning on October 1, 2012.[15]

Comment: One commenter expressed concern that revisions to the IRF–PAI do not allow IRFs to adequately document suspected deep tissue injury (DTI) that is present when the patient is admitted to the IRF. The commenter stated that DTIs are ''wounds'' that are evolving or in the process of ''declaring'' their final stage. The commenter stated that if the suspected DTI cannot be adequately recorded upon admission, and the wound later progresses to its final stage (stage 3 or 4), it will appear that the IRF was responsible for the pressure ulcer, instead of the location where the DTI occurred.

Response: We believe that it is important to do a thorough admission assessment on each patient who is admitted to an IRF at the soonest possible time after admission. This admission assessment should include a through skin assessment and should include the documentation of the presence of any pressure ulcers as well as any unstageable pressure ulcers, including suspected deep tissue injury. The IRF–PAI admission assessments must be performed within 3 days after admission. However, the IRF staff would also document the admission

[15] For quality reporting purposes, only those patients that are admitted on after 10/01/2012 will be included in the measure. Data obtained from patients that are admitted before 10/01/2012 but discharged after 10/01/2012 will not be used in the measure calculations. For more information about this policy, we refer readers to the IRF–PAI training manual.

assessment findings in their medical records as well.

We also agree with the commenter that it is not possible to directly document suspected DTIs on the revised IRF–PAI (which became effective on October 1, 2012) immediately when doing the IRF–PAI admission assessment. However, an IRF provider can and certainly should, as part of its normal patient assessment and good care, perform the skin assessment and note any finding of suspected DTI or pressure ulcers at any stage in the patient's medical record. Documentation of pressure ulcer data on the IRF–PAI is not a replacement for proper clinical documentation in a patient's medical record.

A suspected DTI is one of three types of unstageable pressure ulcers, which can be documented on the IRF–PAI after it becomes stageable and ''declares'' its final stage. We believe that we have given IRF providers instructions about how to document unstageable pressure ulcers on the IRF–PAI on several different occasions. This issue was discussed during a question and answer session that took place during the IRF QRP special open door forum held on July 26, 2012, and at another IRF QRP special open door forum held on August 16, 2012. In addition, this issue was discussed again at another IRF QRP special open door forum held on September 20, 2012. The September 20, 2012 open door forum was devoted solely to the discussion of staging and documentation of pressure ulcers on the IRF–PAI. PowerPoint slides used during the September 20, 2012 special open door forum included scenarios in the form of questions and answers, as well as examples of the IRF–PAI with the correct coding to correspond to the scenario presented in each question. As noted above, the PowerPoint slides used at any of the IRF QRP open door forums are available to IRFs on the IRF QRP Web page (*http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html?redirect=/IRF-Quality-Reporting/*).

Also, we have provided written guidance on how to document unstageable pressure ulcers that have become stageable on the IRF–PAI in Section 4 of the IRF–PAI training manual. On page IV–3 of Section 4 of the IRF–PAI training manual, suspected deep tissue injury is defined as one of the three types of unstageable pressure ulcers. Section 4 of the IRF–PAI training manual further states that unstageable pressure ulcers that are present at the time of admission are not documented on the IRF–PAI.

As documented in Section 4 of the IRF–PAI training manual, if a pressure ulcer is unstageable upon admission, but becomes stageable later during the patient's IRF stay, this pressure ulcer should be considered as present on admission, at the stage at which it first becomes stageable. The admission assessment should be modified to reflect this. For example, if the IRF had documented on the patient's admission assessment that there were no pressure ulcers on admission, and then a suspected DTI progressed to a Stage 2 or higher pressure ulcer, the IRF would change the admission assessment to document the final stage of that pressure ulcer. Doing so will help to ensure that the IRF–PAI reflects that this pressure ulcer was present on admission, and what stage the ulcer was when it first became stageable. We believe that this effectively prevents the finding that an unstageable pressure ulcer that became stageable during the IRF stay developed during the patient's IRF stay and/or is attributed to the IRF.

Comment: One commenter expressed concern about making comparisons in pressure ulcer rates between IRFs because of the differences in patient populations that are served by each IRF. The commenter suggested that CMS develop a mechanism whereby these IRFs are not unfairly compared against peers that do not care for like populations of patients in any public reporting of the pressure ulcer measure data or other quality measures.

Response: The specifications for both the application of the pressure ulcer measure that we adopted in the FY 2012 IRF PPS final rule, as well as the specifications for the updated NQF-endorsed version of the measure (NQF #0678), include data elements that allow the measure to be risk adjusted when calculated in the IRF setting. These risk adjustment specifications take into consideration items such as the patient's height, weight, and co-morbid conditions. When we were revising the ''Quality Indicator'' section of the IRF–PAI by replacing the old voluntary quality items with the mandatory pressure ulcer questions, we worked within the existing format and framework of the IRF–PAI. We recognize that placement of quality measurement data items within the format of the IRF–PAI has resulted in some unintended limitations in the type and amount of pressure ulcer data that can be collected.

We will continue to work with stakeholders to address their concerns and make the appropriate modifications to the ''Quality Indicator'' section of the IRF–PAI. However, we do not believe that it would benefit IRFs to delay the start of the pressure ulcer measure data reporting during the time that we are working to make the necessary revision to the IRF–PAI. We say this for several reasons. First, evaluating the pressure ulcer data that is reported to us during the first several reporting periods is one of the best ways for us to see what changes and modifications are needed to the IRF–PAI to ensure that it properly collects all of the data elements needed to calculate risk-adjusted rates. Second, many IRFs have incurred a significant amount of time and money to prepare themselves to report pressure ulcer data. Also, use of a non-risk adjusted version of the NQF-endorsed pressure ulcer measure will not cause IRF providers any increased burden because it will not require any change in the way that IRFs are required to collect and report pressure ulcer data.

After giving full consideration to the public comments we have received, we have decided to: (1) Adopt a non-risk-adjusted version (numerator and denominator data only) of the NQF #0678 pressure ulcer measure; (2) collect the pressure ulcer measure data using the current version of the IRF–PAI; and (3) not begin public reporting of pressure ulcer measure data until we have: (a) Thoroughly reviewed and researched this matter and consulted technical experts; (b) made appropriate modifications to the ''Quality Indicator'' section of the IRF–PAI to add the risk adjustment items; and (c) adopted the NQF-endorsed pressure ulcer measure (#0678) and notified stakeholders of our intentions through the rulemaking process.

Comment: MedPAC made suggestions related to additional quality measures that it believed CMS should add to the IRF QRP. MedPAC suggested that CMS develop a risk-adjusted readmission measure. Further, MedPAC requested that CMS comment, in this final rule with comment period, on the progress of the development of this type of readmission measure. MedPAC also urged CMS to consider adding a measure of functional improvement. MedPAC pointed out that regaining functional status represents a central goal of IRF care.

Response: We appreciate MedPAC's input. We agree that both a risk-adjusted readmission measure and a measure of functional improvement would be extremely valuable measures of quality in the IRF setting. We are working to develop and implement these measures in the IRF QRP at the soonest possible time. We invite MedPAC to meet with the CMS IRF QRP team for further discussion of these quality measures.

Comment: One commenter made reference to the IRF quality measures that CMS included on a list made publicly available in late 2012 in accordance with section 1890A(a)(2) of the Act. The commenter noted that none of these measures were proposed for adoption into the IRF QRP in the proposed rule. This commenter offered their opinion and rationale as to whether some of measures should, or should not be added to the IRF QRP. The measures are as follows:

- *Incidence of potentially preventable venous thromboembolism (VTE)*—The commenter stated that this measure requires considerable clarification because, many, if not most, rehabilitation patients are at very high risk for VTE. The commenter further pointed out that many IRF patients are on VTE prophylaxis, yet, some of the IRF patients still get VTEs.
- *Health care worker influenza immunization*—This commenter supported adoption of this measure as long as data is reported by IRFs to NHSN;
- *The percent of patients/residents on a scheduled pain medication regimen on admission who self-report*—The commenter stated that in intensive rehabilitation, providers need to strike a balance between relieving pain completely, and avoiding overmedication so that the patient can safely participate in an intensive rehabilitation program;
- *Percent of nursing home residents who were assessed and appropriately given the seasonal influenza vaccine*—Because most patients that enter IRFs were previously hospitalized, it is likely that their influenza vaccination status already was established in the hospital during the flu season. The commenter further stated that, in some cases, with repeat questioning, some patients may elect vaccination after they have left the acute care facility or had a change of mind within the facility;
- *Percent of nursing home residents who were assessed and appropriately given the pneumococcal vaccine.*—This commenter stated that the same problems that may occur with the patient influenza vaccination measure may also occur with this measure;
- *Functional improvement measure*—Of particular note is that the commenter expressed opposition to the use of a functional measure that is based upon the FIM™ scale. The commenter stated that data related to FIM™ change are impacted dramatically by high rates of discharges back to acute care hospitals from rehabilitation facilities caring for the most complex and unstable rehabilitation patients. The commenter further stated that if quality measures for rehabilitation emphasize FIM™ change during rehabilitation, it is quite possible that IRFs will be incentivized to deny admission to the most complex patients who, in fact, have the greatest need for rehabilitation.

Response: We appreciate the commenter's thoughts and suggestions offered regarding the above-stated quality measures. All of these measures remain under active consideration for future adoption into the IRF QRP, and we will consider this information during future rulemaking cycles when we are selecting quality measures for inclusion under the IRF QRP.

XVIII. Revisions to the Quality Improvement Organization (QIO) Regulations (42 CFR Parts 476, 478, and 480)

A. Summary of Changes

The Utilization and Quality Control Peer Review Program was originally established by sections 142 and 143 of the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982 (Pub. L. 97–248). The name of the individual organizations covered under the program was previously changed from ''Peer Review Organizations'' to ''Quality Improvement Organizations'' through rulemaking (67 FR 36539). In the CY 2013 OPPS/ASC proposed rule (77 FR 45196 through 45205), we identified several changes that we proposed because they are essential to remedying longstanding problematic aspects of the QIOs' review activities. These proposed changes would enable us to improve the QIO program by ensuring that QIOs are better able to meet the needs of Medicare beneficiaries.

Several of the proposed changes are specific to the QIOs' processing of quality of care reviews, which includes beneficiary complaint reviews. Although references are made to QIO sanction activities, the proposed changes did not impact QIO sanction activities or the regulations located in 42 CFR part 1004.

In addition, as part of our review of our regulations in light of the President's Executive Order on Regulatory Reform, Executive Order 13563 (January 18, 2011), we have identified several technical corrections that would improve the readability and use of the QIO regulations.

B. Quality of Care Reviews

Section 9353(c) of Public Law 99–509 amended section 1154(a) of the Act (adding a new paragraph (14)) to require that QIOs (then PROs), effective August 1, 1987, conduct an appropriate review of all written complaints from beneficiaries or their representatives about the quality of services (for which payment may otherwise be made under Medicare) not meeting professionally recognized standards of health care. This authority was in addition to the QIOs' already existing authority under section 1154(a)(1)(B) of the Act to perform quality of care reviews. In order to provide more clarity regarding the QIOs' roles, in the CY 2013 OPPS/ASC proposed rule (77 FR 45196), we proposed to add a definition of ''quality of care review'' under § 476.1 to make clear that this review type refers to both beneficiary complaint reviews (written or oral) and general quality of care reviews. We also proposed to add under § 476.1 definitions for ''beneficiary complaint'' to mean a complaint by a beneficiary or a beneficiary's representative alleging that the quality of services received by the beneficiary did not meet professionally recognized standards of care and may consist of one or more quality of care concerns; ''beneficiary complaint review'' to mean a review conducted by a QIO in response to the receipt of a written beneficiary complaint to determine whether the quality of Medicare covered services provided to beneficiaries was consistent with professionally recognized standards of health care; and ''general quality of care review'' to mean a review conducted by a QIO to determine whether the quality of services provided to a beneficiary(s) was consistent with professionally recognized standards of health care. We proposed that a general quality of care review may be carried out as a result of a referral to the QIO or a QIO's identification of a potential concern during the course of another review activity or through the analysis of data. In addition, we proposed to revise the language under § 476.71(a)(2) to make clear that the scope of a QIO's review includes the right to conduct quality of care reviews, including beneficiary complaint reviews and general quality of care reviews, as well as a new review process that QIOs can offer Medicare beneficiaries called ''immediate advocacy,'' which is described more fully in section XVIII.B.1. of this final rule with comment period.

We proposed additional changes to the QIO regulations related to the following issues:

1. Beneficiary Complaint Reviews

At the time QIOs assumed the authority under section 9353(c) of Public Law 99–509 to conduct reviews of written beneficiary complaints, we

made a decision to rely upon the existing regulations for certain requirements (for example, the timeframes for requesting medical records and the practitioner's right to consent to the release of specific findings to beneficiaries), and to subsequently establish other remaining procedural requirements through manual instructions. While this approach has provided QIOs with a basic framework for completing the reviews, we have become aware of other issues that need to be addressed through the promulgation of new regulations as well as revisions to existing regulations.

In 2003, the United States Court of Appeals for the District of Columbia Circuit issued a decision in the case of *Public Citizen, Inc.* v. *U.S. Department of Health and Human Services* (332 F.3d 654, June 20, 2003) (referred to below as *Public Citizen*) in which the court determined that QIOs must, at a minimum, notify a complainant of the results of its review. We recently completed a comprehensive revision to the manual instructions governing both beneficiary complaints and quality of care reviews, which, in part, was designed to ensure compliance with this court decision (Transmittal 17, April 6, 2012, CMS Manual System, Pub. 100–10 Medicare Quality Improvement Organizations, Chapter 5, Quality of Care Review) (available at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R17QIO.pdf*). These new instructions were effective May 7, 2012. While these manual revisions were necessary, we believe that additional regulatory changes are needed in order to improve QIO operations. In order to subject these additional changes to the processing of beneficiary complaint reviews and general quality of care reviews to notice-and-comment rulemaking, in the proposed rule, we proposed to add new §§ 476.110, 476.120, 476.130, 476.140, 476.150, 476.160, and 476.170 as described below in this section. We also proposed to add new definitions of ''authorized representative'', ''appointed representative; ''beneficiary representative'' and ''quality improvement initiative,'' and revise the definition of ''preadmission certification'' in § 476.1. In addition, to ensure consistency with the proposed revisions to or additional sections under Part 476, we proposed to revise §§ 480.107, 480.132, and 480.133, as discussed more fully below.

The proposed revisions to the regulations under Part 476 include several changes that would improve the beneficiary's experience when contacting a QIO about the quality of health care he or she has received and also shorten key timeframes so that beneficiaries can achieve resolution of their health care concerns in less time. We proposed regulations under new proposed § 476.110 regarding a new alternative dispute resolution process called ''immediate advocacy.'' We proposed to add a definition of ''immediate advocacy'' under § 476.1, and to make clear that this process is specific to oral complaints. We proposed to define ''immediate advocacy'' as an informal alternative dispute resolution process used to quickly resolve an oral complaint that a beneficiary or his or her representative has regarding the quality of health care received, and that this process involves a QIO representative's direct contact with the provider and/or practitioner.

Comment: Several commenters expressed support for the proposed definitions and stated that the availability of clear definitions would help ensure consistent interpretation and application of rules and processes, as well as prevent confusion and dissatisfaction for beneficiaries, providers, practitioners, and QIOs. Other commenters, although supportive of the definitions, raised concerns with specific definitions such as the inclusion of ''oral beneficiary complaints'' in the definition of quality of care reviews, because, in the opinion of the commenters, beneficiary complaints must be written. In addition, other commenters suggested that the wording of a beneficiary complaint should be modified to denote that a complaint must contain at least one quality of care concern because nonmedical, ancillary issues, including perceptions that staff are impolite, it is too hot or cold in the facility, or complaints about the reception process in the waiting room, are not considered to be quality of care issues. Moreover, some commenters suggested that the definition of beneficiary complaint should be modified so that the focus is not on whether the care met professionally recognized standards because care, even when meeting professionally recognized standards of care, could raise quality issues that a QIO should address.

One commenter believed that a definition of professionally recognized standards of health care should be included because it is not clear what this entails. Another commenter requested further clarification regarding what is considered as an episode of care and asked if it relates to one setting, one continuous course of treatment across multiple settings, or something else.

Response: We appreciate the commenters' support of our proposed definitions. With regard to the inclusion of oral beneficiary complaints in the definition of quality of care reviews, we recognize that, under section 1154(a)(14) of the Act, QIOs are required to review written complaints submitted by Medicare beneficiaries. However, section 1154(a)(1)(B) of the Act also gives QIOs general authority to conduct quality of care reviews based on concerns conveyed from a variety of different sources, regardless of the manner in which these concerns have been conveyed. Therefore, a QIO can review concerns that have been expressed orally by any parties, including beneficiaries. Moreover, with regard to the comment that all beneficiary complaints include at least one quality of care concern and that nonmedical, ancillary issues should be excluded, we do not believe that the statute limits the concept of a beneficiary complaint in this way. Beneficiaries have the right to lodge complaints under section 1154 (a)(14) of the Act based on their perception that the quality of services they received did not meet recognized standards of care. This concept of a complaint does not require that the complaint allege a concern that the QIO believes could actually relate to a violation of a standard of care, only that the complaint be about the quality of services not meeting the standard. Many beneficiaries are not in the position of being able to determine whether or not some aspect of their care actually violated a medical standard—nor should beneficiaries be discouraged from filing complaints because they must first make a judgment about standards of care. Additionally, we believe that the examples provided, such as impolite staff, the facility being too hot or too cold, or the reception process in the waiting room, can potentially contribute to the QIO's overall assessment of whether particular services met standards of care. The specific facets that impact the quality of care are not always readily quantifiable, and the QIO must consider various factors before determining whether an issue does or does not relate to the standard of care received. As such, we are not making any change to the definition at this time.

While we considered the concern that quality of care issues could be evident even where professionally recognized standards of care are met, we believe that QIOs must fulfill their statutory obligation to focus their efforts on determining, in any given situation,

whether professionally recognized standards of care have been met. At this time, we also have determined that a definition of professionally recognized standards of care is not something we can define for all QIOs in all States. Section 1154(a)(6) of the Act specifically requires that each QIO apply professionally developed norms of care based upon typical patterns of practice within the QIO's own geographic area as principal points of evaluation and review, taking into consideration national norms where appropriate. The norms of care must be based on a list of specific elements that each QIO must consider. The intricacies on what must go into a standard of care are further discussed in the QIO regulations at 42 CFR 476.1 (definitions of norms; standards; and regional norms, criteria, and standards), and 42 CFR 476.100, which includes details on establishing these elements of review for a QIO's particular locale. Moreover, the QIOs have extensive experience in identifying and implementing their own standards of care. Regarding the questions about an ''episode of care,'' this term is designed to incorporate flexibility so that QIOs can identify the best approach to assessing complaints. As such, we believe that defining the term could unintentionally restrict QIOs' flexibility to link different settings and/or services when the QIO believes that a particular complaint spans a beneficiary's experience with medical care across different settings and/or services. An ''episode'' in one case might therefore be different for different beneficiaries.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45197 through 45199), we proposed an informal review process for beneficiary complaints. Historically, the only option available to beneficiaries, regardless of the severity or type of issue, has been the right to file a written complaint. Once a written complaint is received, the QIO is then obligated to conduct a formal peer review of the complaint, which includes a review of the beneficiary's medical information. Although this peer review process is effective, it can be quite lengthy and burdensome on providers and practitioners, given the various steps that must be completed by the QIO prior to the QIO rendering its final decision, with providers and practitioners cooperating with the QIO throughout this process. These steps include the time needed by the QIO to follow up with beneficiaries to ensure receipt of the complaint in writing, request and receive the medical information from the provider and/or practitioner, discuss the QIO's interim decision with the practitioner and/or provider, respond to a practitioner's and/or provider's request that a QIO conduct a re-review of the initial peer reviewer's decision, and obtain the practitioner's consent to the release of specific findings in the final letter to the beneficiary. By regulation, QIOs must disclose to patients or their representatives information they have requested within 30 calendar days (42 CFR 480.132); it is possible that obtaining a practitioner's consent alone could take 30 calendar days. Even if there are no delays at any point in the current peer review process, it can take over 150 calendar days for a QIO to complete its review of a beneficiary's written complaint.

At times, the length of the current peer review process can render the beneficiary's original concern moot, particularly where the beneficiary's concern relates to a communication issue between his or her providers and/or practitioners, the prescribing of medications, or the failure to receive a necessary medical item, such as a wheelchair. For these types of concerns, we believe that requiring a beneficiary to submit the complaint in writing and waiting more than 150 calendar days so that the QIO can complete its review does not provide prompt and customer friendly service to Medicare beneficiaries. Moreover, at times, certain issues raised by a Medicare beneficiary in a complaint may not even be documented in the beneficiary's medical information. This is particularly true for complaints related to communication or coordination issues surrounding the beneficiary's care. Thus, a QIO may actually know at the outset of a review that the peer review process will not divulge any information related to the beneficiary's complaint.

We believe that, under an informal process such as ''immediate advocacy,'' the QIO would be able to offer an alternative to a Medicare beneficiary in those situations where a resolution is needed more quickly than the current traditional peer review process. We believe that the proposed new informal process would also be beneficial in those instances where information relevant to a complaint would most likely not be contained in the medical information or where the Medicare beneficiary may simply be put off by the formality of the traditional peer review process. We specified in proposed § 476.110(a) that this new informal process would be available for oral complaints so that there is a clear distinction from the process requiring a written complaint under section 1154(a)(14) of the Act. Again, the proposed definition of ''immediate advocacy'' under § 476.1 also would make this clear.

We also proposed that the use of ''immediate advocacy'' would not be available if the QIO makes a preliminary determination that the complaint includes concerns that could be deemed significant, substantial, or gross and flagrant violations of the standard of care to which a beneficiary is entitled (proposed § 476.110(a)(2)(ii)). In addition, we proposed to add definitions of ''quality of care concern'' and ''significant quality of care concern'' under § 476.1, and to incorporate the definitions of ''gross and flagrant violation'' and ''substantial violation in a substantial number of cases'' as these two terms are used in 42 CFR 1004.1. Section 1004.1 covers definitions that apply to a QIO's sanction authority under 42 CFR part 1004. We proposed to define ''quality of care concern'' to mean a concern that care provided did not meet a professionally recognized standard of health care, and that a general quality of care review or a beneficiary complaint review may cover a single concern or multiple concerns. ''Significant quality of care concern'' would mean a determination by the QIO that the quality of care provided to a beneficiary(s) did not meet the standard of care and while not a gross and flagrant or substantial violation of the standard, represents a noticeable departure from the standard that could reasonably be expected to have a negative impact on the health of a beneficiary. ''Gross and flagrant violation'' would mean that a violation of an obligation specified in section 1156(a) of the Act has occurred in one or more instances which presents an imminent danger to the health, safety, or well-being of a program patient or places the program patient unnecessarily in high-risk situations (as specified in 42 CFR 1004.1). ''Substantial violation in a substantial number of cases'' would mean a pattern of providing care that is inappropriate, unnecessary, or does not meet recognized professional standards of care, or is not supported by the necessary documentation of care as required by the QIO (as specified in 42 CFR 1004.1).

We stated that we believe that the proposed definitions would give improved clarity to the distinctions made among concerns that do not meet the standard of care and demonstrate that QIOs are responsible for reviewing all quality-related cases to determine whether care provided to a beneficiary could have violated a standard, and to

address any violation, not just the most significant or flagrant failures to meet a standard of care. With regard to ''immediate advocacy,'' we believe that this informal process is not appropriate for those situations where a QIO preliminarily determines that a complaint could involve a ''gross and flagrant'' or ''substantial'' concern. In these circumstances, the QIO would not offer the immediate advocacy process, but instead would inform the beneficiary of the right to file a written complaint. Moreover, while we proposed to exclude the use of the immediate advocacy process for those instances where ''significant quality of care concerns'' might be present, we requested public comments regarding whether the immediate advocacy process should be made available for these concerns as well. In addition, while we proposed to restrict the use of the immediate advocacy process to a period of 6 months after a beneficiary has received the care at issue (proposed § 476.110(a)(1)), we also requested public comments on whether this time period should be extended beyond 6 months, whether based on the proposed structure or in order to accommodate the potential broadening of its use for ''significant quality of care concerns.'' The public comments that we received are discussed later in this section.

We proposed, under proposed § 476.110(a)(2), to specify that the immediate advocacy process can be used for issues that are not directly related to the clinical quality of health care itself or that accompany or are incidental to the medical care received, but might, as a general matter, contribute to a standard of care not being met. This includes, but is not limited to, issues such as delays in obtaining much needed medical items (for example, wheelchairs). In addition, under § 476.110(a)(3), we proposed that the Medicare beneficiary must agree to the disclosure of his or her name in order for the immediate advocacy process to be used. We believe that it is important for the Medicare beneficiary to disclose his or her name because the immediate advocacy process is based on the need for open discussions to quickly resolve a beneficiary's concerns. Moreover, we also proposed that all parties orally consent to the use of immediate advocacy (proposed § 476.110(a)(4)). Because our goal is to work with the providers and practitioners to resolve a beneficiary's concerns, we believe that consent is necessary. The use of oral consent, and not written consent, is in keeping with the cost-saving attributes of alternative dispute resolution processes.

Although we believe that the immediate advocacy process will be of great value to Medicare beneficiaries, providers, practitioners, and the QIOs, we recognize that, for some, the process may not provide the desired resolution. In addition, there could be situations where a QIO determines, after the immediate advocacy process has begun, that more serious concerns are evident. Therefore, we proposed under § 476.110(b) that the QIO and either party can discontinue participation in immediate advocacy at any time and the steps a QIO will take when this occurs. This includes informing the beneficiary of his or her right to submit a written complaint.

Under proposed § 476.110(c), we proposed to convey the need to maintain the confidentiality of the immediate advocacy proceedings by specifically referencing the redisclosure restrictions under § 480.107. We proposed to make a corresponding change to § 480.107 by adding new paragraph (l), to specify that the redisclosure of confidential information related to immediate advocacy proceedings can occur when there is consent by all parties. Under proposed § 476.110(d), we proposed to include procedures that QIOs would follow in those instances where a party fails to participate or otherwise comply with the immediate advocacy procedures. This includes making a beneficiary aware of his or her right to submit a written complaint.

We believe that the use of the immediate advocacy process will greatly reduce the burden on practitioners and providers by avoiding the formality of the traditional peer review process in appropriate situations and quickly identifying resolutions and improvements in the provision of health care. In fact, the immediate advocacy process has already been introduced through the recently completed manual instructions, and preliminary feedback indicates that it is being received positively by providers, practitioners, and Medicare beneficiaries. Medicare beneficiaries have indicated their appreciation of the quicker and more appropriate resolution of their concerns. Many times, Medicare beneficiaries would wait months for the resolution of a formal written complaint, only to be disappointed in what the QIO actually found or frustrated that the concern initially raised was rendered obsolete by more recent events. Under the immediate advocacy process, the QIO has a mechanism to resolve beneficiaries' concerns, sometimes the same day the beneficiary calls. Moreover, providers and practitioners have responded positively to being given the opportunity to immediately address beneficiary's concerns and improve care, particularly where communication is one of the beneficiary's primary concerns. In addition, the provider's or practitioner's ability to avoid receiving and processing a formal complaint letter from the QIO and the related time and costs related to forwarding medical records and engaging in the lengthy review process also have been positively received. The decreased burden on Medicare beneficiaries, providers, and practitioners and the time and cost savings are cornerstones of alternative dispute resolution processes. We are confident the positive responses to this new option will continue.

Comment: Commenters supported the establishment of the immediate advocacy process. The commenters noted the efficiencies of immediate advocacy and the ability to identify and achieve quality improvements much more quickly in a less formal environment. Many commenters noted that immediate advocacy will enable providers and practitioners to avoid the costly and time-consuming written beneficiary complaint process and, thus, dedicate already scarce resources to delivering high-quality care. Some commenters noted that swift and effective resolutions should be the goal, whether the complaint is oral or written, and that immediate advocacy is best for nonsignificant concerns related to the experience of care or issues that stem from a breakdown in communication that likely would not be documented in a medical record. One commenter suggested that CMS ensure the general public is aware of the availability of immediate advocacy.

Some commenters suggested that immediate advocacy be used for all complaints unrelated to quality of care or patient safety issues, and that the formal beneficiary complaint process be restricted to complaints involving patient safety issues or quality of care issues. One commenter asked whether immediate advocacy could tie up hospital and QIO resources in the long run, leading to slower response times and more administrative burden and whether it could increase ''busy work'' for providers. The same commenter then suggested that immediate advocacy be used only on a trial basis until the benefits are clear. Another commenter was similarly concerned that the immediate advocacy process would place a greater burden on the providers

and practitioners because the QIOs would be contacting them directly.

Other commenters indicated that CMS should consider not implementing immediate advocacy because other avenues already exist for addressing complaints about the quality of care, such as reporting the concerns directly to the provider or to State-based agencies, and that having multiple complaint processes impacts the resources of providers because they are sometimes forced to respond multiple times to the same issues. One commenter suggested that, because the QIOs would be documenting the complaint in its own words and it does not require a proper investigation of the patient's experience and the staff's actions, the QIO will lose neutrality and thus become an agent of the patient.

Response: We appreciate the commenters' support of the use of immediate advocacy, and we have already taken steps to ensure that beneficiaries, providers, and practitioners are aware that this new alternative dispute resolution process is available. We acknowledge the commenters' suggestion that the division of precise categories or types of concerns for which immediate advocacy should be used be distinct from those covered by the formal beneficiary complaint process. However, we believe that the proposed structure, which considers the severity of the concern and not the type of concern, represents the best approach to the design of both the immediate advocacy process and the beneficiary complaint review process. This approach gives beneficiaries as well as providers and practitioners options in achieving resolutions of complaints. Moreover, the immediate advocacy process is designed using the principles of the well-established alternative dispute resolution process, which focuses on achieving results in less time with lower costs. This is certainly true when compared to the traditional beneficiary complaint review process, which can take months and necessitates multiple reviews by physician reviewers, along with ongoing repetitive involvement of the pertinent practitioners and/or providers. While we appreciate the suggestion that immediate advocacy only be used on a trial basis, we indicated in the proposed rule that immediate advocacy is already being used and that initial results are positive in that there is improved satisfaction with results, with less time and resources being expended to achieve the results. This initial feedback from practitioners and providers indicates that the process is, in fact, less burdensome and directly attributable to the complaint being resolved within hours or a couple of days versus several months, the avoidance of responding to a request for medical records, and a provider's and/or practitioner's limited involvement in the immediate advocacy process compared to the repeated back and forth communication necessitated throughout the lengthy formal beneficiary complaint review process. However, if any provider or practitioner believes that immediate advocacy is more burdensome and costly in any given situation, the provider or practitioner has the option to decline to participate in the immediate advocacy process. Although reference was made to the impact on providers and practitioners resulting from the availability of multiple options for filing a complaint, Federal law has specifically provided Medicare beneficiaries with the right to file written complaints with the QIOs. Thus, QIOs are obligated to appropriately review these complaints. We believe that the QIOs' substantial experience in resolving beneficiary complaints will enable them to determine what is necessary to conduct an appropriate review of a patient's experiences and staff reactions. Moreover, because immediate advocacy will only be used for less severe quality of care concerns, we believe the QIOs are well equipped to determine the appropriate and necessary level of their review efforts. We also believe the QIOs' substantial experience in resolving complaints will enable them to effectively fulfill their roles in immediate advocacy without becoming agents of the beneficiaries, providers, or practitioners.

Comment: Numerous commenters opposed the expansion of immediate advocacy for use with significant quality of care concerns. Many commenters indicated that the immediate advocacy approach is not appropriate for these significant concerns because the roots of these concerns do not lend themselves to rapid resolution, and there is a risk that the cursory analysis may not sufficiently address the concerns in light of the short timeframe (8 hours to 2 days) within which immediate advocacy is intended to be completed. These commenters believed that this could ultimately be a disservice to beneficiaries and that, for these significant concerns, the medical record should be reviewed. Some commenters suggested that the review of medical records offers the best protection for providers, practitioners, and beneficiaries. Others commenters stated that the use of oral consent is not sufficient if significant quality of care concerns are present.

Response: We appreciate the commenters' responses on this issue. In light of these comments, we are not expanding the use of immediate advocacy for significant quality of care concerns at this time. As the QIOs continue to use immediate advocacy, we will continue to evaluate its use to determine if the future expansion to include significant quality of care concerns is warranted.

Comment: Several commenters agreed with the proposed 6 month timeframe regarding complaints that are eligible for immediate advocacy because they believed that this time seemed reasonable. Others commenters stated that, while the 6 month timeframe is reasonable, exceptions should be granted for extenuating circumstances. However, other commenters believed that 6 months is too long because frequently these cases involve issues happening at the time of the call and, as such, 3 months is more appropriate. They believed that the shorter timeframe also would facilitate using these issues as ''teaching tools'' for practitioners and providers.

Commenters noted that the longer window could result in staff involved in the complaint no longer being with the provider, which is significant because the medical record is not being reviewed. Other commenters believed that immediate advocacy could be effective for complaints received up to a year after the date of care.

Response: In considering the exact period of time applicable to the use of immediate advocacy, we believe we must balance the cost-saving aspects, the desire to timely resolve the complaints, and the level of involvement required by practitioner and provider staff. We continue to believe that 6 months represents the best balance of these factors. We appreciate the comments provided and will consider making additional adjustments as the QIOs gain experience in using immediate advocacy.

While we believe that the immediate advocacy process represents a significant step forward in ensuring the timely, appropriate, and cost-efficient resolution of Medicare beneficiaries' concerns, we recognize that additional changes are needed to improve the QIOs' review process in general. Therefore, in the CY 2013 OPPS/ASC proposed rule (77 FR 45198 through 45202), we proposed regulations governing written beneficiary complaint reviews as well as general quality of care reviews. We proposed to add a new § 476.120 that would govern a Medicare

beneficiary's submission of a written complaint and proposed, under proposed § 476.120(a), language limiting the time period for submitting a written complaint to 3 years from the date on which the care giving rise to the complaint occurred. We believe this is necessary because the ability of a QIO to thoroughly review a complaint becomes more problematic the longer the period of time is between the circumstances giving rise to a complaint and the actual filing of the complaint. An individual's memory can fade, and we are aware of some instances where Medicare beneficiaries have submitted complaints about issues that have occurred decades ago. In these situations, the QIOs' ability to obtain the necessary information, let alone render a valid decision, has been severely compromised. As such, we believe that a 3-year look back period should be sufficient to ensure that a QIO can effectively complete its review.

Under proposed § 476.120(a)(1), we proposed that a complaint submitted electronically to the QIO would meet the requirement for the submission of a written complaint. We proposed, under proposed § 476.120(a)(2), that if a beneficiary contacts a QIO about a potential complaint but decides not to submit it in writing (and the QIO did not believe it was appropriate to offer immediate advocacy), the QIO may use its authority under section 1154(a)(1)(B) of the Act to complete a general quality of care review in accordance with new proposed procedures at proposed § 476.160. We noted that, in these situations, the beneficiary would not receive any results of the QIO's review. We also proposed to limit the QIO's authority to conduct a general quality of care review in response to an oral complaint to those situations where the QIO makes a preliminary determination that the complaint contains a potential gross and flagrant, substantial, or significant quality of care concern.

Under proposed § 476.120(b), we proposed instructions for QIOs when a beneficiary submits additional concerns after the initial submission of a written complaint. We believe that the focus on an episode of care, which we proposed in § 476.130(a)(1), gives the QIO adequate flexibility to consider all related concerns surrounding a complaint, but for those rare instances where a beneficiary does convey a new concern, the QIO would now have specific instructions regarding the right to consider the additional concerns either during the same complaint review or as a separate complaint.

Under proposed § 476.130(a), we proposed to convey the QIO's obligation to consider any information submitted by the beneficiary or his/her representative and by the provider and/or practitioner, along with the QIO's obligation to maintain the information received as confidential information, if that information falls within the definition of ''confidential information'' under existing § 480.101. Moreover, proposed § 476.130(a)(1) also would convey that the focus of the QIO's review will be on the episode of care from which the complaint arose and that in completing its review, the QIO will respond to the specific concerns raised by the beneficiary along with any additional concerns the QIO identifies while processing the complaint. We believe that the focus on the episode of care could potentially reduce the burden on providers and practitioners and reduce timeframes for completing individual reviews. Historically, QIOs would closely track the complaint as originally conveyed by a Medicare beneficiary. However, often Medicare beneficiaries would become dissatisfied with the focus and/or results of the QIO's review, and the QIO would be forced to reexamine the same complaint in light of these entirely new issues, either in addition to or replacing the original issues. On occasion, this could result in the beneficiary raising concerns that should have been filed as an entirely new complaint, based on issues that might be related to, but were not reviewed as part of, the original complaint. This situation could slow the progress of the complaint indefinitely because there were no limits on what beneficiaries could add to existing complaints and the time span in which they could do this. These situations also could add to the burden on providers and practitioners because they would be required to participate in the review of the additional concerns and even provide additional medical documentation related to a complaint that might have changed course multiple times.

In conjunction with limiting complaints to an episode of care, we proposed, under proposed § 476.130(a)(1), to specify the details of the QIO's authority to separate a beneficiary's concerns into separate complaints if the QIO determines that the concerns relate to different episodes of care. We believe that focusing on the episode of care will put QIOs in a better position to identify all potential concerns at the onset and help alleviate any potential back and forth based on the specter of new or different concerns arising after the review has begun.

Under proposed § 476.130(a)(2), we proposed to set forth the QIO's use of evidence-based standards of care to the maximum extent practicable, and specify the method that the QIO must use to establish standards if no standard exists. Moreover, this paragraph (a)(2) also conveys the finality of a QIO's determination regarding the standard to be used for a particular concern, in that the QIO's determination regarding the standard used is not subject to appeal. We believe that the focus on evidence-based standards of care is vital to the improvement of health care nationally.

Under proposed § 476.130(b), we proposed to specify the timeframes that practitioners and providers must follow when a QIO requests medical information in response to a written beneficiary complaint. We proposed a 10 calendar day timeframe for responding to these requests and believed providers and practitioners would also benefit from the faster resolution of complaints. We also noted that QIOs have historically employed a different, shorter timeframe for reviews where a Medicare beneficiary is still receiving care (concurrent review), compared to those situations where a Medicare beneficiary has already been discharged (retrospective review). For concurrent reviews, QIOs request that medical information be received within 1 calendar day, and typically this timeframe has been adhered to by providers and practitioners. Although we did not propose the continued use of the concurrent and retrospective review framework for responding to written complaints, we recognize that there could be circumstances in which an even shorter timeframe for receiving medical information is warranted, and we proposed to include language detailing a QIO's right to earlier receipt of medical information. We proposed that this right to earlier receipt of medical information be related to potential gross and flagrant or substantial quality of care concerns. However, we requested public comments on whether there are other circumstances, involving less serious kinds of concerns, for which this authority to employ a shorter timeframe should be used.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53664 through 53665), we finalized proposed changes to § 476.78 to add references to ''practitioners'' in parts of this section, which referred only to ''providers,'' in order to equalize the 30-day and 21-day timeframes for submitting records. In that final rule, we also made changes to § 476.90 to equalize the ramifications for not submitting records on time, including denying payment, because we saw no reason to differentiate between a

provider's and a practitioner's records. We note that these changes had not been finalized when we issued the CY 2013 OPPS/ASC proposed rule, and in anticipation of the changes proposed in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28119 through 28120), we requested public comment in the CY 2013 OPPS/ASC proposed rule on whether changes similar to those we proposed for beneficiary complaints, including shortening of the 30-day and 21-day timeframes, should be incorporated into § 476.78(b) for requests for medical information in general, for any kind of QIO reviews, including nonquality related reviews. In the CY 2013 OPPS/ASC proposed rule, we also proposed to apply a shorter timeframe for all of a QIO's requests for records, without limiting this application to quality reviews in just one instance: Where secure transmissions of electronic versions of medical information are available, we proposed a shorter timeframe. Our proposal regarding secure transmissions of electronic versions of medical information is discussed more fully later in this section.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45200), under proposed § 476.130(c), we proposed to include a requirement for beneficiary complaints that the QIO issue its interim initial determination within 7 calendar days after receiving all medical information. We stated that we believe that this timeframe is sufficient to evaluate a complaint and identify the key aspects of the care provided. Under proposed § 476.130(c)(1), we proposed to specify the provider's and/or practitioner's right to discuss the QIO's determination before it is finalized, and to specify that the QIO's initial notification will be made by telephone. We proposed a 7-calendar day timeframe for completion of the discussion. In addition, we proposed that the QIO's interim initial determination would become the QIO's final determination if the discussion is not completed timely because the provider and/or practitioner has failed to respond (proposed § 476.130(c)(2)). Again, our focus is on obtaining resolutions to complaints within reasonable timeframes, and the completion of the discussion is an area where improved instructions may benefit the timeliness of complaint processing because we have experienced significant delays in completing this particular step. The term ''final initial determination'' should not be confused with the term used in 42 CFR Part 405, because Part 405 relates to whether a beneficiary is entitled to services or the amount of those services, while this regulation covers only the quality of services as specified in the QIO statute. At the same time, we proposed, under proposed § 476.130(c)(3), the provider's or practitioner's right to submit a written statement in lieu of a discussion, with the requirement that the written statement be received within the same 7-calendar day timeframe from the date of the initial offer. We believed that allowing the submission of a written statement would benefit practitioners or providers that may have trouble being available at a specific time within the 7-calendar day timeframe. Moreover, under proposed § 476.130(c)(4), we proposed to include the QIO's right to extend the timeframe for holding the discussion or submission of a written statement in lieu of a discussion in those rare instances where a practitioner or provider is unavailable, whether because of military tours of duty, travel or other unforeseen circumstances.

In addition, we noted in the CY 2013 OPPS/ASC proposed rule that we were considering restricting a provider's or practitioner's right to submit new or additional medical evidence in the form of test results, X-rays, and other evidence, as part of this discussion. We stated that we believe that doing so would emphasize the need for providers and practitioners to supply all relevant evidence when first requested by the QIO and also would maintain the focus on the discussion a physician or provider is due in accordance with section 1154(a)(14) of the Act. Allowing the submission of additional or new evidence could also substantially raise the possibility that the discussion will become, in effect, an entirely new review by the QIO. Moreover, providers and practitioners will still be able to submit information as part of a request for a reconsideration review. We requested public comments on whether providers and/or practitioners should be prohibited from submitting new or additional medical evidence in response to the offer of a discussion.

Under proposed § 476.130(d), we proposed to specify the QIO's obligation to issue a written final initial determination, regardless of whether care did or did not meet standards for all concerns, and that this determination must be issued within 72 hours after completion of the QIO's review or, in cases where the standard was not met, the QIO's discussion or receipt of the provider's and/or practitioner's written statement. In addition, we proposed, under proposed § 476.130(d)(1), to specify that the notice of the final initial determination will be forwarded to all parties, and paragraph (d)(2) lists the actual content of the notice. We also proposed to specify that the QIO would not forward the notice if either party requests a reconsideration of the final initial determination.

These proposed changes represent significant departures from the process QIOs have historically used when resolving beneficiary complaints and are necessary to improve the fairness of the review process and increase the transparency of the QIO review process. When the process was originally established, CMS determined that physicians, providers, or Medicare beneficiaries would not be afforded the right to request a reconsideration of these determinations under section 1155 of the Act. However, providers and practitioners were afforded an administratively created option, referred to as a ''re-review,'' if the provider or practitioner disagreed with the QIO's initial decision. Medicare beneficiaries were not provided this re-review opportunity and, in fact, were not given any response until after completion of the re-review. Moreover, the actual information a beneficiary received in response to the submission of a complaint was further limited by certain provisions in the existing regulations. Section 480.132 covers the general requirements that a QIO must meet in disclosing information to a beneficiary when that beneficiary has requested information about him or herself. Section 480.132(a)(1)(iii) states that this information cannot include any practitioner-specific information. We have read this provision in conjunction with § 480.133(a)(2)(iii), which authorizes a QIO to disclose practitioner-specific information when the practitioner has consented to the disclosure. In the past, we have interpreted these provisions as applying in the context of beneficiary complaints. This limitation greatly reduced a beneficiary's access to information related to the QIO's specific findings. In fact, § 480.132 also gave attending practitioners the authority to direct that a QIO not provide results directly to a Medicare beneficiary should that practitioner determine that the released information could ''harm the patient.'' This same provision gave QIOs a full 30 calendar days before they had to respond to a beneficiary's request for information, which would apply even in the context of a complaint. Thus, the QIO was required to obtain a practitioner's consent to disclose information within this 30-calendar day timeframe before the QIO could disclose

the specific results of its complaint review to the beneficiary.

As a result of the provisions in the existing regulation, the QIO was often delayed in its ability to respond to the beneficiary, and was sometimes forced to identify a representative and then give the results to the representative even if the Medicare beneficiary believed he or she was able to represent himself or herself and legally had not been deemed otherwise. This scenario has frustrated Medicare beneficiaries over time and placed QIOs in difficult situations. Furthermore, if a practitioner did not consent to any disclosures or to limited disclosures of information that would identify the practitioner, a QIO's decision typically contained a conclusory statement about the results of the QIO's review but no information about the standards of care the QIO used, the evidence the QIO considered, or the rationale for how the QIO arrived at its conclusion. The limitations on what information Medicare beneficiaries received and broad authority given to attending practitioners have been particularly troubling in those instances in which the beneficiary's complaint relates to care that the attending physician provided. In fact, the lack of information given to Medicare beneficiaries in response to a complaint was the precise issue addressed in the *Public Citizen* decision.

We stated in the proposed rule that we believe that the proposed changes to § 476.130(d), including paragraphs (d)(1) and (d)(2), are necessary to ensure beneficiaries are given the same information and rights as practitioners and providers. The proposed changes make clear that the timeframe given to QIOs for issuing the final initial determination in response to a complaint is separate and distinct from the timeframe given to QIOs when responding to a beneficiary's request for information. Any requests for information, including requests for information pertaining to beneficiary complaint reviews that are unrelated to a QIO's issuance of its final initial determination, would continue to be governed by § 480.132. Moreover, while the proposed 72-hour timeframe in § 476.130 appears short in comparison to the 30-calendar day timeframe in § 480.132 that has historically been used, we believe that the 72-hour timeframe represents a more appropriate and reasonable period of time in which to issue these decisions. In most cases, the QIO's final initial determination may not change significantly from the interim initial determination. Thus, QIOs would be able to rely heavily upon the interim initial determination in most instances, with only minor adjustments being made in light of information received in response to the opportunity for discussion. In addition, in paragraph (d)(2), we proposed the content of the written decision to be given to the beneficiary, provider, and/or practitioner. We proposed that the content include a statement for each concern that the care did or did not meet the standard of care, the standard identified by the QIO for each of the concerns, and a summary of the specific facts that the QIO determines are pertinent to its findings. This list makes clear that § 480.132 will no longer govern what information a QIO may provide to a beneficiary in resolving a complaint. We believe this approach more fully supports the court's decision in the *Public Citizen* case.

In addition, we believe that the language under section 1155 of the Act supports the decision to give all parties the right to request that the QIO reconsider its initial decision, and we proposed to offer providers, practitioners, and beneficiaries the right to request a reconsideration in proposed § 476.140(a) for complaints filed after July 31, 2014. This includes proposed specific requirements regarding the manner in which these requests are to be submitted and the obligations of beneficiaries, providers, and practitioners to participate in the reconsideration process in proposed § 476.140(a)(1) through (a)(3). We proposed to delay implementation of this new proposed right to ensure all processing requirements are fully developed for QIOs to follow in reviewing these reconsideration requests.

In addition to the proposed specific content of the notice at proposed § 476.130(d)(2) when a final initial determination is issued and under proposed § 476.140(b) when a reconsideration final decision is issued, we proposed to make corresponding changes to existing §§ 480.132(a) and (b) and 480.133(a) (proposed new paragraph (a)(2)(iv)). In order to make clear that § 480.132 relates solely to a beneficiary's request for information, but not to a beneficiary's receipt of information from a QIO in resolution of a complaint review, we proposed the inclusion of a cross-reference to §§ 476.130(d) and 476.140(b) in paragraph (a). Similarly, we proposed to include language in § 480.132(a)(1)(iii) to denote that the removal of all other patient and practitioner identifiers does not apply to disclosures described in § 480.132(b). We also proposed clarifications to § 480.132(b) to improve the link between paragraph (b) and the provisions of § 478.24 regarding requests for information relied upon in rendering initial denial determinations, which are cross-referenced in paragraph (b). We note that § 478.24 does not require seeking the advice or consent of the practitioner that treated the patient, nor does it prohibit the QIO from disclosing practitioner identifiers. We have made this clear by the proposed deletion of paragraph (b)(1)(i) and added language to the end of current paragraph (b)(1)(ii) to indicate that the information provided under § 478.24 includes relevant practitioner identifiers. With the deletion of paragraph (b)(1)(i), there is no longer a need for multiple paragraphs in (b)(1). Therefore, we proposed to eliminate the current designation for paragraph (b)(1)(ii), with the provision being included as part of paragraph (b)(1). We also proposed a corresponding change to § 480.133(a)(2)(iv) that makes clear a practitioner's or provider's consent is not required prior to releasing information to a beneficiary in connection with an initial denial determination or in providing a beneficiary with the results of the QIO's findings related to a beneficiary complaint review as described in §§ 476.130(d) and 476.140(b).

We also proposed to remove from existing § 480.132(a)(2) and (c)(1) the right of an attending practitioner to direct a QIO to withhold information based on a ''harm'' determination. This included the proposed removal of the requirement from existing § 480.132(c)(2) that a QIO release results to a beneficiary's representative if a ''harm'' determination has been made by the attending practitioner. This also included our proposed decrease in the timeframe that QIOs must follow in responding to a beneficiary's request for information (in any situation, as well as in the context of a beneficiary complaint) in § 480.132(a)(2) from 30 calendar days to 14 calendar days. This timeframe is strictly related to those situations where a beneficiary is making a request for information and will no longer be associated with obtaining responses to beneficiary complaints in the form of the QIO's final initial determination and the QIO's issuance of a final decision after a reconsideration, which are detailed in proposed §§ 476.130(d) and 476.140(b). We believe the decrease from 30 calendar days to 14 calendar days is warranted in light of the improved ability to maintain data, including in electronic formats, so that less time is needed when responding to requests. The proposed changes would ensure that Medicare

beneficiaries have more control over the designation of their representatives and also give a QIO more appropriate steps to follow in identifying a representative when one is actually needed. As an example, the existing regulations at § 480.132(c)(3) direct a QIO to ''first'' look to the medical record to identify a representative but then direct the QIO to ''rely on the attending practitioner'' if no information is contained in the medical record. The changes we proposed to § 480.132(c) place more emphasis on the obligation of the QIO to follow the requirements under State law regarding the designation of health care representatives or agents, rather than focusing on ''where'' the information might be contained.

Lastly, under proposed § 476.140(b), we proposed to specify that the QIO must notify the beneficiary and the practitioner and/or provider of its final, reconsidered, decision within 72 hours after receipt of the request for a reconsideration or, if later, 72 hours after receipt of any medical or other records needed for such a reconsideration. The QIO may do so orally, by telephone, in order to meet this timeframe. Proposed § 476.140(b)(1) also would specify that a written notice must be mailed by noon of the next calendar day and specifies the content of the notice. In addition, under proposed § 476.140(b)(2), we proposed to describe the QIO's authority to provide information in its final decision to beneficiaries, providers and/or practitioners regarding improvement opportunities. The information QIOs provide regarding potential improvements could include specific opportunities related to the practitioner's or the provider's delivery of care and/or even broader improvements focusing on the community served by the practitioners and/or the providers. Some QIOs have, in fact, been providing this information to beneficiaries since it can offer the beneficiaries assurance that their complaints and any underlying problems are being addressed.

We proposed to include, under proposed new § 476.150, specific requirements for QIOs to follow in response to abandoned complaints. We believe that these instructions are necessary in light of a QIO's experience when handling complaints where a Medicare beneficiary initially submits a complaint but then all attempts by the QIO to contact the beneficiary are unsuccessful. Historically, QIOs have been responsible for continual follow-up with beneficiaries, even if months later the beneficiary still had not responded. We believe that giving QIOs the discretion to close these cases will eliminate this unnecessary follow-up and reduce costs. Moreover, it will alleviate provider's and/or practitioner's concerns in those situations where the QIO may have already reached out to them about a potential complaint. We also proposed to add, under proposed § 476.150(b), instructions for QIOs to follow in those situations, which we believe will be rare, where a QIO must reopen a beneficiary complaint review. We would have QIOs apply the same procedures that appear in the already existing regulations at § 476.96 for the reopening of cases involving initial denial determinations and changes as a result of DRG validation, simply using those same procedures for a different purpose. We proposed to do this by placing a reference in § 476.150(b) to the procedures in § 476.96.

Comment: Numerous commenters supported the establishment of regulatory provisions addressing beneficiary complaint reviews, including the streamlining of the overall process. Several commenters supported a beneficiary's right to submit additional concerns after the initial submission of a written complaint, a QIO's right to determine whether concerns should be processed as a single complaint or separated into multiple complaints, as well as the procedures for handling abandoned complaints. In addition, one commenter supported the provision allowing payment denials for practitioners and providers.

However, several commenters noted that a strong operational infrastructure must be developed to ensure the stricter timeframes in the beneficiary complaint review process can be effectively implemented, particularly in light of the QIO's budget limits and the aggressive system-wide changes being attempted. Other commenters supported the provision allowing the submission of complaints electronically, although one commenter stated that CMS does not allow QIOs to accept electronic beneficiary complaints. One commenter also suggested that QIOs should not be communicating directly with physicians in resolving beneficiary complaints since this undercuts quality management of physician practices and instead the QIOs should communicate directly with the quality offices of the practices' system so that more orderly systematic approach to quality control can be maintained. Another commenter recommended that all communications exchanged between QIOs and beneficiaries be written at a 6th grade level and that, due to disabilities, visual impairments and non-English speaking Medicare beneficiaries, communications must be available in alternative formats.

Response: We appreciate the support for these regulatory provisions. With regard to the need for a strong operational infrastructure, the QIOs have been performing beneficiary complaint reviews for over 25 years and already have a strong operational infrastructure in place. While some adjustments could be necessary to the content of letters, any changes to the infrastructure will most likely be related to the new reconsideration right to be given to beneficiaries. In recognition of this, we proposed delaying the implementation of this new right until August 2014. In addition, we appreciate the commenters' support for the submission of complaints electronically. However, we are concerned by the comment that QIOs have been advised by CMS that complaints cannot be accepted electronically. This is incorrect, and we have communicated this to QIOs on several occasions. As these regulations will make clear, beneficiaries have the right to submit complaints electronically, including by email, if they desire. Although we appreciate the concern that QIOs communicate with the provider's system quality office in resolving beneficiary complaints, we believe that communication must ensure the involved practitioner is also involved and nothing in these regulations limit the QIOs' ability to communicate directly with the provider's quality improvement staff. We appreciate the recommendations regarding the QIOs communications and availability of alternative formats and have already taken steps to ensure that communications are written in plain language and offered in other languages so that the needs of Medicare beneficiaries are met.

Comment: Some commenters suggested that CMS also require that, when QIOs investigate a complaint, all parties are informed as to who else has received the complaint, such as State survey agencies and the Joint Commission. Commenters suggested that this level of coordination is necessary because resources are being expended by all of the various entities, including the involved providers and/or practitioners, and coordinating the initial investigation or interview would be a cost-effective method that could also lead to an earlier resolution of the complaint. Moreover, the commenters believed that this would also ensure that information is better shared between oversight entities. They believed that doing so could alleviate duplicative efforts.

Response: While we recognize that, at times, several agencies could be investigating the same or similar concerns, our concern at this time is ensuring that beneficiaries, providers, practitioners, and QIOs have clear instructions regarding the processing of beneficiary complaints. As such, we are not recommending specific changes designed to improve the coordination among various entities as a direct result of these regulations.

Comment: Several commenters expressed concern regarding the impact of the proposed regulations on the recently effectuated manual instructions included in Transmittal 17 (issued on April 6, 2012, CMS Manual System, Pub. 100–10 Medicare Quality Improvement Organizations, Chapter 5, Quality of Care Review). Specifically, commenters raised concerns regarding the extent to which beneficiaries can rely on the additional protections included in Transmittal 17 because the notice-and-comment rulemaking process may take a different and conflicting turn, leaving the beneficiary who relied on the transmittal in an insecure and vulnerable position.

Response: While we recognize that the timing of Transmittal 17 could cause confusion in light of the proposed regulations, this rule does not remove any of the additional protections conveyed through Transmittal 17. Rather, the regulatory provisions are designed to bring about additional changes that will improve the processing of beneficiary complaint reviews for all parties and provide beneficiaries with even more access to information. We anticipate making additional changes to the manual instructions to comply with the new regulatory provisions once the regulations are in effect.

Comment: Many commenters supported the 3-year period for submitting beneficiary complaints, while other commenters believed that 3 years is too long. Many commenters urged CMS to consider a 1- or 2-year timeframe, with the potential to allow for additional time in rare circumstances. Many of the commenters' concerns about the 3-year time period were based on the ability of providers to reasonably defend against allegations of inappropriate care after three years, since memories fade. Moreover, the commenters believed that the time lapse could result in the standards of care being different in light of clinical advances that have occurred. Other commenters believed that the timeframe should be shortened because the proposed time practitioners and/or providers are being given to provide medical evidence is much shorter.

Response: While we recognize that a variety of factors could impact the success of the QIO's review process, we believe that because these reviews are primarily conducted by reviewing medical information supplied by the practitioner and/or provider, the longer time period is appropriate. Moreover, QIOs are experienced at identifying the appropriate standard of care, including any changes or updates to the standard of care since the time the actual care was provided. Therefore, we believe that 3 years represents a reasonable period of time for submitting complaints.

Comment: Numerous commenters opposed giving QIOs the authority to identify the standard of care, including the right to determine a standard of care where a clear standard does not exist. Commenters noted that standards of care are complex and can be reliably developed only with clinical experts assessing the available medical information, and there is no reason to believe that QIOs will have more relevant medical expertise available to make such determinations for all medical care issues. Some commenters also noted that there are numerous areas of medical practice for which insufficient evidence exists to guide the conclusion of what should be the standard of practice and that the QIOs should not be expected to make up a standard where evidence to support it does not exist. One commenter noted that allowing QIOs to determine the standards of care will actually create more variation in the standards. In addition, some commenters believed that it was cause for concern that the QIO would make a determination as to whether the care provided met professionally recognized standards of care but the provider's/practitioner's perspective, including the provider's/practitioner's intimate knowledge of the patient's care, was secondary. Many commenters were troubled that a QIO's decision regarding the standard of care is not subject to appeal and believed that an independent third party entity should be established to review QIOs' decisions regarding the standard of care. One commenter also suggested that giving beneficiaries results of reviews could be more problematic in light of these concerns over the standards of care.

Response: QIOs were specifically established to make available a cadre of peer reviewers, including both physician and nonphysician practitioners, with expertise who could review complaints and other quality of care concerns in order to make determinations as to whether the care provided met professionally recognized standards of care. As part of this process, QIOs take care in matching the clinical background of their peer reviewers with the specific care at issue in the complaint and ensure that the peer reviewer's knowledge of existing practices in the relevant health care setting and the particular geographic area is current. Moreover, the identification of the standard of care is based on a robust review of current literature and available evidence pertaining to the standard in addition to the peer reviewer's own clinical judgment. QIOs have been reviewing quality of care concerns and making decisions regarding the standards of care to be used when conducting these reviews for over 30 years. The regulations merely continue a process that has been in place since the program was initially established, and we see no reason to change the process at this time. In particular, we believe the suggestion that a third party be created to review the QIOs' decisions is unnecessarily duplicative because this is the precise reason QIOs were created, and a QIO is specifically tasked with applying the standards of care as described in section 1154(a)(6)(A) of the Act based on its evaluation of the typical patterns of practice within the geographic area it serves. This responsibility is also detailed in 42 CFR 476.100.

Comment: Numerous commenters supported the regulatory changes giving beneficiaries more detailed results of review findings, the removal of a physician's right to consent to the release of specific findings, and the provision of information to beneficiaries regarding quality improvement activities in the final decision letters. Many commenters believed that it is imperative that beneficiaries have the same access to information about complaints as practitioners and providers and that this right should not be defeated by the objection of a practitioner or provider. Many commenters also agreed that the elimination of the consent requirement would improve beneficiary satisfaction and that it aligns with the value of patient centered care in addition to reducing the processing timeframe by 30 days.

Other commenters supported the providing of information regarding quality improvement activities, but believed that the QIOs will need to take care that the information is presented in an easily understandable manner because it can be difficult at times for

a beneficiary to discern how particular quality improvement activities relate to the quality of care the beneficiary received. One commenter supported the proposal to reduce the time that a QIO is given in responding to requests for information from beneficiaries from 30 to 14 calendar days. However, another commenter noted that giving beneficiaries more information could be contrary to State law, and provided an example that, under Florida law, psychiatrists may redact notes or provide a summary statement to patients in lieu of providing them clinical notes, which may be harmful to the patient. Another commenter suggested that the failure to obtain a practitioner's consent could expose the QIO to legal activity, which would result in the need for increased liability insurance, additional costs for the QIO and for CMS and potentially peer reviewers refusing to participate in the process because of concerns over potential litigation.

Response: We regard the provision of more detailed information to beneficiaries to be a direct, logical, and reasonable outgrowth of the *Public Citizen* decision and recognize the benefits of providing this more detailed information to beneficiaries. We appreciate the support for providing this information and agree that quality improvement activities must be conveyed in an easy and understandable way to beneficiaries. We believe that the QIOs are already well-equipped to effectively communicate this information. With regard to the provision being contrary to State law, we do not agree that this provision will place a QIO in jeopardy of violating State law requirements. QIOs would be effectuating the procedures of a Federal program that is mandated by a Federal statute and interpreted under Federal regulations. As such, a QIO's obligations to provide information under a Federal statute and regulations would preempt any State law requirements that conflict with the QIO's obligations. The information conveyed by the QIO will be limited because it will be specific to the care a beneficiary has received, and relate only to the facts that are essential to determining whether a provider or practitioner met professionally recognized standards of care. Lastly, with regard to a QIO or a peer reviewer being exposed to legal action, the liability protections afforded under section 1157 of the Act would apply to the QIO and its staff. Section 1157(b) of the Act states that any QIO or person employed by or who provides professional services to the QIO, or who has a fiduciary relationship with a QIO, cannot be held to have violated any criminal law or to be civilly liable under any Federal or State law as a result of his or her performance of any duties, functions, or activities required under or authorized by the QIO statute or under the QIO's contract with CMS.

Comment: Several commenters supported the reduction in timeframes related to requests for medical information. One commenter noted that, because providers have already demonstrated the ability to respond to requests for medical information related to expedited appeals within 4 hours, 10 days should be ample time. One commenter also supported the removal of the retrospective and concurrent distinction in processing complaints, as well as the authority to request medical information in less time when circumstances warranted. Other commenters believed that the shorter timeframes were necessary in order to give beneficiaries results in a reasonable period of time in response to a complaint.

Some commenters supported the efforts to shorten the timeframes associated with completing quality of care reviews, but believed that the 10-day timeframe was insufficient because navigating a hospital's complex medical records system is time-consuming. Moreover, some commenters expressed concerns that the shorter timeframes would disrupt the providers' and practitioners' daily work in order to comply with the decreased timeframe and will ultimately lead to additional costs, including for providers and/or practitioners using vendors. Other commenters noted that a 10-day timeframe could not be met until providers and practitioners have established electronic health record systems that would easily facilitate the collection of medical information and that the current 21-day and 30-day timeframes should be maintained. Many of these commenters noted that a significant number of providers and practitioners either still rely entirely on paper records or are in a hybrid state with some paper records and some electronic records. Several commenters suggested that the 3-year ''look back'' period for complaints affected the ability to comply with this requirement because the providers and practitioners may have to retrieve medical information from offsite facilities. Other commenters noted that providers and practitioners receive numerous requests for medical information from various entities and that frequently the timeframes for responding are different for each entity, and these issues impact the ability of providers and practitioners to respond in a timely fashion. Several commenters also questioned whether the shorter timeframes will have any material benefit for beneficiaries that have submitted complaints. One commenter noted that, for one QIO, approximately 75 percent of providers are already complying with the 10-day timeframe, and that the other 25 percent are taking up to 25 days to respond, with the non-hospital providers and practitioners taking the longest to respond.

In addition, many commenters supported a similar shortening of the timeframes for replying to requests for medical information in response to other review activities. However, several commenters believed that the 21-day and 30-day timeframes should be maintained for other review activities for the same reasons they supported maintaining the current timeframes associated with completing quality of care reviews.

Response: In determining the precise number of days for responding to requests for medical information, we must consider the impact on the QIOs' ability to make timely decisions, the beneficiaries' right to have complaints or other review activities decided in a timely fashion, as well as the burden on practitioners and providers in responding to medical record requests. While we recognize that the shorter timeframes could cause concerns for some practitioners and providers, particularly nonhospital providers, we also considered the additional flexibilities we have proposed regarding the ability to securely transmit electronic versions of medical information.

In light of the concerns raised, we are modifying the proposed regulations to require that medical information be obtained within 14 calendar days when requested in response to a quality of care review. In addition, we are adopting this same 14 calendar day timeframe for all QIO review activities. We believe that having a single timeframe will facilitate provider's and practitioner's response times. This same timeframe will be applicable whether the provider or practitioner is forwarding paper copies of medical records or electronic versions. We believe that the ability to timely comply with these requests will be further enhanced by additional infrastructure changes we are working towards implementing in the near future, including electronic facsimile capabilities and secure file-sharing capabilities. We will continue evaluating additional changes to this

timeframe as providers and practitioners increasingly move towards electronic health records. However, we are finalizing the proposed regulatory language that gives QIOs authority to request medical information in less time if circumstances warrant the earlier receipt.

Comment: Several commenters supported the proposed decrease in timeframes for completing various steps of the review process, and several commenters commended CMS for streamlining the process. Some commenters noted that the prior lengthy timeframes were not patient-centered and have historically been a point of beneficiary dissatisfaction. Other commenters believed that the reduced timeframes were necessary so that providers and practitioners obtain results more quickly, and this is particularly helpful where the concerns are unfounded.

However, numerous commenters expressed concerns regarding the decreased timeframes. In particular, commenters raised concerns regarding the ability to meet the 7-day timeframe for completing the interim initial determinations and that, in order to do so, the more aggressive process improvements for expedited appeals would need to be adopted. Some commenters alleged that CMS is attempting to make the beneficiary complaint process similar to the expedited appeals process, and that this is not appropriate because these are not payment determinations in need of rapid resolution. Some commenters mentioned that the need of a QIO to complete a Quality Review Decision form for each concern and need to identify evidence-based standards of care will impact the ability of QIOs to meet the reduced timeframes for making the interim initial determination.

Some commenters also noted that the 72-hour timeframe for rendering the final initial determination and the 72-hour timeframe for rendering the reconsideration decision are too short in consideration of the scope of the review necessary and need to thoroughly evaluate the medical information. Other commenters also believed that the requirement that reconsideration requests be submitted by noon the day after the notification of the final initial determination is too short because the beneficiary and the providers and/or practitioners need adequate time to consider the essence of the QIO's decision. Moreover, the commenters stated that the fact that the interim and final initial determinations are conveyed orally could impact the ability to fully evaluate whether a reconsideration request should be filed and may even violate confidentiality and privacy rights of the individual. Some commenters alleged that the provider, practitioner, or beneficiary could question the identity of the caller. Still other commenters noted that it is critical not to rush the QIOs' investigations of these issues, particularly because, when final, the determinations could be used by plaintiffs' attorneys to pursue additional actions against providers and practitioners. Another commenter noted that shortening the timeframes too extensively could have unintentional negative consequences resulting in the value of the review process being compromised for the beneficiaries who would prefer that their concerns are properly addressed. One commenter noted that there are already shorter processing timeframes currently in place through the concurrent review process and, thus, it is not clear why there is a need for decreased timeframes when responding to retrospective reviews. Another commenter expressed concern regarding the sequence of the reconsideration right, for example, should the review of a beneficiary's reconsideration request occur before or after the practitioner's or provider's request, and believed that a beneficiary could be upset should a concern be confirmed at the conclusion of the final initial determination only to have it overturned as a result of a practitioner's or provider's reconsideration request. Other commenters believed that the shorter timeframes would increase costs, including the compensation costs for physician reviewers. Several commenters noted that the new Chapter 5 instructions already include shorter timeframes for completing various steps of the review process and that these timeframes should be maintained until medical information can be received electronically from providers and practitioners and also conveyed electronically to peer reviewers. Some commenters questioned why a beneficiary's right to request a reconsideration cannot be implemented sooner than August 2014.

Response: In considering the reduced timeframes for various steps, we attempted to identify timeframes that would balance the interests of beneficiaries, providers, and practitioners in obtaining timely resolution of complaints with the time necessary for the QIOs to effectively and thoroughly complete the various tasks involved in the review process. We have routinely heard from beneficiaries that the time necessary to complete reviews is a point of dissatisfaction, and clearly a process that requires more than 150 days to complete a review can be frustrating to all involved. Moreover, we disagree with the suggestion that our goal is to make the beneficiary complaint review process similar to the expedited appeals process. Because the expedited appeal decisions are typically made within 24 to 48 hours of the filing of the appeal, the expedited appeal process is quite different from the proposed complaint process, which allows 7 days to make the interim initial determination, offers providers and practitioners the opportunity to discuss the results, and then permits several more days before the final initial determination is made.

We are concerned by the statement of the commenter who noted the need to create a Quality Review Decision form for each concern identified during the review. That is inaccurate. Only one Quality Review Decision form needs to be created to track the QIO's review of a beneficiary complaint or completion of a general quality of care review. Moreover, with regard to the comment that these shorter timeframes appear unnecessary in light of the already existing authority to conduct concurrent beneficiary complaint reviews, we advised in the proposed rule that the retrospective and concurrent distinction in reviews would no longer be used. Our goal is to move away from having a distinction in processing requirements that is determined by the beneficiary's inpatient (concurrent) or discharge (retrospective) status and instead consider the severity of the issues in order to determine how quickly to process the complaints. We have already addressed that QIOs have the authority to request medical information within shorter periods of time if circumstances warranted. Moreover, the timeframes for completing the interim initial determination and final initial determination convey that the QIO must complete its review ''within'' the prescribed period of time. We believe that our timeframe should be sufficient, even for complaints that are unexpectedly complex, and that QIOs have the flexibility to use the full time allotted for the interim and final initial determinations or to complete these steps in less time if circumstances warrant it, such as when circumstances surrounding the complaint have a severe impact on the quality of care received.

With regard to the sequence, all parties will be offered the right to request a reconsideration at the same time, and each party must understand that the review will be an independent

review that could result in the final initial determination being overturned. In addition, while it is accurate that the new Chapter 5 manual instructions contain processing timeframes that are shorter than those historically used, we undertook the task of writing these new regulatory provisions because we believed that additional improvements, including the potential incorporation of even shorter timeframes, could be made and that any additional and more comprehensive timeframes should be accomplished through notice-and-comment rulemaking.

However, we recognize that some of the timeframes are considerably more aggressive than those followed by the QIOs as recently as 6 months ago. After considering the public comments we received, we have decided to extend the timeframe for the QIO to make the interim initial determination from 7 calendar days to 10 calendar days. Although we do not agree that QIOs will be unable to meet the proposed 7-day timeframe based on the need to identify evidence-based standards of care because QIOs have always been responsible for identifying standards of care and will have a readily available repository of up-to-date standards of care for most concerns, we nonetheless choose to extend the timeframe to 10 days based on the concerns that peer reviewers be given adequate time to review the medical information, particularly if the medical information is somewhat voluminous.

In addition, in this final rule with comment period, we have modified the timeframe for making the final initial determination from 72 hours to 3 business days. We also have extended the timeframe for filing reconsideration requests from noon the calendar day following the initial notification to 3 calendar days. In addition, to ensure that all parties can properly evaluate the need to file a reconsideration request, we have modified the regulatory requirements to require that QIOs issue the final initial determination in writing. Lastly, we have extended the timeframe for QIOs to render the reconsideration decision from 72 hours to 5 calendar days. Although it was suggested that the right to request reconsiderations could be implemented sooner than August 2014, we continue to believe that this period of time is necessary to ensure all process and system requirements can be effectively implemented. This includes ensuring that beneficiaries, providers, and practitioners are aware of this new right.

Comment: Several commenters believed that the reduction of time for completing the opportunity for discussion could impact the accuracy and thoroughness of the review process and that because the results of the interim initial determination and right to an opportunity for discussion are initially conveyed orally, this will require a physician with quality improvement experience to ensure that the issues are accurately conveyed to the practitioner or provider and to ensure that any response from the practitioner is correctly transcribed. Several commenters believed that it would be better for the response to be in writing in all circumstances. Other commenters believed that the timeframe for completing the opportunity should be extended to 10 days with exceptions built in for certain events. One commenter noted that more time was necessary because it is hard to reach practitioners and/or providers and leaving messages is not appropriate. The commenter believed that this timeframe is even more problematic where multiple practitioners and/or providers are involved in a single complaint and that should the practitioners and providers be reached on different days, the QIOs would be forced to separately track the response time period applicable to each practitioner and/or provider.

Several commenters suggested that practitioners and providers be allowed to submit new or additional medical information during the opportunity for discussion. Some commenters suggested that refusing to allow the submission of additional medical information is grossly unfair if the amount of time provided for submitting medical information is reduced. Moreover, commenters noted that providers and practitioners could find additional medical documentation in researching the results of the interim initial determination. Other commenters believed that not allowing the submission of additional evidence during the opportunity for discussion would result in the unnecessary filing of additional reconsideration requests. In addition, commenters noted that, frequently, when a physician or provider receives a call regarding the opportunity to discuss the QIOs findings, this is the first time the provider and/or practitioner learns that a complaint has been filed. Thus, the commenters added, the discussion can be helpful to explain the content of the discussion, particularly because the content of the medical information may not be readily available.

Response: While we recognize that any shortening of timeframes creates concerns, our objective is to identify a period of time that ensures beneficiaries obtain resolution of complaints in a timely fashion, while also giving a practitioner or provider an adequate period of time to discuss the QIO's initial findings. In considering the comments, we noted that, while some concerns were related to the ability to reach the physician and/or provider, the primary concerns related to the impact on the QIO's initial decision and request for medical information and not the discussion itself. In fact, QIOs have noted that, rather than focus being given to the discussion of a QIO's findings, the ''discussion'' instead frequently becomes an additional period of time during which the provider or practitioner attempts to convey additional medical information that was not provided when the request was first made. In shortening the timeframe and restricting the submission of additional medical information, we intend that more focus be given to the discussion with emphasis on improving the quality of care provided. Moreover, many QIOs already conduct the opportunity for discussion based solely on oral communications with the providers and/or practitioners, and we see no need to restrict the process to written exchanges of information in light of the QIOs' historical experience in effectively completing the discussions orally. At the time of the discussion, the QIO has made its interim initial determination, with the specific problematic care and pertinent standard of care being identified. Thus, the discussions can be narrowly focused to the QIO's findings. As such, in considering the public comments provided regarding the opportunity for discussion, we have determined that the 7-day time period is an appropriate period of time to complete this step. However, we recognized that the offer of the opportunity to discuss the QIO's interim initial determination findings can be the first time the provider and/or practitioner is made aware that a complaint has been filed. Therefore, we have modified the regulations at § 476.130(b) to add new language at paragraph (2) that when requesting medical information in response to a complaint, the QIO must advise that the information is being requested as the result of a complaint and convey to the provider and/or practitioner that they will be given the right to discuss the QIO's interim initial determination. The QIO also must request, at that time, a contact name to ensure the opportunity for discussion can be completed in a timely fashion.

We are not persuaded that an opportunity to submit additional

medical information is necessary as part of the opportunity for a discussion. While we appreciate the fact that the ability to submit additional medical information could facilitate the resolution of concerns and avoid the submission of reconsideration requests, we believe that there is sufficient time to ensure QIOs receive the correct medical information to resolve the complaint correctly the first time such that the discussion does not routinely result in the QIO learning that its review was completed without all the medical information. Making providers and practitioners aware that the initial request for medical information is the result of a beneficiary complaint will facilitate the QIOs' receipt of thorough and complete medical information. This will also ensure that the discussions are focused more on ways to improve the quality of care rather than the continued pursuit of obtaining all pertinent medical records.

After consideration of the public comments we received, we are adopting our proposals regarding the beneficiary complaint review process, except for those modifications to the proposed timeframes related to the issuance of the interim initial determination, the issuance of the final initial determination, the time period provided for requesting a reconsideration, the time given to QIOs for issuing the reconsideration decision, the new notification requirement for medical information requests in response to beneficiary complaints, and the change requiring that written notice of the final initial determination be forwarded in all situations.

2. Completion of General Quality of Care Reviews

As we noted in the proposed rule, although the QIO's responsibility for completing quality of care reviews is already set forth in the QIO program regulations at existing § 476.71(a)(2), the procedures that QIOs use in completing these reviews are not. As we previously noted, many process improvements were incorporated into the new manual instructions mentioned previously (Transmittal 17, April 6, 2012, CMS Manual System, Pub. 100–10 Medicare Quality Improvement Organizations, Chapter 5, Quality of Care Review) (available at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R17QIO.pdf*). These new instructions were effective May 7, 2012. However, we believe that it was also necessary to propose these regulations to attain additional improvements and to ensure transparency of the QIO program operations.

First, in the CY 2013 OPPS/ASC proposed rule (77 FR 45202), under new § 476.160(a)(1), we proposed to specify those circumstances in which a QIO may conduct a general quality of care review. These circumstances would include those situations where a potential quality of care issue is referred to the QIO by another source, such as by another CMS contractor, an individual submitting a request anonymously, or another Federal or State entity. In addition, we recognize that more frequently the QIOs are working to use the substantial data available to them to identify potential areas where improvements in the quality of health care could be attained, and we believe these instances should be accounted for as we move forward. We also are aware that QIOs frequently identify potential quality of care issues when conducting other case review activities, including medical necessity reviews, expedited discharge appeals, among others; therefore, we have included this as an instance where a general quality of care review can be initiated.

Under proposed new § 476.160(a)(2), we proposed to specify that the QIO's review will focus on all concerns raised by the source of a referral or report and/or identified by the QIO. While the episode of care should still be considered, it may be less significant for these reviews than those in response to a complaint submitted by a beneficiary, because the main goal of complaint reviews is to address a beneficiary's particular experiences with receiving certain services at a particular time. However, we again proposed under proposed § 476.160(a)(3) that the QIO will use evidence-based standards of care to the maximum extent practicable in completing these reviews, and that the QIO's determination regarding the standard used in completing the review is not subject to appeal.

Under proposed new § 476.160(b), we proposed to specify the responsibility of providers and practitioners to supply requested medical information. This language is identical to the language in proposed new § 476.130(b) applicable to written beneficiary complaints, including the proposed 10-calendar day timeframe for practitioners and providers to respond to requests for medical information and the QIO's right to request even earlier receipt when the QIO preliminarily determines that a concern may be serious enough to qualify as a gross and flagrant or substantial quality of care concern. Although the decreased timeframe is not related to the goal of providing beneficiaries with more timely resolution of their complaints (because beneficiaries will not be getting results of these reviews), we still believe there is ample justification to warrant the reduced timeframe. Providers and practitioners will benefit from the faster resolution of these reviews and the increased focus on identifying and resolving impediments to improved health care (particularly in cases involving potential serious concerns). These improvements will ultimately benefit patients. Additionally, as with written beneficiary complaints, the timeframes are comparable to models typically used by vendors. We also considered that, as with written beneficiary complaints, the QIOs currently use shorter timeframes where the beneficiaries impacted by the general quality of care review are still receiving care (concurrent review), compared to those situations where a beneficiary has already been discharged (retrospective review). Again, while we did not propose the continued use of the concurrent and retrospective designations, we recognize that there are circumstances, even with general quality of care reviews, where even shorter timeframes may be warranted.

As mentioned previously, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53664 through 53665), we finalized proposed changes to § 476.78 to add references to ''practitioners'' in parts of this section, which previously referred only to ''providers,'' in order to equalize the 30-day and 21-day timeframes for submitting records. We also made changes to § 476.90 to equalize the ramifications for not submitting records on time because we see no reason to differentiate between a provider's and a practitioner's records. While these changes in the FY 2013 IPPS/LTCH PPS final rule had not been finalized when we issued the CY 2013 OPPS/ASC proposed rule, in the CY 2013 OPPS/ASC proposed rule, we proposed to modify the current general 30-day and 21-day timeframes in § 476.78(b) to reflect the new timeframes in §§ 476.130(b) and 476.160(b), which apply only to records submitted for purposes of beneficiary complaint and general quality reviews. We also requested public comment on whether changes similar to those we proposed for beneficiary complaints and general quality of care reviews, including shortening of the 30-day and 21-day timeframes, should be incorporated more broadly into § 476.78(b) for requests for medical information in general, for any kind of QIO reviews,

including nonquality-related reviews. We proposed to apply a shorter timeframe for all of a QIO's requests for records, without limiting this application to beneficiary complaints or general quality reviews in just one instance; where secure transmissions of electronic versions of medical information are available, we proposed a shorter timeframe. Our proposal regarding secure transmissions of electronic versions of medical information is discussed more fully later in this section.

We also proposed new § 476.160(c), which would specify that the QIO peer reviewer will render the initial determination within 7 calendar days of the receipt of all medical information; this paragraph is substantially different from the proposed beneficiary complaint review procedures in proposed new § 476.130 in two areas. First, beneficiaries would not be provided any information regarding these reviews. Although we recognize that, at times, potential quality concerns a QIO identifies could impact a specific beneficiary, we believe that this type of review does not warrant any communication directly to the beneficiary. In fact, we believe that giving feedback of potentially poor care to an unknowing beneficiary could cause more anxiety than is warranted by the circumstances, and that is not our goal. We also recognize that, in many situations, the reviews could relate to or involve numerous beneficiaries. However, those beneficiaries may only be a sample of the beneficiaries potentially impacted. This is particularly true in those circumstances where the QIO is reviewing system-related aspects of care, and it will be incumbent upon the QIO to determine what medical information—and by extension the sample of beneficiaries receiving care—to be analyzed in completing these reviews.

Second, we proposed that practitioners and providers not be given an opportunity to discuss the QIO's initial determination before it becomes final. We believe that giving such an opportunity is not necessary, particularly because these discussions frequently become, in effect, an entirely new review by the QIO and not merely a discussion, and because we already proposed at proposed new § 476.170(a) that the practitioner and/or provider be given the right to request a reconsideration of the QIO's initial determination. As with beneficiary complaint reviews, we proposed that this right not be available until after July 31, 2014, to give us time to fully establish the process requirements and ensure that this right is meaningful for providers and practitioners, although they continue to have the right to request a re-review.

In addition, under proposed new § 476.170(a)(1) through (a)(3), we proposed requirements similar to those in § 476.140 regarding the timeframe for submitting a request for a reconsideration (by noon of the calendar day following initial notification), the obligation of a practitioner and/or provider to be available to answer questions or supply information, as well as the QIO's obligation to offer the provider the opportunity to provide information as part of the reconsideration request. We also proposed provisions under proposed new § 476.170(b) concerning the QIO's issuance of its final decision. This includes the requirement that the QIO's decision be issued within 72 hours after receipt of the request for a reconsideration, or, if later, 72 hours after receiving any medical information or other records needed for such a reconsideration, the specific content of the final decision, and the right of the QIO to provide information to the provider or practitioner regarding opportunities for improving care given to beneficiaries based on the specific findings of its review. The information QIOs provide regarding potential improvements could include specific opportunities related to the practitioner's or provider's delivery of care and/or even broader improvements focusing on the community served by the practitioners and/or providers.

Comment: Commenters conveyed the same concerns regarding several aspects of general quality of care reviews as were raised with beneficiary complaint reviews, including the authority to establish the standards of care and lack of an appeal mechanism for these standards, shorter timeframes for medical information requests, decreased timeframes for various steps, including the timeframe for rendering the initial determination, the time given to submit reconsideration requests, and the timeframe given to QIOs to render reconsideration decisions.

Response: For the same reasons we discussed regarding beneficiary complaint reviews, we are not making any changes to the proposed regulations regarding the QIOs' authority to establish standards of care, but we are modifying several key timeframes as discussed below. As previously mentioned, we are extending the time period for responding to medical record requests from 10 calendar days to 14 calendar days for all review types, including general quality of care reviews. We are extending the period of time given to the QIO peer reviewer in rendering the initial determination from 7 calendar days to 10 calendar days, and we believe this additional time is warranted to ensure the peer reviewer has adequate time to render a thorough decision. In addition, as with reconsideration requests submitted in response to beneficiary complaints, we are increasing the time to file a reconsideration request from noon of the calendar day following the initial notification to 3 calendar days. We also are increasing the time given to a QIO to complete the reconsideration decision from 72 hours to 5 calendar days. Moreover, we are modifying § 476.160(c) to make clear that the initial determination must be issued in writing and also are adding a corresponding change to § 476.170(a) denoting that a reconsideration request be received within 3 calendar days of the receipt of the written determination.

Comment: Some commenters expressed support for the QIOs' authority to pursue quality of care concerns when a beneficiary decides not to file a complaint. However, some commenters noted that using the ''imminent danger'' criterion embedded within the definition of ''gross and flagrant'' violations was too limiting and QIOs should have more authority to pursue these issues. One commenter questioned why CMS was creating this ''new authority''—and a second oversight body—when States already have oversight over hospital quality. This commenter also suggested that the QIOs' efforts are duplicative and thus the overlap of State efforts is problematic.

Response: We appreciate the commenters' support and agree that having QIOs pursue certain quality of care issues, even when a beneficiary chooses not to file a complaint, can be helpful in identifying improvements to the quality of care. However, we believe that some limits should be placed on the type or severity of concerns that QIOs should pursue in order to maximize the use of QIO resources. Thus, we are maintaining the limit on the QIOs' authority to pursue these as conveyed in the proposed regulation.

With regard to the concern that we are creating a ''new authority,'' this is inaccurate. QIOs have actually had and used this authority for more than 30 years, although this is the first time the process requirements have been detailed in regulations. We are obligated to ensure the effective implementation of the QIO program in light of the statutory authority granted the QIOs, regardless of whether certain State programs have

been established to address similar issues.

Comment: Several commenters expressed concern regarding the proposed removal of the right to request an opportunity for discussion. The commenters expressed concern that the QIO could make decisions on these concerns without an opportunity for a counter argument from the involved practitioner and/or provider. Several commenters suggested that the change would merely result in the receipt of more reconsideration requests being filed based on initial determinations being made without input from the involved practitioner and/or provider or the ability to obtain additional medical information. Other commenters suggested that providers and practitioners should have the same rights to due process here as with beneficiary complaint reviews and that the discussion can often clarify the concerns so that the provider or practitioner is better able to respond. Some commenters suggested that the opportunity for discussion was necessary because, in comparison to beneficiary complaints, these concerns are often the most serious cases because they include issues identified by the QIO through evaluation of other QIO review activities or from referrals from other agencies.

Response: Although we appreciate the concerns raised regarding the removal of this step, we believe that it is not necessary for purposes of general quality of care reviews because, as many commenters acknowledged, the discussion has become little more than an opportunity to convey additional medical information to the QIO with no actual discussion occurring about ways to improve the quality of care. We believe that there are modifications that can be made to the manner in which medical information is initially requested by the QIO to ensure that all medical information is obtained prior to the QIO's review, and we will work to ensure that these modifications are incorporated into the QIO's processing requirements. This will then eliminate what many commenters suggested was the primary purpose of the opportunity for discussion.

Moreover, there is a statutory distinction between situations in which discussions have been specifically required and those in which they are not. In those circumstances where Congress believed that such an opportunity to discuss a particular type of issue was warranted, the right was specifically added to the statute, as in section 1154(a)(3)(B)(ii) of the Act regarding those situations where an item or service furnished or to be furnished is disapproved and section 1154(a)(14) of the Act regarding written beneficiary complaints.

In terms of the commenters' other concerns—that providers and practitioners will not have an opportunity to make counter arguments, that decisions would be made without input from the involved practitioners or providers, that providers and practitioners will not have the same rights to due process as in beneficiary complaint reviews, and that providers' and practitioners' concerns in general quality reviews often involve the most serious cases—we would note that these parties continue to have the opportunity to make counter arguments and give input on the QIO's decisions by requesting a re-review until the reconsideration right becomes available. A provider's or practitioner's right to request a re-review is, in fact, a due process right that beneficiaries are not given. Providers and practitioners also will have an opportunity to present their point of view in the context of a reconsideration when that right is implemented, and beneficiaries will be afforded the same right.

After consideration of the public comments we received, we are adopting as final our proposals regarding general quality of care reviews, except that we have extended the timeframes for submitting medical records to 14 calendar days, rendering the initial determination to 10 calendar days, filing a reconsideration request to 3 calendar days, and issuing the reconsideration decision to 5 calendar days.

C. Use of Confidential Information That Explicitly or Implicitly Identifies Patients

The QIO regulations at § 480.101(b) define any information that explicitly or implicitly identifies an individual patient as confidential information. Although provisions are included in 42 CFR part 480 governing a practitioner's and/or provider's right to allow a QIO to use or disclose confidential information about the named practitioner or provider (§§ 480.105(b), 480.133(a)(2)(iii), and 480.140(d)), a similar right is not conveyed for beneficiaries. Thus, QIOs are prohibited from obtaining a beneficiary's authorization to use or disclose the beneficiary's confidential information, even in situations where a use or disclosure could be helpful to the beneficiary and his or her health care or even where the beneficiary specifically asks the QIO to disclose the information.

One of the key challenges for the QIOs is identifying improvements in health care delivery systems. In fact, the ''patient-centeredness'' aim of the QIO's current scope of work requires more patient involvement, and the goal of many patient and family engagement efforts is to incorporate a ''real-world person's'' experiences to demonstrate the compelling and urgent need for healthcare delivery reform. Additionally, beneficiaries have asked to participate in the QIO's work in a meaningful way. Unfortunately, we are often unable to accommodate these requests in light of the current regulatory restriction. We believe that this restriction, which was developed may years ago, is outdated, and that beneficiaries should be given the right to make choices regarding the use and disclosure of their confidential information.

Therefore, in the CY 2013 OPPS/ASC proposed rule (77 FR 45204), we proposed new § 480.145 that will govern a beneficiary's right to authorize a QIO's use or disclosure of the beneficiary's confidential information. Under proposed § 480.145(a), we proposed that, except as otherwise authorized by the QIO confidentiality regulations, a QIO may not use or disclose a beneficiary's confidential information without an authorization from the beneficiary and that the QIO's use or disclosure must be consistent with the authorization. Under proposed § 480.145(b)(1) through (b)(6), we listed those aspects of an authorization necessary to make the authorization valid. This includes the requirements that a specific and meaningful description of the confidential information be included, and that the authorization also include the name(s) of the QIO(s) and QIO point(s) of contact making the request to use or disclose the information, the name or other specific identification of the person, or class of persons to whom the QIO may allow the requested use or make the requested disclosure, a description of the purpose(s) of the use or disclosure, the date or event upon which the authorization will expire, and the signature and date of the beneficiary authorizing the use and/or disclosure of the information. We also proposed under § 480.145(c)(1) and (c)(2) that the authorization must contain a statement that the beneficiary maintains the right to revoke his or her authorization in writing and that the QIO must specify any exceptions to the right to revoke, as well as the process a beneficiary must use to revoke the authorization. In addition, under § 480.145(c)(3), we

proposed the requirement that the QIO convey to the beneficiary its inability to condition the review or other activities it is responsible for (such as beneficiary complaint reviews, medical necessity of a beneficiary's services, or discharge appeals) on whether or not the beneficiary provides authorization. We also proposed under § 480.145(c)(4) to make clear the consequences of authorizing the use or disclosure of information, and the fact that the QIO may be unable to protect the information from redisclosure. Under § 480.145(d), we proposed that an authorization must be written in plain language, and under § 480.145(e) that a QIO must provide the beneficiary with a copy of the signed authorization. Lastly, although we make reference to a beneficiary's right to revoke authorization under proposed § 480.145(c)(1), in paragraph (f) we proposed a specific provision that will make clear that a beneficiary may revoke, in writing, an authorization at any time, except when the QIO has taken action in reliance upon the authorization.

We believe that these proposed changes appropriately relax some of the historical restraints on the QIO's use of a beneficiary's confidential information, enable QIOs to better meet the needs of Medicare beneficiaries, and give beneficiaries the opportunity to participate in efforts to improve the quality of their health care.

Comment: Several commenters supported this new authority. One commenter requested that the regulations should also be changed to allow for the use of video as well as social media, while another commenter requested that whatever authorization form CMS develops should be in plain, understandable language and as short as possible.

Response: We appreciate the support for this new regulatory authority. We believe that the regulatory provisions as proposed already give the flexibility to use video and social media. The proposed regulations specify the beneficiary's right to authorize the use of his or her confidential information and the mechanism through which QIO's can obtain this authorization. However, the provisions do not, in any way, restrict the use of the confidential information to one specific mechanism, such as print advertisements. In terms of the development of an authorization form, at this time we do not intend to develop such a form. Each QIO will be responsible for developing an authorization form that meets the requirements of the new regulatory provisions.

After consideration of the public comments we received, we are adopting, without modification, our proposals regarding the use of confidential information that implicitly or explicitly identifies patients.

D. Secure Transmissions of Electronic Versions of Medical Information

When the QIO program regulations were first written in 1985, computers, along with digitally or electronically stored information, were still in their infancy. Thus, the QIO program regulations were written based on the perspective that most information sharing would be through the exchange of paper copies of medical records and other information. Since that time, we have seen great advances in the ability to electronically share data, whether through the use of mass storage devices (flash drives), the sending and receipt of electronic facsimiles, and even the use of email. At the same time, several laws, including HIPAA and the Federal Information Security and Management Act (FISMA), have been established to protect sensitive information. However, because the QIO program regulations have not undergone significant modification since they were originally adopted, the regulations do not account for electronic sharing of information and the QIOs' work is carried out within the context of exchanging paper copies of documents and information. At times, this creates additional work and costs because those providers and practitioners who have the ability to securely share electronic versions of medical records must actually print out the records and pay to have the paper copies mailed to the QIOs.

To address these issues, in the CY 2013 OPPS/ASC proposed rule (77 FR 45204) we proposed to revise existing § 476.78(b)(2) to add a new paragraph (iii) to make clear the QIOs' right to exchange secure transmissions of electronic versions of medical information, subject to a QIO's ability to support the exchange of the electronic version. We believe that this proposal would enable QIOs to receive and send medical information in a variety of formats, including through secure electronic faxes, and would reduce costs for providers and practitioners because they would no longer have to print and mail paper copies. In addition, to fully take advantage of the ability to receive and send electronic versions of medical information, we believe that a reduced timeframe is warranted for those instances where electronic versions are to be forwarded in response to requests from a QIO. Therefore, we proposed under proposed § 476.78 (b)(2)(iii) to require providers and practitioners to deliver electronic versions of medical information within 10 calendar days of the request from the QIO. As we noted previously, changes to existing § 476.78(b) have already been adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53664 through 53665). As discussed earlier in this preamble, we proposed in the CY 2013 OPPS/ASC proposed rule additional changes to § 476.78 to take into account the different, more expedited timeframes we proposed for medical records related to beneficiary complaint and general quality of care reviews. In the CY 2013 OPPS/ASC proposed rule (77 FR 45204), we also requested public comments on whether additional changes should be made to § 476.78(b) to expand the different timeframes to cover medical records for all kinds of reviews. We also requested public comments on whether any modifications should be made to the reimbursement methodologies for paper copies described in § 476.78(c). We note that we carried forth in the proposed rule the proposed change to the section heading for § 476.78 that was included in the FY 2013 IPPS/LTCH PPS proposed rule, that is, the proposed change from ''Responsibilities of health care facilities'' to ''Responsibilities of providers and practitioners'' (which has now been finalized).

Comment: Several commenters supported the proposed regulation that would enable QIOs to securely transmit electronic versions of medical information. Some commenters noted that the ability to transmit information electronically is a long overdue process change and the QIOs have been ''severely hampered'' by not being allowed to incorporate more electronic exchanges of information into their activities. These commenters also urged CMS to consider how QIOs can more effectively accept electronic records. Other commenters, while supportive of the proposal to allow QIOs to securely transmit electronic versions of medical information, cautioned CMS that QIOs will need instructions, equipment and electronic exchange infrastructure to be in place before these changes are implemented. Some commenters noted that ensuring remote access to CMS information systems for QIO staff and access to medical information is necessary to achieve the full benefits of this proposed regulation because peer reviewers frequently are not located onsite at the QIOs' place of business. Some commenters noted that the ability to securely transmit electronic versions of information is particularly significant in light of the proposed tighter

timeframes for completing review activities, while other commenters expressed concerns surrounding the ability to correctly track the differences in timeframes for responding to different types of requests. In addition, some commenters suggested that the proposed provision could help reduce costs related to the shipping of paper copies of medical information from providers and practitioners to the QIO, as well as from the QIOs to their physician reviewers and then back to the QIOs.

Response: We appreciate the commenters' support and agree that instructions, equipment, and electronic exchange infrastructure must be put in place in order to take full advantage of this new flexibility. We are currently initiating efforts to allow QIOs to receive electronic versions of medical information in multiple ways, as well as exchange these electronic versions with staff, including peer reviewers, remotely. We agree that this new flexibility can only facilitate providers' and practitioners' ability to comply with requests for medical information and also anticipate that the opportunity to use electronic exchanges will enable QIOs to complete their activities more quickly at reduced costs compared to the use of paper copies of medical records. Moreover, we appreciate that providers and practitioners receive a variety of requests for medical records and that these requests are not just from QIOs. Thus, tracking the different timeframes can be problematic. As we previously noted, we are adopting a uniform 14 calendar day timeframe for responding to requests for medical information for all requests, except that QIOs will maintain the authority to request medical information more quickly if circumstances warrant earlier receipt.

Comment: Some commenters stated that the amounts of reimbursement for photocopies do not adequately cover the cost of what it takes to generate the requested records and that the methodology for determining reimbursement rates needs to be routinely updated to keep pace with inflation.

Response: We thank the commenters for their input. At this time we are continuing to examine ways to possibly accommodate changes in reimbursement rates. We plan to consider various factors, such as how the new flexibility to securely transmit electronic versions of medical information might affect the payments we will be able to make for the submission of paper records. We are not making specific changes at this time, but will consider the commenters' input as we pursue possible changes to these regulations in future rulemaking.

After consideration of the public comments we received, we are adopting, as final, our proposals regarding secure transmissions of electronic versions of medical information, except that we are extending the timeframe for submission of medical information to 14 calendar days.

E. Active Staff Privileges

In our efforts to ensure the QIO program is able to meet the needs of Medicare beneficiaries and improve the quality of health care moving forward, we have identified an aspect of the QIO program regulations that has become increasingly problematic for the QIOs. Under existing § 476.98(a)(1), QIOs are required to use an individual with ''active staff privileges in one or more hospitals'' in making initial denial determinations. However, there is an accelerating trend toward primary care physicians (family physicians/internists) who provide care solely in the outpatient care settings and a corresponding decline in the number of family practice physicians who provide any care in hospitals. In fact, many of these individuals do not provide any inpatient care and either have no hospital privileges or only ''courtesy'' privileges, which do not meet the definition in existing § 476.1 of ''active staff privileges.'' While we believe that the continued use of peer reviewers is necessary and vital to the success of the QIO program, the need to use physicians with ''active staff privileges'' is not. We believe that the proposed removal of this requirement would increase the number of peer reviewers available for use by the QIOs, which, at times, has become particularly problematic for the QIOs. Therefore, in the CY 2013 OPPS/ASC proposed rule (77 FR 45204 through 45205), we proposed to remove the definition of ''active staff privileges'' under § 476.1 and to remove the phrase referring to using individuals ''with active staff privileges in one or more hospitals in the QIO area'' in making initial denial determinations under § 476.98(a)(1).

Comment: Several commenters opposed the proposal to remove ''active staff privileges'' as a requirement for peer reviewers making an initial denial determination and indicated that having active staff privileges is necessary because there is a need to ensure peer reviewers are cognizant of ''emerging clinical evidence and practices,'' particularly because clinical practice can change so rapidly. Others commenters noted that CMS should at least require active staff privileges in the State where the care was provided, while some commenters may have misunderstood the terminology and believed that the change would enable QIOs to use physicians who are not actively practicing. Some commenters also noted that requiring QIOs to use physicians with active staff privileges made assessing the care provided by potential reviewers easier because it supplemented the information QIOs could glean from State licensure, National Practitioner Data Bank, and self-reported information, and that the use of physicians with active staff privileges added to the credibility of the QIOs' peer review activities in the medical community.

Several commenters supported the removal of this requirement and believed it would allow for the inclusion of more specialized physician reviewers, provide more flexibility to QIOs in hiring peer reviewers by increasing the pool of eligible reviewers, and more closely mirror the current practicing medical environment. In particular, one commenter noted that, by removing this language, QIOs would be able to rely more on ''setting-based'' expertise (such as a nursing home or clinic), than is currently allowed by the more narrow active staff privilege requirement. Another commenter supported the change but not the removal of the phrase ''in the QIO area'' because of a concern that it could be interpreted to mean that a physician from outside the QIO's review area could conduct the review.

Response: We appreciate the comments and agree that having physicians with current, relevant knowledge of medical care is imperative to the operations of the QIOs and its cadre of physician reviewers. However, it appears that some commenters erroneously equated the removal of the active staff privileges requirement to the QIOs' use of physicians who were not actively practicing medicine. This is inaccurate and QIOs are obligated to use physicians who are actively practicing. Other commenters believed that physicians with active staff privileges would be those with the most current and relevant knowledge of medical care that is the subject of the QIO's review. However, we are unaware of any studies or research supporting this claim. In identifying physicians for use as reviewers, the QIOs would still be able to procure the services of actively practicing physicians with knowledge of the most current, relevant medical care. We believe that the removal of the active staff privileges requirement, however, would enable QIOs to better

match and utilize the expertise of physicians to the actual settings in which the care in question is provided. That is because, historically, the requirement to use a physician with active staff privileges could prevent the use of a physician who practiced in, and was more intimately familiar with, the care provided in a particular setting (for example, a nursing home setting) if that physician lacked active staff privileges in a hospital.

While it is possible that the removal of this requirement might result in a QIO being obligated to take some additional steps in evaluating the performance or effectiveness of a potential peer reviewer, we see no reason why having QIOs assume these extra steps should amount to a significant addition to their workload. We regard these steps as an essential part of the process a QIO should follow in finding the best match, including by specialty and setting, for any particular review activity. Lastly, while we appreciate the concern that removal of the language ''in the QIO area'' could cause confusion surrounding the QIO's obligation to use a physician within the QIO's area, we note that, in fact, this obligation continues to be clearly laid out in provisions of the statute, including in section 1154(a)(7) of the Act, and in other references within the regulations at 42 CFR Part 476. However, in order to minimize any possible confusion, we are modifying the proposal to maintain the ''in the QIO area'' language within § 476.98(a)(1).

After consideration of the public comments we received, we are adopting as final our proposal to remove the language regarding active staff privileges, except that we are maintaining the language ''in the QIO area.''

F. Technical Corrections

In addition to the proposed changes discussed above, in the CY 2013 OPPS/ASC proposed rule (77 FR 45205), we proposed to make the following technical corrections to the QIO regulations:

• In 1989, several sections in 42 CFR part 405 were redesignated to 42 CFR part 411 (54 FR 41746), but the cross-references to these sections in the QIO regulations was never made. Therefore, we proposed to make the following reference changes:

± Changing the reference ''§ 405.330(b)'' in existing § 476.71(b) to ''§ 411.400(b)'';

± Changing the reference ''§ 405.332'' in § 476.74 to ''§ 411.402'';

+ Changing the references ''§ 405.310(g) or § 405.310(k)'' in § 476.86 to ''§ 411.15(g) or § 411.15(k)''.

• In 1999, 42 CFR parts 466, 473, and 476 were redesignated as 42 CFR parts 476, 478, and 480, respectively (64 FR 66236). Therefore, we proposed to make changes to correct several cross-references to sections in these Parts:

+ Changing the reference ''§ 466.73(b)(3)'' in § 476.73 to ''§ 476.78(b)(3)''.

+ Changing the reference ''part 473'' in § 476.78(f) to ''part 478''.

+ Changing the reference ''part 473'' in § 476.94(c)(3) to ''part 478''.

+ Changing the reference ''§ 473.24'' in §§ 480.132 and 480.133 to ''§ 478.24''.

+ Changing the reference ''§ 466.98'' in § 478.28 to ''§ 476.98''.

+ Changing the reference to ''Part 478'' in §§ 478.15, 478.16, 478.20, 478.38, 478.42, and 478.48 to ''Part 473''.

+ Changing the reference ''§ 473.24'' in § 480.132 to ''§ 478.24''.

+ Changing the references ''Part 466'' and ''§ 473.24'' in § 480.133(b) to ''Part 476'' and ''§ 478.24'', respectively.

• We proposed the deletion of several provisions in Part 476 regarding risk-basis contracts because risk-basis contracts previously under section 1876 of the Act no longer exist. As such, these provisions are obsolete and no longer used under the QIO program. Specifically, we are deleting the following sentence from § 476.70(a): ''Section 1154(a)(4) of the Act requires QIOs, or, in certain circumstances, non-QIO entities, to perform quality of care reviews of services furnished under risk-basis contracts by health maintenance organizations (HMOs) and competitive medical plans (CMPs) that are covered under subpart C of part 417 of this chapter.'' We proposed to delete the following sentence from § 476.70(b): ''Section 466.72 of this part also applies, for purposes of quality of care review under section 1154(a)(4) of the Act, to non-QIO entities that enter into contracts to perform reviews of services furnished under risk basis contracts by HMOs and CMPs under subpart C of part 417 of this chapter.'' We proposed to delete § 476.72—Review of the quality of care of risk-basis health maintenance organizations and competitive medical plans, in its entirety for the same reason.

• In § 476.70(a), we proposed to change the word ''basis'' to ''bases'' to match the title of this section and to correctly denote that there is more than one statutory basis described in paragraph (a).

• We proposed technical corrections to sections in Part 476 and 480 to accurately reflect the transition to Medicare administrative contractors (MACs) to process Medicare claims and conduct other actions. This transition is ongoing, and fiscal intermediaries and carriers still exist. However, we believe that the presence of MACs should be accounted for to accurately reflect current contractual relationships. As such, we proposed to incorporate references to ''Medicare administrator contractors'' in the following sections, where appropriate:

+ § 476.1, in the definition of ''Preadmission Certification'';

+ § 476.71(c)(1);

+ § 476.73(a);

+ § 476.74(b) and (c)(1);

+ § 476.80 section heading, and §§ 476.80(a), (a)(1), (a)(2), (b)(1), (c), (c)(3)(ii), (d)(1), (d)(2), (e) paragraph heading, (e)(1), and (e)(2);

+ § 476.86(a)(2), (c) introductory text, (c)(1), and (d);

+ § 476.94(a)(1)(iv) and (d);

+ § 476.104(a); and

+ § 480.105(a).

• We proposed a technical correction to § 480.139 by adding a paragraph ''(a)'' in front of ''(1)'' to the beginning of the text of the section to correct a recent inadvertent coding error which had removed the ''(a)''.

• We proposed to correct the statutory citation in § 480.132(b) by changing ''section 1154(a)(3)'' to ''section 1154(a)(2)''.

Comment: Commenters agreed with the proposed technical changes.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are adopting, without modification, our proposals regarding the technical changes.

XIX. Files Available to the Public via the Internet

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. To view the Addenda of this final rule with comment period pertaining to the CY 2013 payments under the OPPS, go to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html* and select ''1589–FC'' from the list of regulations. All Addenda for this final rule with comment period are contained in the zipped folder entitled ''2013 OPPS 1589–FC Addenda'' at the bottom of the page.

To view the Addenda of this final rule with comment period pertaining to the CY 2013 payments under the ASC payment system, go to the CMS Web site

at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.html* and select ''1589–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.

XX. Collection of Information Requirements

A. Legislative Requirements for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 30-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 estimated 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 2013 OPPS/ASC proposed rule (77 FR 45206), we solicited public comments on each of the issues outlined above as discussed below that contained information collection requirements.

B. Requirements in Regulation Text

1. 2013 Medicare EHR Incentive Program Electronic Reporting Pilot for Hospitals and CAHs (§ 495.8)

Under the definition of ''meaningful EHR user'' in 42 CFR 495.4, we require eligible hospitals and CAHs participating in the Medicare EHR Incentive Program (which would include those participating in the 2013 Medicare EHR Incentive Program Electronic Reporting Pilot) to successfully report the hospital clinical quality measures (CQMs) selected by CMS to CMS in the form and manner specified by CMS. Although eligible hospitals and CAHs may continue to report CQM results as calculated by certified EHR technology by attestation for 2013, they also may choose to participate in the 2013 Medicare EHR Incentive Program Electronic Reporting Pilot for Hospitals and CAHs. Eligible hospitals and CAHs participating in the 2013 Medicare EHR Incentive Program Electronic Reporting Pilot must submit CQM data on all 15 CQMs (listed in Table 10 of the Stage 1 final rule (75 FR 44418 through 44420) for the Medicare and Medicaid EHR Incentive Program) to CMS, via a secure transmission based on data obtained from the eligible hospital or CAH's certified EHR technology.

Eligible hospitals and CAHs are required to report on core and menu set criteria for Stage 1 of meaningful use. We estimated that it would take an eligible hospital or CAH 0.5 hour to submit the required CQM information via the proposed 2013 Medicare EHR Incentive Program Electronic Reporting Pilot. Therefore, the estimated total burden for all 4,922 Medicare eligible hospitals and CAHs participating in the Pilot (3,620 acute care hospitals and 1,302 CAHs) 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 its behalf. We estimated the cost burden for an eligible hospital or CAH to submit the CQMs and hospital quality requirements is $30.21 (0.5 hour × $60.41 (mean hourly rate for a computer and information systems manager based on the 2011 Bureau of Labor Statistics)) and the total estimated annual cost burden for all eligible hospitals and CAHs to submit the required CQMs is $148,694 ($30.21 × 4,922 hospitals and CAHs). We solicited public comments on the estimated numbers of eligible hospitals and CAHs that may register for the Medicare EHR Incentive Program Electronic Reporting Pilot that would submit the CQM information via the proposed Electronic Reporting Pilot in 2013. We also invited 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 public comments on these information collection requirements. Therefore, we are finalizing the proposed burden estimates.

C. Associated Information Collections Not Specified in Regulatory Text

In the CY 2013 OPPS/ASC proposed rule, we made reference to proposed associated information collection requirements that are not discussed in the regulation text contained in the proposed rule. The following is a discussion of those requirements.

1. Hospital OQR Program

As previously stated in section XIV. of the CY 2012 OPPS/ASC 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) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74549 through 74554) for detailed discussions of the 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 had to 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. This approval expires on 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 laboratory 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.

b. Hospital OQR Program Measures for the CY 2014 Payment Determination

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 the CY 2012 OPPS/ASC final rule with comment period, we added, for the CY 2014 payment determination, 1 chart-abstracted measure and 2 structural measures (including hospital outpatient volume data for selected outpatient surgical procedures). However, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74456), we did not implement public reporting of the claims-based OP: 15 Use of Brain Computed Tomography (CT) in the ED for Atraumatic Headache. Because this is a claims-based measure, hospitals continue to submit relevant claims to be paid, but these administrative data and any measure calculations from them are not being made publicly available as specified for required hospital outpatient hospital quality of care measure data under section 1833(t)(17)(E) of the Act.

In addition, in section XV.C. of the proposed rule, we stated that we were confirming that, using a subregulatory process, we have suspended indefinitely data collection for one measure, OP–19: Transition Record with Specified Elements Received by Discharged Patients, and have deferred data collection for another measure, OP–24: Cardiac Rehabilitation Patient Referral From an Outpatient Setting. (We note that, in this final rule with comment period, we are confirming the removal of the measure, 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, and we will cease data collection in the system for this measure effective January 1, 2013.) Thus, for the CY 2014 and subsequent years payment determinations, as proposed, we are finalizing in this final rule with comment period a total of 25 measures (rather than 26 measures as we indicated in the proposed rule (77 FR 45207), with hospitals reporting data on only 22 of them (rather than 23 measures as we indicated in the proposed rule (77 FR 45207)). The required measure set for the CY 2014 and subsequent years' payment determinations includes the measures shown below; all measures were previously adopted.

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Hospital OQR Program Measures for the CY 2014, CY 2015 and Subsequent Years 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-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 ED 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

Procedure Category	Corresponding HCPCS Codes
Gastrointestinal	40000 through 49999, G0104, G0105, G0121, C9716, C9724, C9725, and 0170T
Eye	65000 through 68999, G0186, 0124T, 0099T, 0017T, 0016T, 0123T, 0100T, 0176T, 0177T, 0186T, 0190T, 0191T, 0192T, 76510, and 0099T
Nervous System	61000 through 64999, G0260, 0027T, 0213T, 0214T, 0215T, 0216T, 0217T, 0218T, and 0062T
Musculoskeletal	20000 through 29999, 0101T, 0102T, 0062T, 0200T, and 0201T
Skin	10000 through 19999, G0247, 0046T, 0268T, G0127, C9726, and C9727
Genitourinary	50000 through 58999, 0193T, and 58805
Cardiovascular	33000 through 37999
Respiratory	30000 through 32999

*Information for OP-15 will not be reported in Hospital Compare in 2012. Public reporting for this measure would occur in July 2013 at the earliest.

**Data collection for OP-19 was suspended effective with January 1, 2012 encounters until further notice.

***Data collection for OP-24 is deferred from January 1, 2013 to January 1, 2014, and its first application toward a payment determination would be for CY 2015 rather than CY 2014.

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We will calculate the six claims-based measures (rather than seven claims-based measures as indicated in the proposed rule (77 FR 45207) 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 data for 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 is the time and effort associated with completing the notice of participation form, and collecting and submitting the data on the required measures. For the chart-abstracted measures (including those measures for which data are 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 estimated that there will be approximately 3,200 respondents per year. For hospitals to collect and submit the information on the chart-abstracted measures (excluding the chart-abstracted OP–22 measure), we estimated it will take 35 minutes per sampled case. Based upon the data submitted for the CY 2011 and CY 2012 payment determinations, we estimated there will be a total of 1,628,800 cases per year, approximately 509 cases per year per respondent. The estimated annual burden associated with the submission requirements for these chart-abstracted measures is 949,590 hours (1,628,800 cases per year × 0.583 hours per case).

For the chart-abstracted OP–22 measure plus the 3 structural measures (excluding the all-patient volume for selected surgical procedures measure), we estimated 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 2,138 hours (3,200 hospitals × 0.167 hours per hospital × 4 measures per hospital). For the proposed rule (77 FR 45208), we inadvertently stated the burden to be 1,603 hours because we excluded the OP–22 measure in our burden computation.

For the collection of all-patient volume for selected outpatient surgical procedures (OP–26: Hospital Outpatient Volume Data on 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 requirement is the reporting of the data using the Web-based tool. We estimated 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 534 hours (3,200 hospitals × 0.167 hours per measure × 1 all-patient volume measure per hospital). We note that we inadvertently indicated that the total of this computation was 53 hours in the proposed rule (77 FR 45208).

We did not receive any public comments on these information collection requirements and, therefore, are finalizing our proposed burden

estimates with the modifications we have described above.

c. Hospital OQR Program Measures for CY 2015

In the CY 2012 OPPS/ASC final rule with comment period, for the CY 2015 payment determination, we retained the requirement that hospitals must complete and submit a notice of participation form in order to participate in the Hospital OQR Program. For the CY 2015 payment determination, we also retained the measures used for CY 2014 payment determination (including the measures adopted in the CY 2012 final rule with comment period) and did not add any additional measures.

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 measures, and collecting and submitting all-patient volume data for selected outpatient surgical procedures. For the chart-abstracted measures, we estimated 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 are submitted directly to CMS (excluding the chart-abstracted OP–22 measure), we estimated it will take 35 minutes per sampled case. Based upon the data submitted for the CY 2011 and CY 2012 payment determinations, we estimated there will be a total of 1,628,800 cases per year, approximately 509 cases per year per respondent. The estimated annual burden associated with the aforementioned submission requirements for the chart-abstracted data is 949,590 hours (1,628,800 cases per year × 0.583 hours per case).

For the chart-abstracted OP–22 measure plus the 3 structural measures (excluding the all-patient volume for selected surgical procedures measure), we estimated 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 2,138 hours (3,200 hospitals × 0.167 hours per hospital × 4 measures per hospital). In the proposed rule (77 FR 45208), we inadvertently excluded the OP–22 measure in our burden computation.

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 estimated 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 534 hours (3,200 hospitals × 0.167 hours per hospital). We note that we inadvertently indicated that the total of this computation was 53 hours in the proposed rule (77 FR 45208).

We invited public comment on the burden associated with the information collection requirements.

We did not receive any public comments on these information collection requirements and, therefore, are finalizing our proposed burden estimates with the modifications we have described above.

3. Hospital OQR Program Validation Requirements for CY 2014

In the CY 2013 OPPS/ASC proposed rule, we proposed to retain the requirements related to data validation for CY 2014 that we adopted in the CY 2011 OPPS/ASC final rule with comment period (76 FR 74486) for CY 2013, and that we revised in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74553). While these requirements are subject to the PRA, they are currently approved under OCN: 0938–1109. This approval expires on October 31, 2013.

Similar to our approach for the CY 2013 Hospital OQR Program payment determination (76 FR 74484 through 74485), we proposed to continue to validate data from randomly selected hospitals for the CY 2014 payment determination, selecting 450 hospitals. 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 75 FR 72106, respectively), we discussed additional data validation conditions under consideration for CY 2013 and subsequent years. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485 and 76 FR 74553), we finalized a policy under which we will select for validation up to 50 additional hospitals based upon targeting criteria.

For each selected hospital (random or targeted), generally we will randomly select up to 48 patient encounters 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 2014 requirement is the time and effort necessary to submit validation data to a CMS contractor. We estimated 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 estimated each hospital must submit up to 48 cases for the affected year for review. All selected hospitals must comply with these requirements each 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 2014 is approximately 6,000 hours.

We proposed to maintain 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 did not receive any public comments on these information collection requirements. Therefore, we are finalizing our burden estimates as proposed.

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. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74487 and 74488 and 76 FR 74553 and 74554), we specified that we were continuing this process for the CY 2013 and subsequent years' payment determinations.

In this CY 2013 OPPS/ASC final rule with comment period, we are making one change to this process—to modify a requirement that the CEO must sign the

reconsideration request to allow the CEO or other designated personnel to sign the required form.

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, or appeals or all of these actions.

We did not receive any public comments on our proposed burden statement and therefore are finalizing it with modification in this final rule with comment period.

5. ASCQR Program Requirements

a. Claims-Based Outcome Measures for the CY 2014 Payment Determination

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74496 through 74504), we adopted five claims-based measures (four outcome and one process) to be used for the CY 2014 payment determination. We will collect quality measure data for the five claims-based measures by using QDCs placed on submitted claims beginning with services furnished from October 1, 2012 through December 31, 2012. The five outcome 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)

The first four measures listed above are outcome measures and the fifth measure is a process measure.

Approximately 71 percent of ASCs participate in Medical Event Reporting, which includes reporting on the first four 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 estimated 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, or about 11.8 events per year).

For the remaining claims-based measure, Prophylactic IV Antibiotic Timing, we estimated the burden associated with submitting QDCs to be nominal, as few procedures performed by ASCs will require prophylactic antibiotic administration.

b. Claims-Based Process, Structural, and Volume Measures for the CY 2015 and CY 2016 Payment Determinations

For the CY 2015 payment determination, we finalized the retention of the five measures we adopted for the CY 2014 payment determination, and we added two structural measures: Safe Surgery Checklist Use and ASC Facility Volume Data on Selected ASC Surgical Procedures (76 FR 74504 through 74509). For the CY 2015 payment determination, we proposed (and are finalizing in this final rule with comment period) that the data collection period for claims-based measures would be for services furnished from January 1, 2013, through December 31, 2013, that are paid by the administrative contractor by April 30, 2014.

For the CY 2016 payment determination, we finalized the retention of the seven measures for the CY 2015 payment determination and added Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) (76 FR 74509). For the CY 2016 payment determination, we proposed (and are finalizing in this final rule with comment period) that the data collection period for claims-based measures would be for services furnished from January 1, 2014, through December 31, 2014, that are paid by the administrative contractor by April 30, 2015.

Based on our data for CY 2014 payment determinations above, extrapolating to 100 percent of ASCs reporting, there would be an average of 11.8 events per year. Thus, we estimated 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 (approximately one case per month per ASC) for the CYs 2015 and CY 2016 payment determinations. We estimated the burden associated with submitting QDCs for the fifth measure to be nominal as well, as discussed above.

For the CY 2015 payment determination, 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 estimated 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 estimated 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).

We have not yet proposed reporting requirements for the Safe Surgery Checklist or the ASC Volume Data on Selected ASC Surgical Procedures nor have we proposed details on submission of the NHSN HAI measure: Influenza Vaccination Coverage Among Healthcare Personnel for the CY 2016 payment determination.

Public comments in reference to the use of the term ''claims-based'' on these information collection requirements are discussed in section XVI.C.1.b. of this final rule with comment period. We did not receive any other public comments on these information collection requirements and, therefore, are finalizing our burden estimates as proposed.

c. Program Administrative Requirements and QualityNet Accounts; Extraordinary Circumstance and Extension Requests; Reconsideration Requests

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74516), we finalized our proposal to consider an ASC to be participating in the ASCQR Program for the CY 2014 payment determination if the ASC includes QDCs specified for the program on their CY 2012 claims relating to the finalized measures.

In the FY 2013 IPPS/LTCH PPS final rule, we finalized, for the CY 2015 payment determination and subsequent payment determination years, that once an ASC submits any quality measure data, it would be considered to be participating in the ASCQR Program. Once an ASC submits quality measure data indicating its participation in the ASCQR Program, in order to withdraw, an ASC must complete and submit an online form indicating that it is withdrawing from the program.

For the CY 2015 payment determination and subsequent payment determination years, if the ASC submits quality measure data, there is no additional action required by the ASC to indicate participation in the program. The burden associated with the requirements to withdraw from the program is the time and effort associated with accessing, completing, and submitting the online form. Based on the number of hospitals that have withdrawn from the Hospital OQR

Program over the past 4 years, we estimated that 2 ASCs would withdraw per year and that an ASC would expend 30 minutes to access and complete the form, for a total burden of 1 hour per year.

In the FY 2013 IPPS/LTCH PPS final rule, we finalized for the CY 2015 payment determination the requirement that ASCs to identify and register a QualityNet administrator in order to set up accounts necessary to enter structural measure data. We estimated that, based upon previous experience with the Hospital OQR Program, it would take an ASC 10 hours to obtain, complete, and submit an application for a QualityNet administrator and then set up the necessary accounts for structural measure data entry. We estimated the total burden to meet these requirements to be 51,750 hours (10 hours × 5,175 ASCs).

In the FY 2013 IPPS/LTCH PPS final rule, we adopted a process for an extension or waiver for submitting information required under the program due to extraordinary circumstances that are not within the ASC's control. We are requiring that an ASC would complete a request form that would be available on the QualityNet Web site, supply requested information, and submit the request. The burden associated with these requirements is the time and effort associated with gathering required information as well as accessing, completing, and submitting the form. Based on the number of hospitals that have submitted a request for an extension or waiver from the Hospital OQR Program over the past 4 years, we estimated that 1 ASC per year would request an extension or waiver and that an ASC would expend 2 hours to gather required information as well as access, complete, and submit the form, for a total burden of 2 hours per year.

We also adopted a reconsideration process that would apply to the CY 2014 payment determination and subsequent payment determination years under the ASCQR Program. While there is burden associated with an ASC filing a reconsideration request, the regulations at 5 CFR 1320.4 for the Paperwork Reduction Act of 1995 exclude data collection activities during the conduct of administrative actions such as redeterminations, reconsiderations, or appeals or all of these actions.

We did not receive any public comments on our burden discussion in the proposed rule.

6. IRF QRP

In the FY 2012 IRF PPS final rule (76 FR 47873 through 47883), we finalized the initial reporting requirements of the IRF QRP, including two quality measures for CY 2012 reporting. These two quality measures are: (1) Percent of Residents with Pressure Ulcers that are New or Worsened (NQF #0678); and (2) Urinary Catheter Associated Urinary Tract Infection (CAUTI) rate per 1,000 urinary catheter days, for Intensive Care Unit (ICU) Patients (NQF #0138).

We also established reporting mechanisms for these two measures in the FY 2012 IRF PPS final rule. IRFs were instructed to use the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF–PAI) (approved under OCN: 0938–0842) to collect pressure ulcer measure data on Medicare Part A, Part B, and Medicare Advantage beneficiaries, and they were to collect CAUTI measure data on all patients and report that data to CDC's National Healthcare Safety Network (NHSN). The burden associated with this collection of information for IRFs was included in the FY 2012 IRF PPS final rule (76 FR 47884 through 47885).

In section XVII. of the proposed rule, we proposed to adopt three proposals for the IRF QRP, which are: (1) A proposal to implement updates made by the NQF to the CAUTI measure which will affect the annual payment update in FY 2014; (2) a proposal that any measure selected for use in the IRF QRP would remain in effect until actively removed, suspended, or replaced; and (3) a proposal to implement policies regarding when rulemaking will be used to update existing IRF QRP measures.

We stated that the first proposal would allow us to incorporate recent updates that were made to the CAUTI measure (NQF#0138) by the NQF. However, we stated that these changes would not affect the type or amount of data that IRFs will be required to collect and submit.

The second proposal involves the implementation of a policy that IRF quality measures will remain in effect until a measure is actively removed, suspended, or replaced. We stated that this policy would not add any additional information collection requirements for CY 2013 and beyond as discussed below.

The third proposal involves implementing a policy regarding when rulemaking would be used to update existing IRF QRP measures that have been updated by the NQF. We stated that this proposal would likewise not create any increased information collection burden on IRFs.

a. Pressure Ulcer Measure

In the CY 2013 OPPS/ASC proposed rule, we did not propose to make any changes in the way the pressure ulcer data are to be collected and submitted to CMS using the current version of the IRF–PAI. As discussed in section XVII.D.2. of this final rule with comment period, we have decided to adopt a nonrisk-adjusted version of the NQF #0678 pressure ulcer measure. We will collect pressure ulcer data using the current version of the IRF–PAI, which became effective on October 1, 2012.

We have decided to use a nonrisk-adjusted application of the NQF #0678 pressure ulcer measure as opposed to the NQF-endorsed version of this measure. However, this change in the nature of the measure will not change the information collection burden that IRFs will incur for the reporting of pressure ulcer data. Nor will the burden differ from that which was stated in the FY 2012 IRF PPS final rule (76 FR 47884 through 47885). Likewise, the information collection burden will not differ from the burden estimated that is currently approved for the IRF–PAI under OCN: 0938–0842. It is important to note that, while the FY 2012 IRF PPS final rule mainly discusses the reporting requirement that will be incurred by IRFs for the FY 2014 payment determination, we do not anticipate that the policies we are finalizing in this final rule with comment will create an increase in the information collection burden for subsequent fiscal years.

b. CAUTI Measure

As discussed above, the FY 2012 IRF PPS final rule adopted the ''Urinary Catheter Associated Urinary Tract Infection (CAUTI) rate per 1,000 urinary catheter days, for Intensive Care Unit (ICU) Patients'' (NQF# 0138) measure for the IRF QRP. However, subsequent to the publication of the FY 2012 IRF PPS final rule, this measure was expanded to several non-ICU settings, including IRFs. The CDC also changed the way the CAUTI measure is calculated from an infection rate per 1,000 days to a standardized infection ratio (''SIR''). The SIR calculation is comprised of the actual rate of infection over the expected rate of infection.

These changes will not impact the type or amount of data that IRFs will be required to collect and submit. Therefore, the information collection estimates that are stated in the FY 2012 IRF PPS final rule (76 FR 47884 through 47885) for reporting CAUTI data remain unchanged for the FY 2014 payment determination as well as for subsequent years payment determinations.

Summaries of the public comments we received on the proposed policies and the burden associated with these proposed information collection requirements and our responses are

discussed in section XVII. of this final rule with comment period.

If you comment on these information collection and recordkeeping requirements, please submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, CMS–1589–FC; Fax: (202) 395–6974; or Email: *OIRAsubmissions_@omb.eop.gov.*

XXI. Waiver of Proposed Rulemaking and Response to Comments

A. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

We utilize HCPCS codes for Medicare payment purposes. The HCPCS is a national coding system comprised of Level I codes (CPT codes) and Level II codes that are intended to provide uniformity to coding procedures, services, and supplies across all types of medical providers and suppliers. CPT codes are copyrighted by the AMA and consist of several categories, including Category I codes which are 5-digit numeric codes, and Category III codes which are temporary codes to track emerging technology, services, and procedures. The AMA issues an annual update of the CPT code set each Fall, with January 1 as the effective date for implementing the updated CPT codes. The HCPCS, including both CPT codes and Level II codes, is similarly updated annually on a calendar year basis. Annual coding changes are not available to the public until the Fall immediately preceding the annual January update of the OPPS and the ASC payment system. Because of the timing of the release of these new codes, it is impracticable for us to provide prior notice and solicit comment on these codes and the payments assigned to them in advance of publication of the final rule that implements the OPPS and the ASC payment system. However, it is imperative that these coding changes be accounted for and recognized timely under the OPPS and the ASC payment system for payment because services represented by these codes will be provided to Medicare beneficiaries in hospital outpatient departments and ASCs during the calendar year in which they become effective. Moreover, regulations implementing HIPAA (42 CFR Parts 160 and 162) require that the HCPCS be used to report health care services, including services paid under the OPPS and the ASC payment system. We assign interim payment amounts and status indicators to any new codes according to our assessment of the most appropriate APC based on clinical and resource homogeneity with other procedures and services in the APC. If we did not assign payment amounts to new codes on an interim basis, the alternative would be to not pay for these services during the initial calendar year in which the codes become effective. We believe it would be contrary to the public interest to delay establishment of payment amounts for these codes.

Therefore, we find good cause to waive the notice of proposed rulemaking for the establishment of payment amounts for selected HCPCS codes identified with comment indicator ''NI'' in Addendum B and Addendum BB to this final rule with comment period. We are providing a 60-day public comment period.

B. 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.

XXII. 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)). This section of the final rule with comment period contains the impact and other economic analyses for the provisions that we are finalizing.

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 (77 FR 45210), 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 OPPS rates. It is necessary to make changes to the payment policies and rates for outpatient services furnished by hospitals and CMHCs in CY 2013. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the OPPS conversion factor used to determine the payment rates for APCs. 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. We must review the clinical integrity of payment groups and relative payment weights at least annually. We revised the APC relative payment weights using claims data for services furnished on and after January 1, 2011, through and including December 31, 2011, and updated cost report information.

For CY 2013, we are continuing the current payment adjustment for rural SCHs, including EACHs. In addition, section 10324 of the Affordable Care Act, as amended by HCERA, authorizes a wage index of 1.00 for certain frontier States. Section 1833(t)(17) of the Act requires that subsection (d) hospitals

that fail to meet quality reporting requirements under the Hospital OQR Program incur a reduction of 2.0 percentage points to their OPD fee schedule increase factor. In this final rule with comment period, we are implementing these payment provisions. Also, we list the 23 drugs and biologicals in Table 32 that we are removing from pass-through payment status for CY 2013.

This final rule with comment period is also necessary to update the ASC payment rates for CY 2013, enabling CMS to make changes to payment policies and payment rates for covered surgical procedures and covered ancillary services that are performed in an ASC in CY 2013. Because the ASC payment rates are based on the OPPS relative payment 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 payment weights. In addition, because the services provided in ASCs are identified by HCPCS codes that are reviewed and revised either quarterly or annually, depending on the type of code, 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. Sections 1833(i)(2)(D)(iv) and 1833(i)(7) of the Act authorize the Secretary to 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 ASCs that fail to meet the quality reporting requirements. For CY 2013, there will be no impacts associated with this payment reduction because it will not be applied until CY 2014.

3. Overall Impacts for OPPS and ASC Payment Provisions

We estimate that the effects of the OPPS payment provisions will result in expenditures exceeding $100 million in any 1 year. We estimate that the total increase from the changes in this final rule with comment period in expenditures under the OPPS for CY 2013 compared to CY 2012 will be approximately $600 million. Taking into account our estimated changes in enrollment, utilization, and case-mix, we estimate that the OPPS expenditures for CY 2013 will be approximately $4.571 billion higher, relative to expenditures in CY 2012. Because this final rule with comment period is ''economically significant'' as measured by the $100 million threshold, we have prepared this regulatory impact analysis that, to the best of our ability, presents its costs and benefits. Table 57 displays the redistributional impact of the CY 2013 changes in OPPS payment to various groups of hospitals and for CMHCs.

We estimate that the update to the conversion factor and other adjustments (not including the effects of outlier payments, the pass-through estimates, and the application of the frontier State wage adjustment for CY 2013) will increase total OPPS payments by 1.8 percent in CY 2013. 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 will be budget neutral. However, these updates will change the distribution of payments within the budget neutral system. We estimate that the total change in payments between CY 2012 and CY 2013, 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), 1833(t)(3)(G) and 1833(t)(17) of the Act, will increase total estimated OPPS payments by 1.9 percent.

We estimate that the effects of the ASC provisions in this final rule with comment period for the ASC payment system would result in expenditures exceeding $100 million in any 1 year. We estimate the total increase (from changes in this final rule with comment period as well as enrollment, utilization, and case-mix changes) in expenditures under the ASC payment system for CY 2013 compared to CY 2012 to be approximately $189 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 the changes to the ASC payment system that, to the best of our ability, presents the costs and benefits of this final rule with comment period. Tables 58 and Table 59 of this final rule with comment period display the redistributional impact of the CY 2013 changes on ASC payment, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

4. Detailed Economic Analyses

a. Estimated Effects of OPPS Changes in This Final Rule With Comment Period

(1) Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the CY 2013 policy changes on various hospital groups. We post on the CMS Web site our hospital-specific estimated payments for CY 2013 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/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. At the Web site, select ''regulations and notices'' from the left side of the page and then select ''CMS–1589–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 57 below. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A. 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, we solicited public comment and information about the anticipated effects of our changes on providers and our methodology for estimating them. Any public comments that we receive are addressed in the applicable sections of this final rule with comment period that discuss the specific policies.

(2) Estimated Effects of OPPS Changes on Hospitals

Table 57 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 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. We now include a second line

for all hospitals, excluding permanently held harmless hospitals and CMHCs.

We present separate impacts for CMHCs in Table 57 and we discuss them separately below, because CMHCs are paid only for partial hospitalization services under the OPPS and are a different provider type from hospitals. In CY 2012, 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 2013, we are finalizing our proposal to continue this APC payment structure and are basing payment fully on the geometric mean costs calculated using data for the type of provider for which rates are being set, that is, hospital or CMHC. We display separately the impact of this policy on CMHCs, and we discuss its impact on hospitals as part of our discussion of the hospital impacts.

The estimated increase in the total payments made under the OPPS is determined largely by the increase to the conversion factor under the statutory methodology. The distributional impacts presented do not include assumptions about changes in volume and service-mix. The conversion factor is updated annually by the OPD fee schedule increase factor as discussed in detail in section II.B of this final rule with comment period. Section 1833(t)(3)(C)(iv) of the Act provides that 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, which we refer to as the IPPS market basket percentage increase. The IPPS market basket percentage increase for FY 2013 is 2.6 percent (77 FR 53258). Section 1833(t)(3)(F)(i) of the Act reduces that 2.6 percent by the multifactor productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is 0.7 percentage points (which is also the MFP adjustment for FY 2013 in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53258); 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 1.8 percent, which we are using in the calculation of the CY 2013 OPPS conversion factor. 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 less than 1.00. The amounts attributable to this frontier State wage index adjustment are incorporated in the CY 2013 estimates in Table 57.

To illustrate the impact of the CY 2013 changes, our analysis begins with a baseline simulation model that uses the CY 2012 relative payment weights, the FY 2012 final IPPS wage indices that include reclassifications, and the final CY 2012 conversion factor. Table 57 shows the estimated redistribution of the increase in payments for CY 2013 over CY 2012 payments to hospitals and CMHCs as a result of the following factors: APC reconfiguration and recalibration based on our historical methodology using median costs (Column 2); the marginal impact of basing the APC relative payment weights on geometric mean costs over basing them on median costs (Column 3); APC recalibration based on geometric mean costs (Column 4, the combined effect of Columns 2 and 3); the wage indices and the rural adjustment (Column 5); the combined impact of APC recalibration based on geometric mean costs, the wage indices and rural adjustment, and the OPD fee schedule increase factor update to the conversion factor (Column 6); the combined impact of APC recalibration based on geometric mean costs, the wage indices and rural adjustment, the conversion factor update, and the CY 2013 frontier State wage index adjustment (Column 7); and the estimated impact taking into account all payments for CY 2013 relative to all payments for CY 2012 (Column 8), 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 did not make any changes to the policy for CY 2013. Because the updates to the conversion factor (including the update of the OPD fee schedule increase factor), the estimated cost of the rural adjustment, and 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 will 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 2012 and CY 2013 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the OPPS rates for CY 2013 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 still result in a 1.9 percent estimated increase in Medicare payments to all other hospitals. Those estimated payments will not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 57 shows the total number of facilities (4,127), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2011 hospital outpatient and CMHC claims data to model CY 2012 and CY 2013 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 2012 or CY 2013 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 (3,905) 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 159 CMHCs at the bottom of

the impact table and discuss that impact separately below.

Columns 2, 3, and 4: APC Recalibration

These columns show the combined effects of the reconfiguration, recalibration, and other policies (such as setting payment for separately payable drugs and biologicals at ASP+6 under our CY 2013 decision to apply the statutory default). Column 2 shows the reclassification effects if we were to base the relative payment weights on the median costs of services. Column 3 shows the marginal effects of using the geometric mean costs compared to the effects if we were to base the relative payment weights on the median costs of services, in other words the effects of our policy change from medians to geometric means. We are providing this column comparing the additional impact of developing the CY 2013 OPPS relative payment weights using geometric mean costs only in the CY 2013 OPPS/ASC proposed and final rules because the CY 2013 OPPS will establish geometric mean costs as a baseline configuration for the OPPS. Column 4 shows the combined effect of Columns 2 and 3, in other words the effect of our decision to base the relative payment weights on geometric mean costs. It reflects the impacts of the reclassification of services among APC groups and the recalibration of APC relative payment weights, based on 12 months of CY 2011 OPPS hospital claims data and the most recent cost report data, and determining relative payment weights using the geometric mean costs of services. We modeled the effect of the APC recalibration changes by varying only the relative payment weights (the final CY 2012 relative weights versus the CY 2013 relative weights calculated using the service-mix and volume in the CY 2011 claims used for this final rule with comment period) and calculating the percent difference in the relative weight. Column 4 also reflects 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.

Overall, we estimate that changes in APC reassignment and recalibration across all services paid under the OPPS will slightly decrease payments to urban hospitals by 0.1 percent. However, the smallest urban hospitals will receive slight payment increases of 0.6 percent (hospitals with 0–99 beds), attributable to increased payments for partial hospitalization, group psychotherapy and cardiac rehabilitation monitoring services furnished in the hospital. Due to recalibration, we estimate that low volume urban hospitals billing fewer than 21,000 lines for OPPS services will experience increases ranging from 1.0 percent to 4.9 percent. The increase of 4.9 percent for urban hospitals billing fewer than 5,000 lines per year is similarly attributable to an increase in payment for partial hospitalization and group psychotherapy services furnished in the hospital.

Overall, we estimate that rural hospitals will experience a small increase of 0.5 percent as a result of changes to the APC structure, with the largest increases going to the smallest hospitals both by number of beds (1.2 percent to those with less than 50 beds) and volume (3.1 percent to those with fewer than 5,000 lines). As a result of the recalibration, we estimate that rural hospitals that report 5,000 or more lines for OPPS services will experience payment increases ranging from 0.3 percent to 1.5 percent.

Classifying hospitals according to teaching status, we estimate that the APC recalibration will lead to small payment decreases of 0.1 to 0.2 percent for major and minor teaching hospitals, respectively. We estimate that nonteaching hospitals will experience an increase of 0.2 percent. Classifying hospitals by type of ownership suggests that voluntary, proprietary, and governmental hospitals will experience changes ranging from a decrease of 0.1 percent to an increase of 0.3 percent as a result of the APC recalibration.

For most hospitals, we estimate insignificant impacts of our final policy of using geometric mean-based relative payment weights. Most hospitals will receive small increases in payments of up to 6.5 percent. We estimate that hospitals for which DSH payments are not available (mostly urban hospitals) will experience an increase of 6.5 percent. Hospitals for which DSH data are not available (non-IPPS hospitals) furnish a large number of psychiatric services and we believe that the increase in payment is due to increased payment for partial hospitalization and group psychotherapy services, as well as for hemodialysis services furnished in the hospital.

Column 5: New Wage Indices and the Effect of the Rural and Cancer Hospital Adjustments

Column 5 demonstrates the combined budget neutral impact of APC recalibration using geometric means; the wage index update; the rural adjustment; and the cancer hospital adjustment. We modeled the independent effect of the budget neutrality adjustments and the OPD fee schedule increase factor by using the relative payment weights and wage indices for each year, and using a CY 2012 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indices.

Column 5 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 7. We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we did not make any changes to the policy for CY 2013. Similarly, the differential impact between the CY 2012 cancer hospital payment adjustment and the CY 2013 cancer hospital payment adjustment had no effect on the budget neutral adjustment to the conversion factor. We modeled the independent effect of updating the wage indices by varying only the wage indices, holding APC relative payment weights, service-mix, and the rural adjustment constant and using the CY 2013 scaled weights and a CY 2012 conversion factor that included a budget neutrality adjustment for the effect of changing the wage indices between CY 2012 and CY 2013. This column estimates the impact of applying the FY 2013 IPPS wage indices for the CY 2013 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 Column 7. We are continuing the rural payment adjustment of 7.1 percent to rural SCHs for CY 2013, 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 as a result of the updated wage indices and the rural adjustment, urban hospitals will experience no change from CY 2012 to CY 2013. Rural sole community hospitals will not be affected, but other rural hospitals will experience decreases of 0.4 percent. Urban hospitals in the East South Central and Pacific regions will experience the most significant payment changes with a decrease of 0.7 percent in the East South Central region and an increase of 1.4 percent in the Pacific region. Overall, we estimate that rural hospitals will

experience a decrease of 0.2 percent as a result of changes to the wage index for CY 2013. Regionally, the changes will range from a decrease of 0.9 percent in the rural Pacific region to an increase of 0.7 percent in the rural Mountain region.

Column 6: All Budget Neutrality Changes Combined With the OPD Fee Schedule Increase

Column 6 demonstrates the cumulative impact of the budget neutral adjustments from Column 5 and the OPD fee schedule increase factor of 1.8 percent. We estimate that for most hospitals, the addition of the OPD fee schedule increase factor of 1.8 percent will mitigate the negative impacts created by the budget neutrality adjustments made in Column 5.

While most classes of hospitals will receive an increase that is more in line with the 1.8 percent overall increase after the update is applied to the budget neutrality adjustments, urban hospitals that bill fewer than 5,000 lines, rural hospitals that bill fewer than 5,000 lines, and hospitals for which DSH information is not available will experience larger increases ranging from 4.5 percent to 8.2 percent. In particular, urban hospitals that report fewer than 5,000 lines will experience a cumulative increase, after application of the OPD fee schedule increase factor and the budget neutrality adjustments, of 6.7 percent, largely as a result of increases in payments to partial hospitalization and group psychotherapy services furnished in the hospital. Similarly, urban hospitals for which DSH data are not available will experience an increase of 8.0 percent, also largely as a result of increases in payment for partial hospitalization, group psychotherapy and hemodialysis services furnished in hospitals.

Overall, we estimate that these changes will increase payments to urban hospitals by 1.8 percent. We estimate that large urban hospitals and ''other'' urban hospitals will also experience increases of 1.9 and 1.6 percent, respectively. Urban hospitals in the Pacific region will experience an increase of 3.3 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 2.1 percent increase as a result of the OPD fee schedule increase factor and other budget neutrality adjustments.

Classifying hospitals by teaching status suggests that the OPD fee schedule increase factor and the budget neutrality adjustments will result in an increase of 1.7 percent for major teaching hospitals, 1.5 percent for minor teaching hospitals and 2.0 percent for nonteaching hospitals.

Classifying hospitals by type of ownership suggests that proprietary hospitals will experience an estimated increase of 2.3 percent, while voluntary hospitals will experience an estimated increase of 2.0 percent and government hospitals will experience an estimated increase of 1.8 percent.

Column 7: All Adjustments With the Frontier State Wage Index Adjustment

This column shows the impact of all budget neutrality adjustments, application of the 1.8 percent OPD fee schedule increase factor, and the nonbudget 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 6). This column differs from Column 6 solely based on application of the non-budget neutral frontier State wage index adjustment.

In general, we estimate that all facilities and all hospitals will experience a combined increase of 0.1 percent due to the nonbudget neutral frontier State wage index adjustment. The index will only affect urban hospitals in the West North Central and Mountain regions. Urban hospital in those regions will experience increases of 1.0 percent (West North Central) and 0.4 percent (Mountain) that are attributable to the frontier State wage index, and rural hospitals will experience increases of 1.2 percent (West North Central) and 2.1 percent (Mountain) that are attributable to the frontier State wage index.

Column 8: All Changes for CY 2013

Column 8 depicts the full impact of the CY 2013 policies on each hospital group by including the effect of all the changes for CY 2013 and comparing them to all estimated payments in CY 2012. Column 8 shows the combined budget neutral effects of Columns 2 through 5; the OPD fee schedule increase; the impact of the frontier State wage index adjustment; the impact of estimated OPPS outlier payments 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 XV. 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 101 hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2012 update (and assumed, for modeling purposes, to be the same number for CY 2013), we included 30 hospitals in our model because they had both CY 2011 claims data and recent cost report data. We estimate that the cumulative effect of all changes for CY 2013 will increase payments to all providers by 1.9 percent for CY 2013. We modeled the independent effect of all changes in Column 8 using the final relative payment weights for CY 2012 and the relative payment weights for CY 2013. We used the final conversion factor for CY 2012 of $70.016 and the CY 2013 conversion factor of $71.313 discussed in section II.B. of this final rule with comment period.

Column 8 contains simulated outlier payments for each year. We used the one year charge inflation factor used in the FY 2013 IPPS/LTCH PPS final rule of 4.24 percent (1.0424) to increase individual costs on the CY 2011 claims, and we used the most recent overall CCR in the July 2012 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2012. Using the CY 2011 claims and a 4.24 percent charge inflation factor, we currently estimate that outlier payments for CY 2012, using a multiple threshold of 1.75 and a fixed-dollar threshold of $2,025 should be approximately 0.9 percent of total payments. The estimated current outlier payments of 0.9 percent are incorporated in the CY 2013 comparison in Column 8. We used the same set of claims and a charge inflation factor of 8.66 percent (1.0866) and the CCRs in the July 2012 OPSF, with an adjustment of 0.9880, to reflect relative changes in cost and charge inflation between CY 2011 and CY 2013, to model the CY 2013 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed-dollar threshold of $2,025.

We estimate that the anticipated change in payment between CY 2012 and CY 2013 for the hospitals failing to meet the Hospital OQR Program requirements will be negligible. Overall, we estimate that facilities will experience an increase of 1.9 percent under this final rule with comment period in CY 2013 relative to total spending in CY 2012. This projected increase (shown in Column 8) of Table 57 reflects the 1.8 percent OPD fee schedule increase factor, with 0.07 percent for the change in the pass-through estimate between CY 2012 and CY 2013, with an additional 0.1 percent for the difference in estimated outlier payments between CY 2012 (0.9 percent) and CY 2013 (1.0 percent), less 0.04 percent due to the expiration of the

section 508 wage adjustment, less 0.1 percent due to the frontier adjustment in CY 2012, plus 0.1 percent due to the frontier State wage index adjustment in CY 2013. When we exclude cancer and children's hospitals (which are held harmless to their pre-BBA amount) and CMHCs, the estimated increase continues to be 1.9 percent after rounding. We estimate that the combined effect of all changes for CY 2013 will increase payments to urban hospitals by 1.9 percent, with large urban hospitals experiencing an estimated 2.0 percent increase and ''other'' urban hospitals experiencing an estimated 1.7 percent increase. We estimate that urban hospitals that bill less than 5,000 lines of OPPS services will experience an increase of 6.8 percent, largely attributable to the increase in payment for partial hospitalization and group psychotherapy services furnished in the hospital. We estimate that urban hospitals that bill 11,000 or more lines of OPPS services will experience increases between 1.8 percent and 3.1 percent, while urban hospitals that report between 5,000 and 10,999 lines will experience an increase of 4.4 percent.

Overall, we estimate that rural hospitals will experience a 2.2 percent increase as a result of the combined effects of all changes for CY 2013. We estimate that rural hospitals that bill less than 5,000 lines of OPPS services will experience an increase of 4.6 percent and that rural hospitals that bill 5,000 or more lines of OPPS services will experience increases ranging from 2.1 to 2.8 percent.

Among teaching hospitals, we estimate that the impacts resulting from the combined effects of all changes will include an increase of 1.8 percent for major teaching hospitals and 2.1 percent for nonteaching hospitals. Minor teaching hospitals will experience an increase of 1.7 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals will experience an increase of 1.9 percent, proprietary hospitals will experience an increase of 2.2 percent, and governmental hospitals will experience an increase of 1.9 percent.

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TABLE 57.—ESTIMATED IMPACT OF THE CY 2013 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENTS SYSTEM

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Number of Hospitals	**APC Recalibration (Median) (%)**	**Impact of Basing Weights Using Geo Mean(%)**	**APC Recalibration (Geo Mean) (%)**	**New Wage Index and Provider Adjustments (%)**	**Comb-ination of Cols 4, 5 with Market Basket Update (%)**	**Column 6 with Frontier Wage Index Adjustment (%)**	**All Changes (%)**
ALL FACILITIES *	4,127	0.0	0.0	0.0	0.0	1.8	1.9	1.9
ALL HOSPITALS	3,905	0.0	0.0	0.0	0.0	1.8	1.9	1.9
(excludes hospitals permanently held harmless and CMHCs)								
URBAN HOSPITALS	2,957	-0.1	0.0	-0.1	0.0	1.8	1.8	1.9
LARGE URBAN	1,611	-0.1	0.0	-0.1	0.2	1.9	1.9	2.0
(GT 1 MILL.)								
OTHER URBAN	1,346	-0.1	0.0	-0.1	-0.1	1.6	1.8	1.7
(LE 1 MILL.)								
RURAL HOSPITALS	948	0.3	0.1	0.5	-0.2	2.1	2.3	2.2
SOLE COMMUNITY	385	0.4	0.1	0.5	0.0	2.3	2.8	2.4
OTHER RURAL	563	0.3	0.1	0.4	-0.4	1.9	1.9	2.0

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Number of Hospitals	**APC Recalibration (Median) (%)**	**Impact of Basing Weights Using Geo Mean(%)**	**APC Recalibration (Geo Mean) (%)**	**New Wage Index and Provider Adjustments (%)**	**Comb-ination of Cols 4, 5 with Market Basket Update (%)**	**Column 6 with Frontier Wage Index Adjustment (%)**	**All Changes (%)**
BEDS (URBAN)								
0 - 99 BEDS	1,047	0.4	0.2	0.6	0.0	2.5	2.6	2.7
100-199 BEDS	833	0.1	0.1	0.2	0.2	2.2	2.3	2.3
200-299 BEDS	458	-0.1	0.0	-0.1	0.1	1.7	1.9	1.9
300-499 BEDS	415	-0.2	0.0	-0.2	0.1	1.7	1.8	1.9
500 + BEDS	204	-0.2	-0.1	-0.3	-0.2	1.3	1.3	1.5
BEDS (RURAL)								
0 - 49 BEDS	356	0.8	0.4	1.2	-0.3	2.8	3.0	2.8
50- 100 BEDS	352	0.5	0.1	0.7	0.0	2.4	2.7	2.6
101- 149 BEDS	137	0.2	0.1	0.2	-0.6	1.5	1.7	1.6
150- 199 BEDS	55	0.3	0.1	0.4	-0.3	1.8	2.4	2.0
200 + BEDS	48	-0.2	0.0	-0.2	0.1	1.7	1.7	1.8
VOLUME (URBAN)								
LT 5,000 Lines	597	2.4	2.5	4.9	-0.1	6.7	6.8	6.8
5,000 - 10,999 Lines	126	1.3	1.3	2.6	-0.3	4.1	4.5	4.4
11,000 - 20,999 Lines	197	0.7	0.3	1.0	0.1	2.9	3.0	3.1

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Number of Hospitals	**APC Recalibration (Median) (%)**	**Impact of Basing Weights Using Geo Mean(%)**	**APC Recalibration (Geo Mean) (%)**	**New Wage Index and Provider Adjustments (%)**	**Comb-ination of Cols 4, 5 with Market Basket Update (%)**	**Column 6 with Frontier Wage Index Adjustment (%)**	**All Changes (%)**
21,000 - 42,999 Lines	429	0.3	0.1	0.4	0.1	2.3	2.4	2.5
42,999 - 89,999 Lines	688	0.0	0.0	0.0	0.1	1.9	1.9	2.0
GT 89,999 Lines	920	-0.2	0.0	-0.2	0.0	1.6	1.7	1.8
VOLUME (RURAL)								
LT 5,000 Lines	59	1.8	1.3	3.1	-0.3	4.5	7.6	4.6
5,000 - 10,999 Lines	61	0.5	0.9	1.5	-0.9	2.3	2.3	2.5
11,000 - 20,999 Lines	146	0.6	0.6	1.2	-0.3	2.7	3.1	2.8
21,000 - 42,999 Lines	282	0.7	0.2	0.9	-0.3	2.4	2.7	2.5
GT 42,999 Lines	400	0.2	0.1	0.3	-0.2	1.9	2.2	2.1
REGION (URBAN)								
NEW ENGLAND	149	0.3	0.0	0.3	-0.6	1.5	1.5	1.5
MIDDLE ATLANTIC	349	-0.1	-0.1	-0.1	-0.3	1.4	1.4	1.5
SOUTH ATLANTIC	453	-0.1	-0.1	-0.2	-0.5	1.1	1.1	1.3
EAST NORTH CENT.	474	-0.2	0.0	-0.2	0.3	1.9	1.9	1.9
EAST SOUTH CENT.	179	-0.3	-0.1	-0.4	-0.7	0.7	0.7	0.8
WEST NORTH CENT.	188	0.0	0.0	0.0	0.3	2.1	3.1	2.5

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Number of Hospitals	**APC Recalibration (Median) (%)**	**Impact of Basing Weights Using Geo Mean(%)**	**APC Recalibratio n (Geo Mean) (%)**	**New Wage Index and Provider Adjustments (%)**	**Comb-ination of Cols 4, 5 with Market Basket Update (%)**	**Column 6 with Frontier Wage Index Adjustment (%)**	**All Changes (%)**
WEST SOUTH CENT.	515	-0.1	0.1	-0.1	-0.4	1.4	1.4	1.6
MOUNTAIN	208	0.2	0.0	0.2	0.6	2.7	3.1	2.8
PACIFIC	395	-0.1	0.1	0.0	1.4	3.3	3.3	3.4
PUERTO RICO	47	-0.1	0.0	-0.1	0.1	1.8	1.8	2.0
REGION (RURAL)								
NEW ENGLAND	25	0.7	0.0	0.7	0.4	3.0	3.0	3.1
MIDDLE ATLANTIC	67	0.4	0.0	0.4	0.0	2.2	2.2	2.3
SOUTH ATLANTIC	161	0.2	0.1	0.3	-0.4	1.6	1.6	1.7
EAST NORTH CENT.	127	0.2	0.1	0.3	0.4	2.5	2.5	2.5
EAST SOUTH CENT.	175	0.0	0.1	0.1	-0.5	1.4	1.4	1.5
WEST NORTH CENT.	98	0.5	0.1	0.7	-0.5	2.0	3.2	2.1
WEST SOUTH CENT.	201	0.5	0.4	0.9	-0.4	2.3	2.3	2.4
MOUNTAIN	65	0.6	0.0	0.6	0.7	3.1	5.2	3.5
PACIFIC	29	0.7	0.1	0.8	-0.9	1.7	1.7	1.8
TEACHING STATUS								
NON-TEACHING	2,930	0.1	0.1	0.2	0.0	2.0	2.1	2.1

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Number of Hospitals	**APC Recalibration (Median) (%)**	**Impact of Basing Weights Using Geo Mean(%)**	**APC Recalibration (Geo Mean) (%)**	**New Wage Index and Provider Adjustments (%)**	**Comb-ination of Cols 4, 5 with Market Basket Update (%)**	**Column 6 with Frontier Wage Index Adjustment (%)**	**All Changes (%)**
MINOR	687	-0.1	0.0	-0.2	-0.1	1.5	1.8	1.7
MAJOR	288	-0.1	-0.1	-0.1	0.1	1.7	1.7	1.8
DSH PATIENT PERCENT								
0	14	1.4	0.0	1.4	-0.1	3.1	3.1	3.2
GT 0 - 0.10	343	0.1	-0.1	0.0	0.0	1.8	1.9	2.0
0.10 - 0.16	327	0.1	0.0	0.0	0.1	1.9	2.0	2.0
0.16 - 0.23	686	0.0	0.0	0.0	0.0	1.7	1.9	1.8
0.23 - 0.35	1,064	0.0	0.0	0.0	-0.1	1.7	1.9	1.9
GE 0.35	832	-0.2	0.0	-0.1	0.1	1.8	1.8	2.0
DSH NOT AVAILABLE **	639	2.1	4.3	6.5	-0.1	8.2	8.2	8.3
URBAN TEACHING/DSH								
TEACHING & DSH	885	-0.1	-0.1	-0.2	0.0	1.6	1.7	1.7
NO TEACHING/DSH	1,458	0.0	0.0	0.0	0.1	1.9	2.0	2.0
NO TEACHING/NO DSH	14	1.4	0.0	1.4	-0.1	3.1	3.1	3.2
DSH NOT AVAILABLE**	600	2.1	4.1	6.2	0.0	8.0	8.0	8.0

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Number of Hospitals	**APC Recalibration (Median) (%)**	**Impact of Basing Weights Using Geo Mean(%)**	**APC Recalibratio n (Geo Mean) (%)**	**New Wage Index and Provider Adjustments (%)**	**Comb-ination of Cols 4, 5 with Market Basket Update (%)**	**Column 6 with Frontier Wage Index Adjustment (%)**	**All Changes (%)**
TYPE OF OWNERSHIP								
VOLUNTARY	2,053	-0.1	0.0	-0.1	0.0	1.8	1.9	1.9
PROPRIETARY	1,294	0.1	0.2	0.3	-0.1	2.0	2.1	2.2
GOVERNMENT	558	0.1	0.0	0.1	-0.1	1.8	1.8	1.9
CMHCs	159	-1.8	-3.9	-5.7	-0.6	-4.5	-4.5	-4.4

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, the use of median costs in developing relative payment weights, and the final recalibration of APC weights based on CY 2011 hospital claims data.

Column (3) shows the estimated impact of basing the CY 2013 OPPS final payments on geometric mean costs, by comparing estimated CY 2013 payments under the policy for a geometric mean cost based system to those under a median based OPPS.

Column (4) shows the impact of changes resulting from the reclassification of HCPCS codes among APC groups, the use of geometric mean costs in developing the CY 2013 final OPPS relative payment weights, and the recalibration of APC weights based on CY 2011 hospital claims data.

Column (5) shows the budget neutral impact of updating the wage index by applying the FY 2013 hospital inpatient wage index. The rural adjustment is 7.1 percent in both years so its budget neutrality factor is 1. Similarly, the differential in estimated cancer hospital payments for the final adjustment is minimal and thus results in a budget neutrality factor of 1.

Column (6) shows the impact of all budget neutrality adjustments and the final addition of the 1.8 percent OPD fee schedule increase factor (2.6 percent reduced by 0.7 percentage points for the multifactor productivity adjustment and further reduced by 0.1 percentage point in order to satisfy statutory requirements set forth in the Affordable Care Act).

Column (7) shows the non-budget neutral impact of applying the frontier State wage adjustment in CY 2013, after application of the CY 2013 final OPD fee schedule increase factor.

Column (8) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate and adds estimated outlier payments. This column also shows the expiration of section 508 wages on March 30, 2012, and the application of the frontier State wage adjustment for CY 2012 and 2013.

*These 4,127 facilities 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.

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(3) Estimated Effects of OPPS Changes on CMHCs

The last line of Table 57 demonstrates the isolated impact on CMHCs, which furnish only partial hospitalization (PHP) services under the OPPS. In CY 2012, CMHCs are paid under two APCs for these services: APC 0172 (Level I Partial Hospitalization (3 services) for CMHCs) and APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs). In contrast, hospitals are paid 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). We first implemented these four APCs for CY 2011 and 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 but provided a transition to CMHC rates based solely on CMHC data for the two CMHC PHP per diem rates. For CY 2013, we are continuing the provider-specific APC structure that we adopted for CY 2011 and are basing payment fully on the 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 2011 claims data used for this 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 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs) decline in CY 2013 using geometric mean-based relative payment weights as opposed to median-based relative payment weights (shown in Columns 3 and 4), we estimate that there will be an overall 4.4 percent decrease in payments to CMHCs (shown in Column 8).

Column 5 shows that the estimated impact of adopting the CY 2013 wage index values will result in a small decrease of 0.6 percent to CMHCs. We note that all providers paid under the OPPS, including CMHCs, will receive a 1.8 percent OPD fee schedule increase factor. Column 6 shows that combining this OPD fee schedule increase factor, along with changes in APC policy for CY 2013 and the CY 2013 wage index updates, results in an estimated decrease of 4.5 percent. Column 7 shows that adding the frontier State wage adjustment will result in no change to the cumulative 4.5 percent decrease. Column 8 shows that adding the changes in outlier and pass-though payments will result in a 0.1 percent decrease in payment for CMHCs. This reflects all changes to CMHCs for CY 2013.

(4) Estimated Effect of OPPS Changes 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 2012 OPPS, the national unadjusted copayment is $227.35, and the minimum unadjusted copayment is $215.00, 20 percent of the national unadjusted payment rate of $1,074.99. For CY 2013, the national unadjusted copayment for APC 0037 is $227.35, the same amount as the national unadjusted copayment in effect for CY 2012. The minimum unadjusted copayment for APC 0037 is $223.71 or 20 percent of the CY 2013 national unadjusted payment rate for APC 0037 of $1,118.54. The minimum unadjusted copayment will increase for CY 2013 compared to CY 2012 because the payment rate for APC 0037 will increase for CY 2013. For further discussion on the calculation of the national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.H. 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 2012 hospital inpatient deductible is $1,156. The amount of the CY 2013 hospital inpatient deductible is not available at the time of publication of this final rule with comment period.

In order to better understand the impact of changes in copayment on beneficiaries, we modeled the percent change in total copayment liability using CY 2011 claims. We estimate, using the claims of the 4,127 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 2012 to 21.5 percent in CY 2013 due largely to changes in service-mix.

(5) Estimated Effects of OPPS Changes on Other Providers

The relative payment weights and payment amounts established under the OPPS affect the payments made to ASCs as discussed in section XIV. of this final rule with comment period. No types of providers or suppliers other than hospitals, CMHCs and ASCs will be affected by the changes in this final rule with comment period.

(6) Estimated Effects of OPPS Changes 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 2013. 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 in section XXII.A. of this final rule with comment period.

(7) Alternative OPPS Policies Considered

Alternatives to the OPPS changes we are making and the reasons for our selected alternatives are discussed throughout this final rule with comment period. In this section, we discuss some of the major issues and the alternatives considered.

• Alternatives Considered for Basing the APC Relative Payment Weights on Geometric Mean Costs Rather than Median Costs

As described in section II.A.2.f. of this final rule with comment period, we are basing the CY 2013 relative payment weights on which OPPS payments are calculated using geometric mean costs rather than median costs. We established this policy based on stakeholder public comments, the improvements we have made to the data process to obtain more data and additional accuracy in estimating cost, and the other reasons described in the geometric mean based relative payment weights section.

In developing this policy, we considered another alternative, which was to continue basing the relative payment weights based on median costs. As discussed in the geometric mean based weights section, medians have historically served as a good measure of central tendency and continue to do so. In the initial establishment of the OPPS, we selected medians as the measure of central tendency on which to base the weights for a number of reasons. Those included statistical bases such as medians' resistance to outlier observations and their impact as well as reasons surrounding the practical implementation of the OPPS as a new payment system. While some of those

reasons for selecting medians continue to apply, others are now less relevant because of changes we have made in our data process, or no longer apply because of factors such as actual development of a working payment system. We have made a number of changes to the OPPS to address some of the challenges in arriving at better estimates of service cost, including trims, more specific application of cost to charge ratios in estimating cost, modeling changes to better simulate payment mechanisms, and methods of obtaining additional claims data through what is already available such as the bypass list.

We believe that those changes have helped to improve the relative costs on which the payment system is based. We also believe that geometric mean costs better incorporate the range of costs associated with providing a service, and thus will represent one such additional improvement. Therefore, in order to improve the accuracy at which we arrive at service costs used to set relative payment weights, to be responsive to stakeholder concerns regarding the degree to which OPPS payment appropriately reflects service cost, and the other reasons described in section II.A.2.f. of this final rule with comment period, we will establish the CY 2013 OPPS relative payment weights based on geometric means rather than continuing our historical practice of modeling costs using median costs.

• Alternatives Considered for Payment of Drugs and Biologicals That Do Not Have Pass-Through Status

We are paying for separately payable drugs and biologicals at ASP+6 percent, based on section 1833(t)(14)(A)(iii)(II) of the Act, also referred to as the statutory default. As detailed in greater depth in section V.B.3 of this final rule with comment period, this payment will represent the combined payment for both the acquisition and pharmacy overhead costs of separately payable drugs and biologicals.

We considered three alternatives for payment for drugs and biologicals that do not have pass-through status for CY 2013 (separately payable drugs and biologicals). The first alternative we considered was to propose to use the standard methodology, as described in the CY 2006 OPPS/ASC final rule with comment period (70 FR 68642). We compared 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, but without redistribution of estimated pharmacy overhead costs. Under this methodology, without a redistribution of overhead costs from packaged drugs to separately payable drugs, using April 2012 ASP information and costs derived from CY 2011 OPPS claims data, we estimated the combined acquisition and overhead costs of separately payable drugs and biologicals to be ASP+0 percent. We also determined that the combined acquisition and overhead costs of packaged drugs are 311 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 was to propose to continue our overhead adjustment methodology for CY 2013 and redistribute $270 million in overhead costs from packaged coded and uncoded drugs and biologicals to separately payable drugs and biologicals. Using this approach, we adjusted the CY 2011 pharmacy overhead redistribution amount of $200 million using the PPI for Pharmaceuticals for Human Use, resulting in a redistribution amount of $270 million and a payment rate for separately payable drugs of ASP+6 percent. We did not choose this alternative because of the reasons discussed below and in further detail in section V.B.3 of this final rule with comment period.

The third option that we considered, and the one that we are adopting for CY 2013, is to pay for separately payable drugs and biologicals administered in the hospital outpatient department, at ASP+6 percent based on the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act, which requires an alternative methodology for determining payment rates for SCODs wherein, if hospital acquisition cost data are not available, payment shall be equal (subject to any adjustment for overhead costs) 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. We determined that this ASP+6 percent payment amount for separately payable drugs and biologicals represents the combined acquisition and pharmacy overhead payment for drugs and biologicals for CY 2013.

As described in further detail in section V.B.3 of this final rule with comment period, we chose this alternative because we are uncertain about the full cost of pharmacy overhead and acquisition cost, due to the limitations of the submitted hospital charge and claims data for drugs. We believe that the continued use of our current drug payment methodologies may not appropriately account for average acquisition and pharmacy overhead cost and therefore could result in future payment rates that are not appropriate.

Therefore, we finalized our proposal to pay for separately payable drugs and biologicals based on the statutory default at the physician's office Part B payment rates, as established in sections 1842(o) and 1847A of the Act, at ASP+6 percent. We believe that paying for separately payable drugs and biologicals at ASP+6 percent based on the statutory default is appropriate at this time as it yields increased predictability in payment for drugs and biologicals under the OPPS while appropriately paying for drugs at a level consistent with payment amounts yielded by our methodology of the past 7 years.

b. Estimated Effects of ASC Payment System Final Policies

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 Pub. L. 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.

ASC payment rates are calculated by multiplying the ASC conversion factor

by the ASC relative payment weight. As discussed fully in section XIV. of this final rule with comment period, we set the CY 2013 ASC relative payment weights by scaling the CY 2013 OPPS relative payment weights by the ASC scaler of 0.9324. The estimated effects of the updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 58 and 59 below.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system (which currently is the CPI–U) after application of any quality reporting reduction be reduced by a 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). Because the ASCQR Program will not affect payment rates until CY 2014, there will be no reduction to the CPI–U for failure to meet the requirements of the ASCQR Program for CY 2013. We calculated the CY 2013 ASC conversion factor by adjusting the CY 2012 ASC conversion factor by 1.0008 to account for changes in the pre-floor and pre-reclassified hospital wage indices between CY 2012 and CY 2013 and by applying the CY 2013 MFP-adjusted CPI–U update factor of 0.6 percent (projected CPI–U update of 1.4 percent minus a projected productivity adjustment of 0.8 percent). The CY 2013 ASC conversion factor is $42.917.

(1) Limitations of Our Analysis

Presented here are the projected effects of the changes for CY 2013 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2011 and CY 2013 with precision. We believe that the net effect on Medicare expenditures resulting from the CY 2013 changes would 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 would experience changes in payment that differ from the aggregated estimated impacts presented below.

(2) Estimated Effects of ASC Payment System Final Policies on 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 2013 payments would 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 2013 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services as reflected in our CY 2011 claims data. Table 58 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2012 payments to estimated CY 2013 payments, and Table 59 shows a comparison of estimated CY 2012 payments to estimated CY 2013 payments for procedures that we estimate would receive the most Medicare payment in CY 2012.

Table 58 shows the estimated effects on aggregate Medicare payments under the 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 58.

- Column 1—Surgical Specialty or Ancillary Items and Services Group indicates the surgical specialty into which ASC procedures are grouped and 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 2012 ASC Payments were calculated using CY 2011 ASC utilization (the most recent full year of ASC utilization) and CY 2012 ASC payment rates. The surgical specialty and ancillary items and services groups are displayed in descending order based on estimated CY 2012 ASC payments.
- Column 3—Estimated CY 2013 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 would be attributable to updates to ASC payment rates for CY 2013 compared to CY 2012.

As seen in Table 58, we estimate that the update to ASC rates for CY 2013 would result in a zero percent change in aggregate payment amounts for eye and ocular adnexa procedures, a 2-percent increase in aggregate payment amounts for digestive system procedures, and a 3-percent increase 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 2013 update are variable. For instance, we estimate that, in the aggregate, payment for integumentary system procedures, respiratory system procedures, and cardiovascular systems procedures would decrease by 3 percent, whereas auditory system procedures would increase by 1 percent under the CY 2013 rates.

An estimated increase in aggregate payment for the specialty group does not mean that all procedures in the group would experience increased payment rates. For example, the estimated increase for CY 2013 for nervous system procedures is likely due to an increase in the ASC payment weight for some of the high volume procedures, such as CPT code 63685 (Insrt/redo spine n generator) where estimated payment would increase by 8 percent for CY 2013.

Also displayed in Table 58 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. We estimate that aggregate payments for these items and services would remain unchanged for CY 2013.

TABLE 58.—ESTIMATED IMPACT OF THE FINAL CY 2013 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2013 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical Specialty Group (1)	Estimated CY 2012 ASC Payments (in Millions) (2)	Estimated CY 2013 Percent Change (3)
Total	$3,480	1%
Eye and ocular adnexa	$1,453	0%
Digestive system	$719	2%
Nervous system	$471	3%
Musculoskeletal system	$433	-2%
Genitourinary system	$160	0%
Integumentary system	$131	-3%
Respiratory system	$45	-3%
Cardiovascular system	$31	-3%
Ancillary items and services	$21	0%
Auditory system	$11	1%
Hematologic & lymphatic systems	$5	0%

Table 59 below shows the estimated impact of the updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2013. The table displays 30 of the procedures receiving the greatest estimated CY 2012 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2012 program payment.

- Column 1–CPT/HCPCS code.
- Column 2–Short Descriptor of the HCPCS code.
- Column 3–Estimated CY 2012 ASC Payments were calculated using CY 2011 ASC utilization (the most recent full year of ASC utilization) and the CY 2012 ASC payment rates. The estimated CY 2012 payments are expressed in millions of dollars.
- Column 4–Estimated CY 2013 Percent Change reflects the percent differences between the estimated ASC payment for CY 2012 and the estimated payment for CY 2013 based on the update.

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TABLE 59.--ESTIMATED IMPACT OF THE FINAL CY 2013 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS Code* (1)	Short Descriptor (2)	Estimated CY 2012 ASC Payments (in millions) (3)	Estimated CY 2013 Percent Change (4)
66984	Cataract surg w/iol, 1 stage	$1,079	1%
43239	Upper GI endoscopy, biopsy	$157	2%
45380	Colonoscopy and biopsy	$144	2%
45385	Lesion removal colonoscopy	$92	2%
45378	Diagnostic colonoscopy	$89	2%
66982	Cataract surgery, complex	$83	1%
64483	Inj foramen epidural l/s	$73	5%
62311	Inject spine l/s (cd)	$68	5%
66821	After cataract laser surgery	$55	5%
63650	Implant neuroelectrodes	$40	-2%
15823	Revision of upper eyelid	$39	-2%
G0105	Colorectal scrn; hi risk ind	$38	2%
64493	Inj paravert f jnt l/s 1 lev	$36	5%
29827	Arthroscop rotator cuff repr	$36	-6%
64721	Carpal tunnel surgery	$31	-1%
G0121	Colon ca scrn not hi rsk ind	$30	2%
29881	Knee arthroscopy/surgery	$30	-1%
63685	Insrt/redo spine n generator	$28	8%
64590	Insrt/redo pn/gastr stimul	$25	8%
29880	Knee arthroscopy/surgery	$25	-1%
45384	Lesion remove colonoscopy	$23	2%
43235	Uppr gi endoscopy diagnosis	$23	2%
52000	Cystoscopy	$20	4%
28285	Repair of hammertoe	$19	-1%
62310	Inject spine c/t	$18	5%
26055	Incise finger tendon sheath	$17	-4%
67042	Vit for macular hole	$17	-1%
29826	Shoulder arthroscopy/surgery	$17	-1%
67904	Repair eyelid defect	$17	-3%
50590	Fragmenting of kidney stone	$17	-4%

*Note that HCPCS codes we are deleting for CY 2013 are not displayed in this table.

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(3) Estimated Effects of ASC Payment System Final Policies on Beneficiaries

We estimate that the CY 2013 update to the ASC payment system would 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 2013. 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 ASC payment system are lower than payment rates for the same procedures under the OPPS. Therefore, the beneficiary coinsurance amount under the ASC payment system will almost always 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 2013, 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 (except for certain preventive services where the coinsurance is waived in both settings).

(4) Alternative ASC Payment Policies Considered

Alternatives to the changes we are making to the ASC payment system 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 the Annual Update to ASC Payments for Inflation

Section 1833(i)(2)(C)(i) of the Act requires that, ''if the Secretary has not updated amounts established'' under the revised ASC payment system 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.'' The statute, therefore, does not mandate the adoption of any particular update mechanism, but it requires the payment amounts to be increased by the CPI–U in the absence of any update. Because the Secretary updates the ASC payment amounts annually under the revised payment system, we are not compelled to increase the ASC payment amounts by the CPI–U. Nonetheless, 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. While we believe the CPI–U is appropriate to apply to update the ASC payment system, we are aware that the CPI–U is highly weighted for housing and transportation and may not best reflect inflation in the cost of providing ASC services. Therefore, as alternatives to using the CPI–U to update ASC payment rates for inflation, in developing this final rule with comment period, we considered using: (1) the hospital market basket, which is used to update OPPS rates for inflation; (2) the PE component of the MEI update, which is used to update the MPFS payment rates for inflation; or (3) the average of the hospital market basket update and the PE component of the MEI update.

However, until we have more information regarding the cost inputs of ASCs, we are not confident that any of the alternatives are a better proxy for ASC cost inputs than the CPI–U. Therefore, we proposed and are finalizing our established policy to continue to base the ASC update on the CPI–U.

• Alternatives Considered for Office-Based Procedures

According to our existing policy for the 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/or, 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 ASC payment system.

In developing this final rule with comment period, we reviewed CY 2011 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 2012 OPPS/ASC final rule with comment period (76 FR 74406 through 74408). Based on that review and as discussed in section XIV.C.1.b. of this final rule with comment period, we are newly designating 6 surgical procedures as permanently office-based, are making temporary office-based designations for 6 procedures in CY 2013 of the 8 procedures that were designated as temporarily office-based for CY 2012, and are making temporary office-based designations for 2 procedures that are new ASC covered surgical procedures for CY 2013. 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 6 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 ASC payment system. We did not select this alternative because our analysis of the data and our clinical review indicated that all 6 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 6 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 selected for CY 2013 is to designate 6 additional procedures as permanently office-based for CY 2013 and to designate 8 procedures as temporarily office-based in CY 2013. We chose this alternative because our claims data and clinical review indicate that these procedures would be considered to be predominantly performed in physicians' offices. We believe that designating these procedures as office-based, which results in the CY 2013 ASC payment rate for these procedures potentially being capped at the CY 2013 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. Effects of the Revisions to the QIO Regulations

In section XVIII. of this final rule with comment period, we discuss our changes to the QIO program regulations, including: adding provisions for processing beneficiary complaints that will give beneficiaries more information about the QIO's review process, which includes a new alternative dispute resolution option (immediate advocacy); giving QIOs the authority to send and receive secure transmissions of electronic versions of health information; conveying beneficiaries the right to authorize the QIOs' use and disclosure of confidential information; and removing outdated regulatory provisions that will enable QIOs to give more information regarding the results of reviews. We believe the changes will improve the QIO program, give beneficiaries better information regarding review activities and reduce burden for both providers and practitioners.

The QIO program requests approximately 62,400 medical records each year for the Hospital IQR and Hospital OQR Programs combined (38,400 for inpatient and 24,000 for outpatient). For the Hospital IQR Program, the average number of pages per medical record is 289 pages, and for the Hospital OQR Program, the average number of pages is 74. Reimbursement is made at a rate of $0.12 per page for PPS hospitals, which includes the costs of toner, paper, and labor associated with the copying of paper medical records. We also note that the labor associated with copying the medical records can be considerable. In fact, many providers and practitioners store health information electronically, and these same providers and practitioners are forced to print hard copies of the information for shipment to the QIOs. Sometimes this may entail using the ''print screen'' function to create the record to be shipped. On average, the cost of shipping the records is approximately $32.35 per shipment, with approximately 5,200 shipments being made. The shipping amount takes into consideration that, for some QIO review activities, multiple records are shipped at one time, which can involve the use of several boxes.

Under our proposal, by example, assuming all hospitals operate under a PPS, should all hospitals transfer health information on a digital versatile device (DVD), the costs associated with the toner and paper would be replaced by the costs of a DVD. In fact, numerous medical records could be copied to a single DVD. Moreover, the labor in copying the records would be substantially reduced because, for example, rather than copying the average 289 pages related to a Hospital IQR Program review, the file could be electronically transferred to a DVD for shipping. We estimate that the $0.12 per page rate could be reduced by as much as $0.07 per page. Based on the overall average number of pages for the Hospital IQR Program and Hospital OQR Program, respectively, reducing the per page rate to $0.05 per page would save $901,152 ((11,097,600 pages × $0.12 = $1,331,712) + (1,776,000 pages × $0.12 = $213,120) − (11,097,600 pages × $0.05 = $554,880) − (1,776,000 pages × $0.05 = $88,800)).

The changes also would reduce the costs associated with mailing the records. For the Hospital IQR Program, hospitals sometimes need to ship as many as four or five large boxes of medical records. By comparison, a single DVD can house multiple medical records and even if multiple DVDs were required, all the DVDs could be mailed in a single envelope at a significantly lower cost. Potentially, the per envelope mailing cost could be as low as $5 compared to the per shipment average cost of $32.35. Thus, if all records were shipped on DVDs, the program would save $142,220 ($168,220 − $26,000).

The changes allowing the sending and receiving of electronic versions of health information also would reduce costs for other QIO review activities. QIOs request approximately 100,000 medical records in completing other review activities, including but not limited to requests related to the processing of general quality of care reviews, written beneficiary complaint reviews, medical necessity reviews, and expedited discharge appeal reviews. The average number of pages associated with each of these reviews varies greatly, and we have estimated an overall average of approximately 175 pages per request. The reimbursement rate for requests associated with these activities is $0.12 per page for PPS providers and $0.15 per page for practitioners and non-PPS providers. Assuming an overall average number of 175 pages for each record, we estimate that the total number of pages requested is approximately 17,500,000. Assuming that approximately 75 percent (13,125,000) of the pages are from practitioners and non-PPS providers, with the remaining 25 percent (4,375,000) from PPS providers, based on the $0.12 or $0.15 per page reimbursement rate, we estimate that the total costs would be approximately $1,968,750 and $525,000, respectively. If all these requests were fulfilled using a DVD or other electronic means, we estimate that the cost per page could be reduced to approximately $0.05 per page for PPS providers and $0.06 per page for practitioners and non-PPS providers. Thus, the estimated savings related to PPS providers would be approximately $306,250 ($525,000 − $218,750) and the estimated savings related to practitioners and non-PPS providers would be approximately $1,181,250 ($1,968,750 − $787,500).

With regard to mailing, we also believe the changes would significantly reduce the costs for other QIO review activities. Moreover, unlike the Hospital IQR and Hospital OQR Programs, the number of medical records requested for these other QIO review activities more closely mirrors the actual number of shipments made. For example, on average, the QIOs request 100,000 medical records related to these other activities, and we estimate that this equates to approximately 82,000 shipments. We estimate that there is a corresponding decrease in the cost per shipment ($7 per shipment compared to $32.35 per shipment for the Hospital IQR and OQR Programs). If DVDs were used instead of paper copies of the medical records, we estimate saving of $164,000 (82,000 × $7 − 82,000 × $5).

Beginning with the QIOs' most recent scope of work, which began August 1, 2011, QIOs began offering immediate advocacy to Medicare beneficiaries for the resolution of certain types of oral complaints. We believe that cost savings will be realized as a result. In developing this new process, we had

several goals. One of these goals was to create a way for Medicare beneficiaries to obtain resolutions of complaints much faster than the traditional peer review process, which usually take over 158 days to complete because, inevitably, various timeframes throughout the review process are not met (for example, providers and practitioners sometimes take more time that allowed to respond to medical record requests or the opportunity for discussion). By comparison, we believe that immediate advocacy normally can be completed within 2 calendar days. However, this process could result in reductions of more than merely a reduction in days. Because immediate advocacy is completed without reviewing a beneficiary's medical record, QIOs would save the costs associated with requesting the records, which includes the labor, supplies (toner and paper), and mailing of the records. Moreover, although there may be some variation among QIOs, immediate advocacy would typically be carried out by a nurse or social worker, and, thus, the QIO can avoid the more expensive costs associated with the use of a physician reviewer.

In addition, for a traditional complaint review, the QIO's peer reviewer completes three separate and distinct reviews (the interim initial determination, the final initial determination, and the reconsideration determination), each time reviewing the medical information and providing his/her conclusion about the quality of care provided. Moreover, the provider and/or practitioner who is the subject of the complaint will be brought into the complaint process each time to respond to the conclusions. With immediate advocacy, the nurse or social work would be involved once, early in the process, with the primary role being to listen to the beneficiary's concerns and then coordinate a resolution with the provider or practitioner, instead of merely reviewing information contained in the beneficiary's medical information. Not only would this process enable beneficiaries to obtain resolution of complaints quicker, but it would decrease the amount of time and energy practitioners and providers would devote to responding to the complaints. This is especially true for certain types of complaints where the issues involved are not even documented in the medical information the physician reviewers would review in the traditional complaint process. Typically, we have estimated a total cost per case of $960 for each case processed using the traditional peer review process. We estimate that, for those instances where immediate advocacy is used, the average cost per case would be approximately $87. On average, QIOs complete approximately 3,500 complaint reviews each year, and we estimate that approximately 10 percent of these reviews (350) would be resolved using immediate advocacy instead of the traditional peer review process. This would result in savings of $305,550 each year (($960 × 350 = $336,000) − ($87 × 350 = $30,450)).

Comment: One commenter stated that the estimate of $87 for immediate advocacy ''seems unreasonably low for the actual staff time involved in these cases.''

Response: We appreciate the comment. However, our ability to evaluate the substance of the comment is limited because the commenter did not give any specific information regarding why the commenter believes the estimated amount is unreasonably low. In identifying the estimated amount, we considered the significantly reduced time frame within which these cases are resolved, the fact that the types of complaints are less severe than what can be handled through the traditional complaint process, and the fact that QIOs will be able to use review analysts in completing these reviews compared to other more costly peer reviewers used as many as three times as part of the traditional complaint review process. While we recognize that the time needed to achieve an actual resolution may be longer, we estimated that, on average, the actual amount of time spent working on these cases to be approximately 70 minutes, and using an hourly rate of approximately $43.17 and adding in other costs, such as leave and other indirect costs, we believe $87 is appropriate. In light of the above, we see no need to adjust the estimated cost.

The technical changes to the QIO regulations under section XVIII.F. of this final rule with comment period that we are making to improve the regulations reflect CMS' commitment to the principles of the President's Executive Order on Regulatory Reform, Executive Order 13563 (January 18, 2011).

Below is a table summarizing the savings associated with both of these provisions.

Provision	Savings per Year
Authority to transmit information electronically	$2,388,622 total per year
Quality Reporting Information (Copying)	$901,152
Quality Reporting Information (Mailing)	$142,220
Other QIO Activities (Copying)	$1,487,500
Other QIO Activities (Mailing)	$164,000
Immediate Advocacy	$305,550 total per year
Total Savings	**$3,000,422 per year**

d. Accounting Statements and Tables

As required by OMB Circular A–4 (available on the Office of Management and Budget Web Site at: *http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/a-4.pdf*, we have prepared three accounting statements to illustrate the impacts of this final rule with comment period. The first accounting statement, Table 60 below, illustrates the classification of expenditures for the CY 2013 estimated hospital OPPS incurred benefit impacts associated with the CY

2013 OPD fee schedule increase, based on the FY 2013 President's Budget. The second accounting statement, Table 61 below, illustrates the classification of expenditures associated with the 0.6 percent CY 2013 update to the ASC payment system, based on the provisions of this final rule with comment period and the baseline spending estimates for ASCs in the FY 2013 President's Budget. The third accounting statement, Table 62 below, illustrates the estimated impact based on the provisions allowing QIOs to securely send and receive electronic versions of health information as well as the use of alternative dispute resolution process called immediate advocacy. Lastly, the three tables classify most estimated impacts as transfers.

TABLE 60.--ACCOUNTING STATEMENT: CY 2013 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2012 TO CY 2013 ASSOCIATED WITH THE CY 2013 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 61.--ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2012 TO CY 2013 AS A RESULT OF THE FINAL CY 2013 UPDATE TO THE REVISED ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	$18 million
From Whom to Whom	Federal Government to Medicare Providers and Suppliers
Total	$18 million

TABLE 62.--ACCOUNTING STATEMENT: CY 2013 ESTIMATED SAVINGS TO MEDICARE FROM THE REVISIONS OF THE QIO REGULATIONS

Category	Transfers
Annualized Monetized Transfers	-$3.0 million
From whom to Whom	Federal Government to Medicare Providers
Total	-$3.0 million

e. Effects of Requirements for the Hospital 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), section XVI. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 72064 through 72110), and section XVI. of the CY 2012 OPPS/ASC final rule with comment period (76 FR 74451 through 74492), we discussed the 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 CYs 2012 through 2014, respectively. In section XV. of this final rule with comment period, we adopted additional policies affecting the Hospital OQR Program.

We determined that 114 hospitals did not meet the requirements to receive the full OPD fee schedule increase factor for CY 2012. Most of these hospitals (106 of the 114) received little or no OPPS payment on an annual basis and did not participate in the Hospital OQR Program. We estimate that 106 hospitals may not receive the full OPD fee schedule increase factor in CY 2014. 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 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 the CY 2012 OPPS/ASC final rule with comment period, we finalized 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 CY 2011, CY 2012, and 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.

In this final rule with comment period, for CY 2014 and subsequent years payment determinations, we are making some modifications to administrative requirements in extending a deadline to submit a Notice of Participation as well as to extraordinary circumstance waiver or extension and reconsideration processes to broaden the scope of personnel who can sign these requests. However, we are not making any modifications to our validation requirements. We expect these policies to have minimal impact on the program.

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 2015. We also are unable to estimate the number of hospitals that would fail the validation documentation submission requirement for the CY 2015 payment update.

The validation requirements for CY 2014 would result in medical record documentation for approximately 6,000 cases per quarter for CY 2014, 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 CY 2014, we estimate that we will have expenditures of approximately $13,200 per quarter for CY 2014. Because we will pay for the data collection effort, we believe that a requirement for medical record documentation for 7,300 total cases for up to 500 hospitals for CY 2014 represents a minimal burden to Hospital OQR Program participating hospitals.

We are maintaining a 45-day timeframe for hospitals to submit requested medical record documentation to meet our validation requirement. 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.

f. Effects of the EHR Electronic Reporting Pilot

Under section XV.K. of this final rule with comment period, we are allowing eligible hospitals and CAHs that are participating in the EHR Incentive Program to meet the CQM reporting requirement of the program in FY 2013 by participating in the Medicare EHR Incentive Program Electronic Reporting Pilot. This will facilitate the use of an electronic infrastructure that supports the use of EHRs by eligible hospitals and CAHs to meet the requirements in various CMS programs and reduce reporting burden simultaneously. Through this pilot, we have encouraged 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 to send, and for CMS, in the future, to receive, quality measures via hospital EHRs for the Hospital IQR Program's measures. Hospitals that choose to participate in the EHR Incentive Program by means of this pilot for the purpose of meeting the CQM reporting requirement of meaningful use will be taking those first steps toward reporting clinical quality data in such a way.

There are no changes to the costs or impact in the 2012 OPPS/ASC final rule for the 2013 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs.

g. Effects of Proposals for the ASCQR Program

In section XVI. of this final rule with comment period, for the ASCQR Program, we discuss public comment on our approach for future measures selection and development as well as on certain measures for potential future inclusion in the ASCQR Program measure set. We are finalizing our approach to future measure selection and development for the ASCQR Program. For the CY 2015 payment determination and subsequent calendar year payment determinations, we are adopting requirements for claims-based measures regarding the dates for submission and payment and data completeness. We also are finalizing our policy regarding how the payment rates will be reduced in CY 2014 and in subsequent calendar years for ASCs that fail to meet program requirements, and we are clarifying our policy on updating measures.

We are unable at this time to estimate the number of ASCs that may not receive the full ASC annual payment update in CYs 2014, 2015, and 2016. However, we do not expect our new policies to significantly affect the number of ASCs that do not receive a full annual payment update.

h. Effects of Updates to the IRF QRP

In section XVII. of this final rule with comment period, we discuss our policy that, once we initially adopt a measure for the IRF QRP for a payment determination, that measure will be automatically adopted for all subsequent fiscal years' payment determinations or until such time as we might propose and finalize the measure's removal, suspension, or replacement.

We also discuss how we will use the CAUTI measure previously finalized. We will use the CAUTI measure that was previously finalized in the FY 2012 IRF PPS final rule (76 FR 24214) with revisions which were made by the NQF after publication of the FY 2012 IRF PPS final rule. We will apply the revised

CAUTI measure for the FY 2014 reporting period, which affects the FY 2012 APU, and each subsequent reporting period thereafter. We also are finalizing the use of a nonrisk-adjusted version of the NQF-endorsed pressure ulcer measure, which does not include public reporting of any nonrisk-adjusted pressure ulcer measure data.

There are no changes to the costs or impact as stated in FY 2012 IRF PPS final rule (76 FR 24214). IRFs will be required to submit CAUTI data on all patients that are admitted to their facility and pressure ulcer data only on those patients for which they are required to submit the IRF–PAI. This policy has not changed. Further, we do not expect our new policies to significantly affect the number of IRFs that do not receive a full annual payment update.

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. We estimate that this final rule with comment period may have a significant impact on approximately 2,053 hospitals with voluntary ownership. 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 Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. We estimate that this final rule with comment period may have a significant impact on approximately 708 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 $139 million. This final rule with comment period does not mandate any requirements for State, local, or tribal governments, or for the private sector.

D. Conclusion

The changes we are making in this final rule with comment period 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 2013. Table 57 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 2013, 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, 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 more significant gains and others will experience modest losses in OPPS payments in CY 2013. We estimate that hospitals for whom DSH data are not available (non-IPPS, largely urban hospitals) will experience an increase of 8.3 percent due to increased payments for partial hospitalization, group psychotherapy and hemodialysis services. CMHCs will see an overall decrease in payment of 4.4 percent as a result of a decrease in their estimated costs.

The updates to the ASC payment system for CY 2013 will affect each of the approximately 5,300 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 who are Medicare beneficiaries, the degree to which the payments for the procedures offered by the ASC are changed under the ASC payment system, and the extent to which the ASC provides a different set of procedures in the coming year. Table 58 demonstrates the estimated distributional impact among ASC surgical specialties of the MFP-adjusted CPI–U update factor of 0.6 percent for CY 2013.

XXIII. 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 57 of this final rule with comment period, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) will increase by 1.9 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. The analyses we have provided in this section of this final rule with comment period, in conjunction with the remainder of this document, demonstrate 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 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 476

Health care, Health professional, Health record, Peer Review Organization (PRO), Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 478

Administrative practice and procedure, Health care, Health

professions, Peer Review Organizations (PRO), Reporting and recordkeeping requirements.

42 CFR Part 480

Health care, Health professions, Health records, Peer Review Organizations (PRO), Privacy, 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 416—AMBULATORY SURGICAL SERVICES

■ 1. 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 and 1395hh).

■ 2. Section 416.160 is amended by revising paragraph (a)(1) to read as follows:

§ 416.160 Basis and scope.

(a) * * *

(1) Section 1833(i)(2)(D) of the Act requires the Secretary to implement a revised payment system for payment of surgical services furnished in ASCs. The statute requires that, in the year such system is implemented, the system shall be designed to result in the same amount of aggregate expenditures for such services as would be made if there was no requirement for a revised payment system. The revised payment system shall be implemented no earlier than January 1, 2006, and no later than January 1, 2008. The statute provides that the Secretary may implement a reduction in any annual update for failure to report on quality measures as specified by the Secretary. The statute also requires that, for CY 2011 and each subsequent year, any annual update to the ASC payment system, after application of any reduction in the annual update for failure to report on quality measures as specified by the Secretary, be reduced by a productivity adjustment. There shall be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the classification system, the relative weights, payment amounts, and the geographic adjustment factor, if any, of the revised payment system.

* * * * *

■ 3. Section 416.171 is amended by—

■ a. Redesignating paragraph (a)(2)(iii) as paragraph (a)(2)(iv) and revising it.

■ b. Adding new paragraph (a)(2)(iii).

The revision and addition read as follows:

§ 416.171 Determination of payment rates for ASC services.

(a) * * *

(2) * * *

(iii) For CY 2014 and subsequent calendar years, the Consumer Price Index for All Urban Consumers update determined under paragraph (a)(2)(ii) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(iv) *Productivity adjustment.* (A) For calendar year 2011 and subsequent years, the Consumer Price Index for All Urban Consumers determined under paragraph (a)(2)(ii) of this section, after application of any reduction under paragraph (a)(2)(iii) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(B) The application of the provisions of paragraph (a)(2)(iv)(A) of this section may result in the update being less than zero percent for a year, and may result in payment rates for a year being less than the payment rates for the preceding year.

* * * * *

■ 4. Section 416.195 is amended by revising paragraphs (a)(2) and (a)(4) introductory text to read as follows:

§ 416.195 Determination of membership in new classes of new technology IOLs.

(a) * * *

(2) The IOL shall have a new lens characteristic in comparison to currently available IOLs. The labeling, which must be approved by FDA, shall contain a claim of a specific clinical benefit imparted by the new lens characteristic.

* * * * *

(4) Any specific clinical benefit referred to in paragraph (a)(2) of this section must be supported by evidence that demonstrates that the IOL results in a measurable, clinically meaningful, improved outcome. Improved outcomes include:

* * * * *

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 5. 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).

■ 6. Section 419.2 is amended by revising paragraph (b) introductory text to read as follows:

§ 419.2 Basis of payment.

* * * * *

(b) *Determination of hospital outpatient prospective payment rates: Packaged costs.* The prospective payment system establishes a national payment rate, standardized for geographic wage differences, 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. In general, these costs include, but are not limited to, the following items and services, the payments for which are packaged into the payments for the related procedures or services.

* * * * *

■ 7. Section 419.31 is amended by revising paragraphs (a)(1), (b), and (c)(2) to read as follows:

§ 419.31 Ambulatory payment classification (APC) system and payment weights.

(a) * * *

(1) CMS classifies outpatient services and procedures that are comparable clinically and in terms of resource use into APC groups. Except as specified in paragraph (a)(2) of this section, items and services within a group are not comparable with respect to the use of resources if the highest geometric mean cost for an item or service within the group is more than 2 times greater than the lowest geometric mean cost for an item or service within the group.

* * * * *

(b) *APC weighting factors.* (1) Using hospital outpatient claims data from calendar year 1996 and data from the most recent available hospital cost reports, CMS determines the geometric mean costs for the services and procedures within each APC group.

(2) CMS assigns to each APC group an appropriate weighting factor to reflect the relative geometric mean costs for the services within the APC group compared to the geometric mean costs for the services in all APC groups.

(c) * * *

(2) CMS standardizes the geometric mean costs determined in paragraph

(b)(1) of this section by adjusting for variations in hospital labor costs across geographic areas.

■ 8. Section 419.32 is amended by revising paragraph (b)(1)(iv)(A) and adding paragraph (b)(1)(iv)(B)(*4*) to 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 OPD fee schedule increase factor, which, subject to the adjustments specified in paragraph (b)(1)(iv)(B) of this section, is the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act.

(B) * * *

(*4*) For calendar year 2013, a multifactor productivity adjustment (as determined by CMS) and 0.1 percentage point.

* * * * *

■ 9. Section 419.70 is amended by revising paragraph (d)(2) introductory text and adding paragraph (d)(7) to 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, 2012, 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, 2011, and 2012 if the hospital—

* * * * *

(7) *Temporary treatment of small sole community hospitals on or after January 1, 2012 through December 31, 2012.* (i) For covered hospital outpatient services furnished on or after January 1, 2012 through December 31, 2012, 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—

(A) 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; and

(B) Has 100 or fewer beds as defined in § 412.105(b) of this chapter, except as provided in paragraph (d)(7)(ii) of this section.

(ii) For covered hospital outpatient services furnished on or after January 1, 2012 through February 29, 2012, the bed size limitation under paragraph (d)(7)(i)(B) of this section does not apply.

* * * * *

PART 476—UTILIZATION AND QUALITY CONTROL REVIEW

■ 10. The authority for Part 476 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 11. Section 476.1 is amended by—

■ a. Removing the definition of ''Active staff privileges''.

■ b. Adding definitions of ''Appointed representative'', ''Authorized representative'', ''Beneficiary complaint'', ''Beneficiary complaint review'', ''Beneficiary representative'', ''General quality of care reviews'', ''Gross and flagrant violation'', ''Immediate advocacy'', ''Quality improvement initiative'', ''Quality of care concern'', ''Quality of care review'', ''Significant quality of care concern'', and ''Substantial violation in a substantial number of cases''.

■ c. Revising the definition of ''Preadmission certification''.

The additions and revisions read as follows:

§ 476.1 Definitions.

* * * * *

Appointed representative means an individual appointed by a Medicare beneficiary to represent the beneficiary in the beneficiary complaint review process.

Authorized representative means an individual authorized, under State or other applicable law, to act on behalf of a Medicare beneficiary. An authorized representative has all of the rights and responsibilities of a Medicare beneficiary throughout the processing of a beneficiary complaint.

Beneficiary complaint means a complaint by a Medicare beneficiary or a Medicare beneficiary's representative alleging that the quality of Medicare covered services received by the beneficiary did not meet professionally recognized standards of care. A complaint may consist of one or more quality of care concerns.

Beneficiary complaint review means a review conducted by a QIO in response to the receipt of a written beneficiary complaint to determine whether the quality of Medicare covered services provided to the beneficiary was consistent with professionally recognized standards of health care.

Beneficiary representative means an individual identified as an authorized or appointed representative of a Medicare beneficiary.

* * * * *

General quality of care review means a review conducted by a QIO to determine whether the quality of Medicare covered services provided to a Medicare beneficiary was consistent with professionally recognized standards of health care. A general quality of care review may be carried out as a result of a referral to the QIO or a QIO's identification of a potential concern during the course of another review activity or through the analysis of data.

Gross and flagrant violation means a violation of an obligation resulting from inappropriate or unnecessary services, services that do not meet recognized professional standards of care, or services that are not supported by evidence of medical necessity or quality as required by the QIO. The violation must have occurred in one or more instances that present an imminent danger to the health, safety, or well-being of a program patient or places the program patient unnecessarily in high-risk situations.

* * * * *

Immediate advocacy means an informal alternative dispute resolution process used to quickly resolve an oral complaint a Medicare beneficiary or his or her representation has regarding the quality of Medicare covered health care received. This process involves a QIO representative's direct contact with the provider and/or practitioner.

* * * * *

Preadmission certification means a favorable determination, transmitted to the hospital and the fiscal intermediary or the Medicare administrative contractor, approving the patient's admission for payment purposes.

* * * * *

Quality improvement initiative means any formal activity designed to serve as a catalyst and support for quality improvement that uses proven methodologies to achieve these improvements. The improvements may relate to safety, health care, health and value and involve providers, practitioners, beneficiaries, and/or communities.

Quality of care concern means a concern that care provided did not meet

a professionally recognized standard of health care. A general quality of care review or a beneficiary complaint review may cover a single or multiple concerns.

Quality of care review means a review conducted by a QIO to determine whether the quality of Medicare covered services provided to beneficiaries was consistent with professionally recognized standards of health care. A quality of care review can either be a beneficiary complaint review or a general quality of care review.

* * * * *

Significant quality of care concern means a determination by the QIO that the quality of care provided to a Medicare beneficiary did not meet the standard of care and, while not a gross and flagrant or substantial violation of the standard, represents a noticeable departure from the standard that could reasonably be expected to have a negative impact on the health of a beneficiary.

Substantial violation in a substantial number of cases means a pattern of providing care that is inappropriate, unnecessary, or does not meet recognized professional standards of care, or is not supported by the necessary documentation of care as required by the QIO.

* * * * *

■ 12. Section 476.70 is revised to read as follows:

§ 476.70 Statutory bases and applicability.

(a) *Statutory bases.* Sections 1154, 1866(a)(1)(F), and 1886(f)(2) of the Act require that a QIO review those services furnished by physicians, other health care professionals, providers and suppliers as specified in its contract with the Secretary.

(b) *Applicability.* The regulations in this subpart apply to review conducted by a QIO and its subcontractors.

■ 13. Section 476.71 is amended by—

■ a. Revising paragraph (a)(2).

■ b. In paragraph (b), removing the reference ''§ 405.330(b)'' and adding in its place the reference ''§ 411.400(b) of this chapter''.

■ c. Revising paragraph (c)(1).

The revisions read as follows:

§ 476.71 QIO review requirements.

(a) * * *

(2) Whether the quality of the services meets professionally recognized standards of health care, as determined through the resolution of oral beneficiary complaints as specified in § 476.110, written beneficiary complaints as specified in § 476.120, or the completion of general quality of care reviews as specified in § 476.160.

* * * * *

(c) * * *

(1) The QIO must review at least a random sample of hospital discharges each quarter and submit new diagnostic and procedural information to the Medicare administrative contractor, fiscal intermediary, or carrier if it determines that the information submitted by the hospital was incorrect.

* * * * *

§ 476.72 [Removed]

■ 14. Section 476.72 is removed.

§ 476.73 [Amended]

■ 15. In § 476.73—

■ a. In paragraph (a), first sentence, the phrase ''and Medicare fiscal intermediaries and carriers.'' is removed and the phrase ''Medicare administrative contractors, fiscal intermediaries, and carriers.'' is added in its place.

■ b. In paragraph (b)(1), the reference ''§ 466.78(b)(3)'' is removed and the reference ''§ 476.78(b)(3)'' is added in its place.

§ 476.74 [Amended]

■ 16. In § 476.74—

■ a. In paragraph (b), the phrase ''appropriate Medicare fiscal intermediary or carrier'' is removed and the phrase ''appropriate Medicare administrative contractor, fiscal intermediary, or carrier'' is added in its place.

■ b. In paragraph (c)(1), the phrase ''Medicare fiscal intermediaries and carriers'' is removed, and the phrase ''Medicare administrative contractors, fiscal intermediaries, and carriers'' is added in its place.

■ c. In paragraph (e), the reference ''§ 405.332'' is removed and the reference ''§ 411.402'' is added in its place.

■ 17. Section 476.78 is amended by—

■ a. Revising the section heading.

■ b. Revising paragraphs (b)(2)(i) and (ii).

The revisions read as follows:

§ 476.78 Responsibilities of providers and practitioners.

* * * * *

(b) * * *

(2) * * *

(i) Except as provided under §§ 476.130(b) and 476.160(b), relating to beneficiary complaint reviews and general quality of care reviews, photocopy and deliver to the QIO all required information within 14 calendar days of a request. A QIO is authorized to require the receipt of the medical information earlier than the 14-day timeframe if the QIO makes a preliminary determination that the review involves a potential gross and flagrant or substantial violation as specified in Part 1004 of this title and circumstances warrant earlier receipt of the medical information. A practitioner's or provider's failure to comply with the request for medical information within the established timeframe may result in the QIO taking action in accordance with § 476.90.

(ii) Send secure transmission of an electronic version of medical information, if available, subject to the QIO's ability to support receipt and transmission of the electronic version. Providers and practitioners must deliver electronic versions of medical information within 14 calendar days of the request. A QIO is authorized to require the receipt of the medical information earlier than the 14-day timeframe if the QIO makes a preliminary determination that the review involves a potential gross and flagrant or substantial violation as specified in Part 1004 of this title and circumstances warrant earlier receipt of the medical information. A practitioner's or provider's failure to comply with the request for medical information within the established timeframe may result in the QIO taking action in accordance with § 476.90.

* * * * *

§ 476.80 [Amended]

■ 18. In § 476.80—

■ a. In the section heading and paragraphs (b)(1) introductory text and (c)(1) (two places), the phrase ''Medicare fiscal intermediaries and carriers'' is removed and the phrase ''Medicare administrative contractors, fiscal intermediaries, and carries'' is added in its place.

■ b. In paragraph (a) introductory text, the phrase ''Medicare fiscal intermediary or carrier'' is removed and the phrase ''Medicare administrative contractor, fiscal intermediary, or carrier'' is added in its place.

■ c. In paragraphs (a)(1), (a)(2) introductory text (two places), (c)(3)(ii), (d)(1), and (d)(2), the phrase ''fiscal intermediary or carrier'' is removed and the phrase ''Medicare administrative contractor, fiscal intermediary, or carrier'' is added in its place.

■ d. In paragraph (e), in the paragraph heading and in paragraphs (e)(1) and (e)(2), the phrase ''fiscal intermediary'' is removed and the phrase ''Medicare administrative contractor or fiscal intermediary'' is added in its place.

§ 476.86 [Amended]

■ 19. In § 476.86—

■ a. In paragraph (a)(1)(iii), the reference ''§ 405.310(g) or § 405.310(k)'' is removed and the reference ''§ 411.15(g) or § 411.15(k)'' is added in its place.

■ b. In paragraph (a)(2) and (d), the phrase ''Medicare fiscal intermediaries and carriers'' is removed and the phrase ''Medicare administrative contractors, fiscal intermediaries, and carriers'' is added in its place.

■ c. In paragraph (c) introductory text, the phrase ''Medicare fiscal intermediary or carrier'' is removed and the phrase ''Medicare administrative contractor, fiscal intermediary, or carrier'' is added in its place.

■ d. In paragraph (c)(1), the phrase ''fiscal intermediary or carrier'' is removed and the phrase ''Medicare administrative contractor, fiscal intermediary, or carrier'' is added in its place.

■ e. In paragraph (e), the phrase ''intermediaries and carriers'' is removed and the phrase ''Medicare administrative contractors, fiscal intermediaries, and carriers'' is added in its place.

■ f. In paragraph (f), the reference ''part 473'' is removed and the reference ''part 478'' is added in its place.

§ 476.94 [Amended]

■ 20. In § 476.94—

■ a. In paragraph (a)(1)(iv), the phrase ''fiscal intermediary or carrier'' is removed and the phrase ''Medicare administrative contractor, fiscal intermediary, or carrier'' is added in its place.

■ b. In paragraph (d), the phrase ''Medicare fiscal intermediary or carrier'' is removed and the phrase ''Medicare administrative contractor, fiscal intermediary, or carrier'' is added in its place.

■ c. In paragraph (c)(3), the reference ''part 473'' is removed and the reference ''part 478'' is added in its place.

§ 476.98 [Amended]

■ 21. In § 476.98, in paragraph (a)(1), the phrase ''with active staff privileges in one or more hospitals'' is removed.

■ 22. Section 476.104 is amended by revising paragraph (a) to read as follows:

§ 476.104 Coordination of activities.

* * * * *

(a) Medicare administrative contractors, fiscal intermediaries, and carriers.

* * * * *

■ 23. Sections 476.110, 476.120, 476.130, 476.140, 476.150, 476.160, 476.170 are added to subpart C to read as follows:

Subpart C—Review Responsibilities of Utilization and Quality Control Quality Improvement Organizations (QIOs)

Sec.

* * * * *

476.110 Use of immediate advocacy to resolve oral beneficiary complaints.
476.120 Submission of written beneficiary complaints.
476.130 Beneficiary complaint review procedures.
476.140 Beneficiary complaint reconsideration procedures.
476.150 Abandoned complaints and reopening rights.
476.160 General quality of care review procedures.
476.170 General quality of care reconsideration procedures.

* * * * *

§ 476.110 Use of immediate advocacy to resolve oral beneficiary complaints.

(a) *Immediate advocacy.* A QIO may offer the option of resolving an oral complaint through the use of immediate advocacy if:

(1) The complaint is received not later than 6 months from the date on which the care giving rise to the complaint occurred.

(2) After initial screening of the complaint, the QIO makes a preliminary determination that—

(i) The complaint is unrelated to the clinical quality of health care itself but relates to items or services that accompany or are incidental to the medical care and are provided by a practitioner and/or provider; or

(ii) The complaint, while related to the clinical quality of health care received by the beneficiary, does not rise to the level of being a gross and flagrant, substantial, or significant quality of care concern.

(3) The beneficiary agrees to the disclosure of his or her name to the involved provider and/or practitioner.

(4) All parties orally consent to the use of immediate advocacy.

(5) All parties agree to the limitations on redisclosure set forth in § 480.107 of this subchapter.

(b) *Discontinuation of immediate advocacy.* The QIO or either party may discontinue participation in immediate advocacy at any time.

(1) The QIO must inform the parties that immediate advocacy will be discontinued; and

(2) The beneficiary must be informed of his or her right to submit a written complaint in accordance with the procedures in § 476.120.

(c) *Confidentiality requirements.* All communications, written and oral, exchanged during the immediate advocacy process must not be redisclosed without the written consent of all parties.

(d) *Abandoned complaints.* If any party fails to participate or otherwise comply with the requirements of the immediate advocacy process, the QIO may determine that the complaint has been abandoned and—

(1) Inform the parties that immediate advocacy will be discontinued; and

(2) Inform the Medicare beneficiary of his or her right to submit a written complaint in accordance with the procedures in § 476.120.

§ 476.120 Submission of written beneficiary complaints.

(a) *Timeframe for submission of written complaints.* A QIO shall be responsible for conducting a review of any written complaint received from a Medicare beneficiary or a Medicare beneficiary's representative about the quality of health care if the complaint is received not later than 3 years from the date on which the care giving rise to the complaint occurred.

(1) A written complaint includes a complaint submitted electronically to the QIO.

(2) In those instances where a Medicare beneficiary contacts the QIO regarding a complaint but declines to submit the complaint in writing and immediate advocacy has not been offered, the QIO may complete a general quality of care review in accordance with § 476.160 if the QIO makes a preliminary determination that the complaint involves a potential gross and flagrant, substantial or significant quality of care concern.

(b) *New concerns raised by a Medicare beneficiary.* If a Medicare beneficiary raises new concerns relating to the same complaint after the completion of the interim initial determination in § 476.130(c), the concerns will be processed as a new complaint. The QIO may process new concerns raised after the receipt of the written complaint as part of the same complaint, provided they are received prior to the completion of the interim initial determination. Even if a concern is received before the interim initial determination, the QIO can address it as a separate complaint if the QIO determines that this is warranted by the circumstances.

§ 476.130 Beneficiary complaint review procedures.

(a) *Scope of the QIO review.* In completing its review, the QIO shall consider any information and materials submitted by the Medicare beneficiary or his or her representative and any information submitted by the provider

and/or practitioner. All information obtained by the QIO that fits within the definition of ''confidential information'' under § 480.101, will be held by the QIO as confidential.

(1) The QIO's review will focus on the episode of care from which the complaint arose and address the specific concerns identified by the beneficiary and any additional concerns identified by the QIO. The QIO may separate concerns into different complaints if the QIO determine that the concerns relate to different episodes of care.

(2) The QIO will use evidence-based standards of care to the maximum extent practicable. If no standard of care exists, the QIO will use available norms, best practices and established guidelines to establish the standard that will be used in completing the review. The QIO's determination regarding the standard used is not subject to appeal.

(b) *Medical information requests.* (1) Upon request by the QIO, a provider or practitioner must deliver all medical information requested in response to a Medicare beneficiary complaint within 14 calendar days of the request. A QIO is authorized to require the receipt of the medical information sooner if the QIO make a preliminary determination that the complaint involves a potential gross and flagrant or substantial quality of care concern as specified in Part 1004 of this title and circumstances warrant earlier receipt of the medical information. A practitioner's or provider's failure to comply with the request for medical information within the established timeframe may result in the QIO taking action in accordance with § 476.90.

(2) In requesting medical information in response to a Medicare beneficiary complaint, the QIO must notify the practitioner and/or provider that the medical record is being requested in response to a beneficiary complaint, explain the practitioner's and/or provider's right to discuss the QIO's interim initial determination, and request the name of a contact person in order to ensure timely completion of the discussion.

(c) *Interim initial determination.* The QIO peer reviewer will complete the review and the practitioner and/or provider will be notified of the interim initial determination within 10 calendar days of the receipt of all medical information.

(1) A practitioner and provider will be notified by telephone of the opportunity to discuss the QIO's interim initial determination with the QIO in those situations where the peer reviewer determines that the quality of services does not meet professionally recognized standards of care for any concern in the complaint. The discussion must be held no later than 7 calendar days from the date of the initial offer.

(2) The interim initial determination becomes the final initial determination if the discussion is not completed timely as a result of the practitioner's and/or provider's failure to respond.

(3) Written statements in lieu of a discussion must be received no later than 7 calendar days from the date of the initial offer.

(4) In rare circumstances, the QIO may grant additional time to complete the discussion or submission of a written statement in lieu of a discussion.

(d) *Final initial determination.* The QIO must issue written notification of its final initial determination in those cases in which the QIO has determined that care met professionally recognized standards, as well as in those cases in which the QIO determined that standards were not met and the opportunity for discussion has been completed.

(1) No later than 3 business days after completion of its review, or for cases in which the standard was not met, no later than 3 business days after the discussion or receipt of the provider's and/or practitioner's written statement, the QIO will notify (by telephone) the beneficiary and the provider/practitioner of its final initial determination and of the right to request a reconsideration of the QIO's final initial determination.

(2) Written notice of the QIO's final initial determination will be forwarded to all parties within 5 calendar days after completion of its review, and must include:

(i) A statement for each concern that care did or did not meet the standard of care;

(ii) The standard identified by the QIO for each of the concerns; and

(iii) A summary of the specific facts that the QIO determines are pertinent to its findings, including references to medical information and, if held, the discussion with the involved practitioner and/or provider.

§ 476.140 Beneficiary complaint reconsideration procedures.

(a) *Right to request a reconsideration.* Beginning with complaints filed after July 31, 2014, a Medicare beneficiary, a provider, or a practitioner who is dissatisfied with a QIO's final initial determination may request a reconsideration by the QIO.

(1) The reconsideration request must be received by the QIO, in writing or by telephone, no later than 3 calendar days following initial notification of the QIO's determination. If the QIO is unable to accept a request, the request must be submitted by noon of the next day the QIO is available to accept a request.

(2) The Medicare beneficiary, or his or her representative, and the practitioner and/or provider must be available to answer any questions or supply any information that the QIO requests in order to conduct its reconsideration.

(3) The QIO must offer the Medicare beneficiary and the practitioner and/or provider an opportunity to provide further information. A Medicare beneficiary, a practitioner, and a provider may, but are not required to, submit evidence to be considered by the QIO in making its reconsideration decision.

(b) *Issuance of the QIO's final decision.* No later than 5 calendar days after receipt of the request for a reconsideration, or, if later, 5 calendar days after receiving any medical or other records needed for such reconsideration, the QIO must complete the review and notify the beneficiary and the practitioner/provider of its decision.

(1) The QIO's initial notification may be done by telephone, followed by the mailing of a written notice by noon of the next calendar day that includes—

(i) A statement for each concern that care did or did not meet the standard of care;

(ii) The standard identified by the QIO for each of the concerns;

(iii) A summary of the specific facts that the QIO determines are pertinent to its findings; and

(iv) A statement that the letter represents the QIO's final determination and that there is no right to further appeal.

(2) The QIO may provide information to the beneficiary, practitioner, and provider regarding opportunities for improving the care given to patients based on the specific findings of its review and the development of quality improvement initiatives.

§ 476.150 Abandoned complaints and reopening rights.

(a) *Abandoned complaints.* If a Medicare beneficiary fails to participate or otherwise comply with the requirements of the beneficiary complaint review process and the QIO does not have sufficient information to complete its review, the QIO may determine that the complaint has been abandoned and—

(1) Inform the parties that its complaint review will be discontinued; and

(2) Inform the beneficiary of his or her right to resubmit a written complaint in accordance with the procedures in § 476.120.

(b) *Reopening complaint reviews.* A QIO may reopen a Medicare beneficiary complaint review using the same procedures that the QIO would use for reopening initial denial determinations and changes as a result of DRG validation, as described in § 476.96.

§ 476.160 General quality of care review procedures.

(a) *Scope of the QIO review.* A QIO may conduct a general quality of care review in accordance with section 1154(a)(1)(B) of the Act.

(1) A QIO may conduct general quality of care reviews based on—

(i) Concerns identified during the course of other QIO review activities;

(ii) Referrals from other sources, including but not limited to individuals, contractors, other Federal or State agencies; or

(iii) Analysis of data.

(2) The QIO's review will focus on all concerns identified by the QIO and/or identified by those who have referred or reported the concerns, with consideration being given to the episode of care related to the concerns.

(3) The QIO will use evidence-based standards of care to the maximum extent practicable. If no standard of care exists, the QIO must use available norms, best practices, and established guidelines to establish the standard that will be used in completing the review. The QIO's determination regarding the standard used is not subject to appeal.

(b) *Medical information requests.* Upon request by the QIO, a provider or practitioner must deliver all medical information requested within 14 calendar days of the request. A QIO is authorized to require the receipt of the medical information sooner if the QIO makes a preliminary determination that the review involves a potential gross and flagrant or substantial quality of care concern and circumstances warrant earlier receipt of the medical information. A practitioner's or provider's failure to comply with the request for medical information within the established timeframe may result in the QIO taking action in accordance with § 476.90.

(c) *Initial determination.* The QIO peer reviewer will complete the review and the practitioner and/or provider will be notified of the initial determination in writing within 10 calendar days of the receipt of all medical information.

§ 476.170 General quality of care reconsideration procedures.

(a) *Right to request a reconsideration.* Beginning with reviews initiated after July 31, 2014, a provider or practitioner who is dissatisfied with a QIO's initial determination may request a reconsideration by the QIO.

(1) The reconsideration request must be received by the QIO, in writing or by telephone, by no later than 3 calendar days following receipt of the QIO's initial determination. If the QIO is unable to accept the request, the request must be submitted by noon of the next day the QIO is available to accept a request.

(2) The practitioner or provider must be available to answer any questions or supply any information that the QIO requests in order to conduct its reconsideration.

(3) The QIO must offer the practitioner or provider an opportunity to provide further information. A practitioner or provider may, but is not required to, submit evidence to be considered by the QIO in making its reconsideration decision.

(b) *Issuance of the QIO's final decision.* No later than 5 calendar days after receipt of the request for a reconsideration, or, if later, 5 calendar days after receiving any medical or other records needed for such reconsideration, the QIO must complete the review and notify the practitioner or provider of its decision.

(1) The QIO's initial notification may be done by telephone, followed by the mailing of a written notice by noon the next calendar day that includes:

(i) A statement for each concern that care did or did not meet the standard of care;

(ii) The standard identified by the QIO for each of the concerns;

(iii) A summary of the specific facts that the QIO determines are pertinent to its findings; and

(iv) A statement that the letter represents the QIO's final determination and that there is no right to further appeal.

(2) The QIO may provide information regarding opportunities for improving the care given to patients based on the specific findings of its review.

PART 478—RECONSIDERATIONS AND APPEALS

■ 24. The authority citation for Part 478 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 478.15 [Amended]

■ 25. In § 478.15(b), the reference ''§§ 473.18 through 473.36, and 473.48(a) and (c)'' is removed and the reference ''§§ 478.18 through 478.36 and 478.48(a) and (c)'' is added in its place.

§ 478.16 [Amended]

■ 26. In § 478.16, the reference ''§ 473.14(a)'' is removed and the reference ''§ 478.14'' is added in its place.

§ 478.20 [Amended]

■ 27. In § 478.20—

■ a. In paragraph (a)(1), the reference ''§ 473.22'' is removed and the reference ''§ 478.22'' is added in its place.

■ b. In paragraph (b), the reference ''§ 473.22'' is removed and the reference ''§ 478.22'' is added in its place.

■ c. In paragraph (c), the reference ''§ 473.18(c)'' is removed and the reference ''§ 478.18(c)'' is added in its place.

§ 478.28 [Amended]

■ 28. In § 478.28(a), the reference ''§ 466.98'' is removed and the reference ''§ 476.98'' is added in its place.

§ 478.38 [Amended]

■ 29. In § 478.38—

■ a. In paragraph (a), the reference ''§ 473.40'' is removed and the reference ''§ 478.40'' is added in its place.

■ b. In paragraph (b), the reference ''§ 473.48'' is removed and the reference ''§ 478.48'' is added in its place.

§ 478.42 [Amended]

■ 30. In § 478.42—

■ a. In paragraph (a) introductory text, the reference ''§ 473.40'' is removed and the reference ''§ 478.40'' is added in its place.

■ b. In paragraph (b), the reference ''§ 473.22'' is removed and the reference ''§ 478.22'' is added in its place.

§ 478.48 [Amended]

■ 31. In § 478.48—

■ a. In paragraph (a)(1), the reference ''§ 473.15'' is removed and the reference ''§ 478.15'' is added in its place.

■ b. In paragraph (a)(2) introductory text, the reference ''§ 473.15'' is removed and the reference ''§ 478.15'' is added in its place.

PART 480—ACQUISITION, PROTECTION, AND DISCLOSURE QUALITY IMPROVEMENT ORGANIZATION REVIEW INFORMATION

■ 32. The authority citation for Part 480 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 480.105 [Amended]

■ 33. In § 480.105(a), the phrase ''Medicare fiscal intermediaries'' is removed and the phrase ''Medicare administrative contractors or fiscal intermediaries'' is added in its place.

■ 34. Section 480.107 is amended by adding paragraph (l) to read as follows:

§ 480.107 Limitations on redisclosure.

* * * * *

(l) Redisclosures of information that is confidential because it identifies the parties involved in immediate advocacy may occur if all parties have consented to the redisclosure, as provided for under § 476.110(c) of this chapter.

■ 35. Section 480.132 is amended by—

■ a. Revising paragraphs (a) introductory text, (a)(1)(iii), and (a)(2).

■ b. Revising paragraph (b)(1).

■ c. Revising paragraph (c).

■ d. Removing the undesignated text following paragraph (c)(3).

The revisions read as follows.

§ 480.132 Disclosure of information about patients.

(a) *General requirements for disclosure.* Except as specified in §§ 476.130(d) and 476.140(b) of this chapter and paragraph (b) of this section, a QIO must—

(1) * * *

(iii) Except as provided under paragraph (b) of this section, all other patient and practitioner identifiers have been removed.

(2) Make disclosure to the patient or the patient's representative within 14 calendar days of receipt of the request.

(b) * * *

(1) If a request for information is in connection with an initial denial determination under section 1154(a)(2) of the Act, the QIO must provide only the information used to support that determination in accordance with the procedures for disclosure of information related to determinations under § 478.24, including relevant practitioner identifiers.

* * * * *

(c) *Manner of disclosure.* (1) The QIO must disclose the patient information directly to the patient or the patient's representative when the representative has been authorized or appointed to receive that information.

(2) In identifying a representative, the QIO must follow pertinent State law requirements regarding the designation of health care representatives and agents. If the patient is unable to designate a representative and the identity of the representative is not already dictated by State law, the QIO must disclose the information to a person whom the QIO determines is responsible for the patient.

* * * * *

■ 36. Section 480.133 is amended by—

■ a. Adding paragraph (a)(2)(iv).

■ b. In paragraph (b)(1), removing the reference to ''Part 466'' and adding the reference ''Part 476'' in its place; and removing the reference ''§ 473.24'' and adding the reference ''§ 478.24 of this subchapter'' is its place.

The addition reads as follows:

§ 480.133 Disclosure of information about practitioners, reviewers, and institutions.

(a) * * *

(2) * * *

(iv) A QIO is not required to obtain the consent of a practitioner or provider prior to the release of information to a beneficiary in connection with an initial denial determination or in providing a beneficiary with the QIO's findings in response to a beneficiary complaint. Information that must be specified in a QIO's final decision in a complaint review is specified in §§ 476.130(d) and 476.140(b) of this subchapter.

* * * * *

§ 480.139 [Amended]

■ 37. Section 480.139 is amended by redesignating the existing paragraph (1) as paragraph (a)(1).

■ 38. Section 480.145 is added to read as follows:

§ 480.145 Beneficiary authorization of use of confidential information.

(a) Except as otherwise provided under this Part, a QIO may not use or disclose a beneficiary's confidential information without an authorization from the beneficiary. The QIO's use or disclosure must be consistent with the authorization.

(b) A valid authorization is a document that contains the following:

(1) A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.

(2) The name or other specific identification of the QIO(s) and QIO point(s) of contact making the request to use or disclose the information.

(3) The name or other specific identification of the person(s), or class of persons, to whom the QIO(s) may disclose the information or allow the requested use.

(4) A description of each purpose of the requested use or disclosure. The statement ''at the request of the individual'' is a sufficient description of the purpose when an individual initiates the authorization and does not, or elects not to, provide a statement of purpose.

(5) An expiration date or an expiration event that relates to the beneficiary or the purpose of the use or disclosure. The statement ''end of the QIO research study,'' ''none,'' or similar language is sufficient if the authorization is for a use or disclosure of confidential information for QIO research, including for the creation and maintenance of a research database or research repository.

(6) Signature of the individual and date. If the authorization is signed by a beneficiary's representative, a description of such representative's authority to act for the beneficiary must also be provided.

(c) In addition to those items contained in paragraph (b) of this section, the authorization must contain statements adequate to place the individual on notice of all of the following:

(1) The individual's right to revoke the authorization in writing; and

(2) Any exceptions to the right to revoke and a description of how the individual may revoke the authorization;

(3) The ability or inability of the QIO to condition its review activities on the authorization, by stating either:

(i) That the QIO may not condition the review of complaints, appeals, or payment determinations, or any other QIO reviews or other tasks within the QIO's responsibility on whether the individual signs the authorization;

(ii) The consequences to the individual of a refusal to sign the authorization when the refusal will render the QIO unable to carry out an activity.

(4) The potential for information disclosed pursuant to the authorization to be subject to either appropriate or inappropriate redisclosure by a recipient, after which the information would no longer be protected by this subpart.

(d) The authorization must be written in plain language.

(e) If a QIO seeks an authorization from a beneficiary for a use or disclosure of confidential information, the QIO must provide the beneficiary with a copy of the signed authorization.

(f) A beneficiary may revoke an authorization provided under this section at any time, provided the revocation is in writing, except to the extent that the QIO has taken action in reliance upon the authorization.

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 45. 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).

■ 46. Section 495.8 is amended by revising paragraph (b)(2)(vi) to read as follows:

§ 495.8 Demonstration of meaningful use criteria.

* * * * *

(b) * * *

(2) * * *

(vi) *Exception for Medicare eligible hospitals and CAHs for FY 2012 and 2013—Participation in the Medicare EHR Incentive Program Electronic Reporting Pilot.* In order to satisfy the clinical quality measure reporting requirements of meaningful use, 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 24, 2012.

Marilyn Tavenner

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: October 30, 2012.

Kathleen Sebelius,

Secretary.

[FR Doc. 2012–26902 Filed 11–1–12; 4:15 pm]

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Part III

Department of Housing and Urban Development

Announcement of Funding Awards for the Continuum of Care Program for Fiscal Year (FY) 2011; Notice

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5500–FA–34]

Announcement of Funding Awards for the Continuum of Care Program for Fiscal Year (FY) 2011

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Announcement of funding awards.

SUMMARY: In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, this announcement notifies the public of past funding decisions made by the Department in a competition for funding under the FY2011 Notice of Funding Availability (NOFAs) for the Homeless Assistance Grants program. This announcement contains the names of the awardees and the amounts of the awards made available by HUD in FY2011.

FOR FURTHER INFORMATION CONTACT: Ann M. Oliva, Director, Office of Special Needs Assistance Programs, Office of Community Planning and Development, 451 7th Street SW., Room 7262, Washington, DC 20410–7000; telephone number 202–708–4300 (this is not a toll-free number). Hearing- and speech-impaired persons may access this number via TTY by calling the Federal Relay Service toll-free at 800–877–8339. For general information on this and other HUD programs, visit the HUD Web site at *www.hud.gov* or *www.hudhre.info.*

SUPPLEMENTARY INFORMATION: HUD's Homeless Assistance Grants provide federal support to one of the nation's most vulnerable populations while working to reduce overall homelessness and end chronic homelessness. Competitive Homeless Assistance Grants include the Supportive Housing Program, Shelter Plus Care, and the Section 8 Moderate Rehabilitation Single Room Occupancy Program, which are distributed through a competitive process called the Continuum of Care (CoC) in which federal funding is driven by the local decisionmaking. The CoC system is a community-based process that provides a coordinated housing and service delivery system that enables communities to plan for and provide a comprehensive response to homeless individuals and families. It is an inclusive process that is coordinated with nonprofit organizations, state and local government agencies, service providers, private foundations, faith-based organizations, law enforcement, local businesses, and homeless or formerly homeless persons.

The FY2011 awards announced in this Notice were selected for funding in the posted at *http://archives.hud.gov/funding/2011/grpcoc.cfm.* Applications were scored and selected for funding based on the selection criteria in the General Section and the CoC program section.

HUD awarded 7,889 competitive Homeless Assistance Grants totaling $1,674,959,117 for FY2011.

In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989 (42 U.S.C. 3545), the Department is publishing the details of these funding grant announcements in Appendix A.

Dated: November 6, 2012.

Mark Johnston,

Assistant Secretary (Acting) for Community Planning and Development.

Appendix A

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY

Applicant name	State	Award amount
Alaska Housing Finance Corporation	AK	$90,792
Alaska Housing Finance Corporation	AK	90,372
Alaska Housing Finance Corporation	AK	51,264
Alaska Housing Finance Corporation	AK	11,542
Alaska Housing Finance Corporation	AK	102,576
Alaska Housing Finance Corporation	AK	290,232
Alaska Housing Finance Corporation	AK	48,180
Alaska Housing Finance Corporation	AK	117,492
Alaska Housing Finance Corporation	AK	18,460
Alaska Housing Finance Corporation	AK	18,397
Alaska Housing Finance Corporation	AK	56,432
Alaska Housing Finance Corporation	AK	208,404
Alaskan AIDS Assistance Association	AK	104,665
Anchorage Community Mental Health Services, Inc	AK	646,563
Anchorage Community Mental Health Services, Inc	AK	203,464
Anchorage Housing Initiatives, Inc	AK	84,578
Catholic Social Services	AK	64,495
Covenant House Alaska	AK	245,629
Interior Alaska Center for Non-Violent Living	AK	50,965
Interior Alaska Center for Non-Violent Living	AK	32,824
Municipality of Anchorage	AK	107,625
Municipality of Anchorage	AK	189,089
Rural Alaska Community Action Program, Inc	AK	502,241
St. Vincent de Paul Society Diocesan Council Southeast Alaska	AK	26,350
The LeeShore Center	AK	73,791
Tundra Women's Coalition	AK	28,212
Valley Residential Services, Inc	AK	115,669
AIDS Alabama	AL	262,903
AIDS Alabama	AL	149,300
AIDS Alabama	AL	186,873
Alabama Coalition Against Domestic Violence	AL	128,638
Aletheia House	AL	108,857
Aletheia House	AL	314,705
City of Gadsden	AL	29,297
City of Tuscaloosa	AL	42,000
East Alabama Mental Health-Mental Retardation Board, Inc	AL	382,353

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
First Light, Inc	AL	86,068
First Light, Inc	AL	504,376
First Light, Inc	AL	82,368
First Stop, Inc	AL	81,009
First Stop, Inc	AL	123,839
First Stop, Inc	AL	67,754
Housing First, Inc	AL	90,284
Housing First, Inc	AL	279,920
Housing First, Inc	AL	409,834
Housing First, Inc	AL	105,000
Housing First, Inc	AL	479,261
Housing First, Inc	AL	94,756
Housing First, Inc	AL	86,100
Housing First, Inc	AL	148,732
Housing First, Inc	AL	120,860
Housing First, Inc	AL	123,088
Housing First, Inc	AL	163,077
Housing First, Inc	AL	146,187
Housing First, Inc	AL	78,178
Housing First, Inc	AL	371,402
Housing First, Inc	AL	123,060
Housing First, Inc	AL	175,061
Housing First, Inc	AL	160,019
Housing First, Inc	AL	103,751
Housing First, Inc	AL	120,861
Huntsville Housing Authority	AL	305,268
Huntsville Housing Authority	AL	53,760
Huntsville/North Alabama Project Applicant	AL	56,393
Huntsville/North Alabama Project Applicant	AL	58,856
Independent Living Resources of Greater Birmingham, Inc	AL	26,460
Jefferson County Housing Authority	AL	3,962,088
Jefferson-Blount-St. Clair Mental Health/Mental Retardation Authority	AL	238,439
Life Time Resolutions	AL	137,690
Lighthouse Counseling Center, Inc	AL	181,414
Lighthouse Counseling Center, Inc	AL	293,602
Lighthouse Counseling Center, Inc	AL	59,902
Lighthouse Counseling Center, Inc	AL	63,625
Lighthouse Counseling Center, Inc	AL	197,854
Mental Health Center of North Central Alabama, Inc	AL	131,593
Metropolitan Birmingham Services for the Homeless	AL	138,600
Montgomery Area Family Violence Program Inc	AL	138,606
Montgomery Area Family Violence Program Inc	AL	164,652
Montgomery Area Mental Health Authority Inc	AL	770,680
Pathways Inc	AL	185,130
Pathways Inc	AL	128,181
Pathways Inc	AL	168,453
Safeplace, Inc	AL	520,531
Sheffield Housing Authority	AL	48,474
State of Alabama	AL	1,080,420
State of Alabama	AL	249,084
The Alabama Rural Coalition for the Homeless, Inc	AL	493,348
The Cooperative Downtown Ministries	AL	47,835
The Cooperative Downtown Ministries	AL	126,426
The Cooperative Downtown Ministries	AL	245,385
The Cooperative Downtown Ministries	AL	146,917
The Cooperative Downtown Ministries	AL	219,089
The SafeHouse of Shelby County, Inc	AL	54,752
The Salvation Army Birmingham Area Command	AL	159,973
The Salvation Army, A Georgia Corporation	AL	69,087
The Tuscaloosa Housing Authority	AL	90,792
The Tuscaloosa Housing Authority	AL	102,840
The Tuscaloosa Housing Authority	AL	62,856
The Tuscaloosa Housing Authority	AL	209,520
University of Alabama at Birmingham	AL	492,515
University of Alabama at Birmingham	AL	250,510
Volunteer & Information Center, Inc	AL	70,327
YWCA CENTRAL ALABAMA	AL	83,867
YWCA CENTRAL ALABAMA	AL	184,285
Arkansas Department of Human Services	AR	379,956
Arkansas Department of Human Services	AR	383,184
Arkansas Department of Human Services	AR	26,112
Arkansas Department of Human Services	AR	899,724

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Bethlehem House, Inc	AR	21,600
Bethlehem House, Inc	AR	200,000
Black Community Developers, Inc	AR	110,125
Black Community Developers, Inc	AR	40,306
City of Pine Bluff	AR	237,426
Committee Against Spouse Abuse	AR	31,307
Delta Hills Continuum of Care	AR	133,596
Delta Hills Continuum of Care	AR	170,224
East Arkansas Continuum of Care	AR	31,824
Economic and Nonprofit Solutions, Inc	AR	50,000
Hot Spring County	AR	206,880
Housing Authority of the City of Fayetteville, Arkansas	AR	96,912
Housing Authority of the City of Fayetteville, Arkansas	AR	43,104
Little Rock Community Mental Health Center	AR	562,993
Little Rock Community Mental Health Center	AR	96,088
Little Rock Community Mental Health Center	AR	45,896
Little Rock Community Mental Health Center	AR	287,729
Little Rock Community Mental Health Center	AR	198,900
Little Rock Community Mental Health Center	AR	99,210
Little Rock Community Mental Health Center	AR	36,311
Little Rock Housing Authority	AR	37,920
Next Step Day Room, Inc	AR	400,000
Our House, Inc	AR	162,568
Our House, Inc	AR	36,370
Paragould Housing Authority	AR	174,960
River City Ministry	AR	68,331
River City Ministry	AR	142,010
Seven Hills Homeless Center	AR	354,510
Seven Hills Homeless Center	AR	68,310
Seven Hills Homeless Center	AR	20,412
The Darnell Brown Community Development Corporation	AR	284,515
Women & Children First	AR	93,058
Youth Bridge	AR	93,485
A New Leaf, Inc	AZ	58,878
A New Leaf, Inc	AZ	510,688
ACHIEVE Human Services	AZ	133,487
Area Agency on Aging, Region One	AZ	60,735
Area Agency on Aging, Region One	AZ	126,575
Area Agency on Aging, Region One	AZ	63,064
Arizona Behavioral Health Corporation	AZ	373,993
Arizona Behavioral Health Corporation	AZ	687,027
Arizona Behavioral Health Corporation	AZ	1,801,534
Arizona Behavioral Health Corporation	AZ	70,456
Arizona Behavioral Health Corporation	AZ	685,755
Arizona Behavioral Health Corporation	AZ	903,424
Arizona Behavioral Health Corporation	AZ	1,114,795
Arizona Behavioral Health Corporation	AZ	938,788
Arizona Behavioral Health Corporation	AZ	435,418
Arizona Behavioral Health Corporation	AZ	519,019
Arizona Behavioral Health Corporation	AZ	693,793
Arizona Behavioral Health Corporation	AZ	202,030
Arizona Behavioral Health Corporation	AZ	20,775
Arizona Department of Housing	AZ	206,340
Arizona Department of Housing	AZ	30,332
Arizona Department of Housing	AZ	93,186
Arizona Department of Housing	AZ	99,805
Arizona Department of Housing	AZ	43,873
Arizona Department of Housing	AZ	164,877
Arizona Department of Housing	AZ	78,195
Arizona Department of Housing	AZ	1,462,368
Arizona Department of Housing	AZ	94,222
Arizona Department of Housing	AZ	925,560
Arizona Department of Housing	AZ	1,844,796
Arizona Department of Housing	AZ	68,358
Arizona Department of Housing	AZ	200,892
Arizona Department of Housing	AZ	102,033
Arizona Department of Housing	AZ	80,660
Arizona Department of Housing	AZ	157,500
Arizona Department of Housing	AZ	230,544
Arizona Department of Housing	AZ	2,847,324
Arizona Department of Housing	AZ	195,943
Arizona Department of Housing	AZ	108,701

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Arizona Department of Housing	AZ	125,647
Arizona Department of Housing	AZ	347,504
Arizona Department of Housing	AZ	124,664
Arizona Department of Housing	AZ	129,225
Arizona Department of Housing	AZ	131,686
Arizona Department of Housing	AZ	76,685
Arizona Department of Housing	AZ	34,604
Arizona Department of Housing	AZ	102,534
Arizona Department of Housing	AZ	47,363
Arizona Department of Housing	AZ	129,747
Arizona Department of Housing	AZ	78,175
Arizona Department of Housing	AZ	34,187
Arizona Department of Housing	AZ	48,937
Arizona Housing, Inc	AZ	78,663
Arizona Housing, Inc	AZ	58,025
Catholic Charities Community Services	AZ	24,039
Chicanos Por La Causa, Inc	AZ	101,737
Chrysalis Shelter for Victims of Domestic Violence, Inc	AZ	24,269
City of Tucson—Housing and Community Development Department—Community Development Division	AZ	741,272
City of Tucson—Housing and Community Development Department—Community Development Division	AZ	842,328
City of Tucson—Housing and Community Development Department—Community Development Division	AZ	91,037
City of Tucson—Housing and Community Development Department—Community Development Division	AZ	334,680
City of Tucson—Housing and Community Development Department—Community Development Division	AZ	60,385
City of Tucson—Housing and Community Development Department—Community Development Division	AZ	327,000
CODAC Behavioral Health Services	AZ	171,443
CODAC Behavioral Health Services	AZ	221,118
Community Bridges, Inc	AZ	344,610
Community Information & Referral	AZ	176,752
Community Information & Referral	AZ	400,921
Community Partnership of Southern Arizona	AZ	461,084
Compass Healthcare, Inc	AZ	156,274
COPE Community Services, Inc	AZ	222,646
Homeward Bound	AZ	26,250
Homeward Bound	AZ	313,761
Human Services Campus	AZ	576,504
La Frontera Center, Inc	AZ	425,148
Labor's Community Service Agency	AZ	279,594
Lifewell Behavioral Wellness, Inc	AZ	99,105
Native American Connections, Inc	AZ	91,043
Native American Connections, Inc	AZ	478,800
Native American Connections, Inc	AZ	163,178
Native American Connections, Inc	AZ	333,370
Native American Connections, Inc	AZ	35,000
Old Pueblo Community Foundation	AZ	68,391
Old Pueblo Community Foundation	AZ	221,516
Our Family Services, Inc	AZ	60,789
Phoenix Shanti Group	AZ	34,599
Pima County	AZ	221,935
Pima County	AZ	461,425
Pima County	AZ	387,476
Pima County	AZ	428,470
Pima County CDNC	AZ	181,089
Pima County CDNC	AZ	434,713
Recovery Innovations of Arizona, Inc	AZ	990,010
Save the Family Foundation of Arizona	AZ	420,100
Save the Family Foundation of Arizona	AZ	215,406
Sojourner Center	AZ	417,763
Southern Arizona AIDS Foundation	AZ	86,499
Southern Arizona AIDS Foundation	AZ	87,783
Southern Arizona AIDS Foundation	AZ	28,373
Southwest Behavioral Health	AZ	205,977
The Primavera Foundation, Inc	AZ	103,306
The Primavera Foundation, Inc	AZ	112,486
The Salvation Army	AZ	45,360
The Salvation Army	AZ	73,080
Tumbleweed Center for Youth Development	AZ	318,729
Tumbleweed Center for Youth Development	AZ	214,429
Tumbleweed Center for Youth Development	AZ	439,700
U.S. Veterans Initiative	AZ	152,948
U.S. Veterans Initiative	AZ	496,557
United Methodist Outreach Ministries	AZ	201,671
United Methodist Outreach Ministries	AZ	187,584

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
United Methodist Outreach Ministries	AZ	391,238
United Methodist Outreach Ministries	AZ	80,126
Women In New Recovery	AZ	46,862
1736 Family Crisis Center	CA	521,823
A Community of Friends	CA	52,250
A Community of Friends	CA	175,000
A Community of Friends	CA	213,003
Abode Services	CA	529,612
Abode Services	CA	133,333
Abode Services	CA	852,468
Affordable Housing Associates	CA	36,665
Alameda County Allied Housing Program	CA	35,490
Alameda County Housing and Community Development Department	CA	520,380
Alameda County Housing and Community Development Department	CA	184,771
Alameda County Housing and Community Development Department	CA	384,582
Alameda County Housing and Community Development Department	CA	1,048,752
Alameda County Housing and Community Development Department	CA	44,122
Alameda County Housing and Community Development Department	CA	687,732
Alameda County Housing and Community Development Department	CA	463,680
Alameda County Housing and Community Development Department	CA	181,335
Alameda County Housing and Community Development Department	CA	140,904
Alameda County Housing and Community Development Department	CA	79,800
Alameda County Housing and Community Development Department	CA	192,266
Alameda County Housing and Community Development Department	CA	42,170
Alameda County Housing and Community Development Department	CA	157,189
Alameda County Housing and Community Development Department	CA	4,334,112
Alameda County Housing and Community Development Department	CA	1,090,393
Alameda County Housing and Community Development Department	CA	288,876
Alliance Against Family Violence and Sexual Assault	CA	350,980
Alpha Project for the Homeless	CA	159,345
Amador-Tuolumne Community Action Agency	CA	31,343
Amador-Tuolumne Community Action Agency	CA	39,900
American Family Housing	CA	419,662
American Family Housing	CA	286,276
American Family Housing	CA	315,478
Anaheim Supportive Housing for Senior Adults, Inc	CA	139,020
Angels of Grace, Inc	CA	93,000
Anka Behavioral Health	CA	102,046
Anka Behavioral Health	CA	155,027
Anka Behavioral Health	CA	117,079
Anka Behavioral Health	CA	447,373
Antelope Valley Domestic Violence Council	CA	143,911
Arcata House	CA	234,726
Arcata House	CA	55,069
Ark of Refuge, Inc	CA	208,502
Asian Pacific Women's Center	CA	149,813
Aspiranet	CA	94,959
AspiraNet	CA	140,000
Berkeley Food and Housing Project	CA	253,627
Berkeley Food and Housing Project	CA	242,217
Berkeley Food and Housing Project	CA	141,019
Bethany Services dba Bakersfield Homeless Center	CA	176,881
Bethany Services dba Bakersfield Homeless Center	CA	269,408
Bethany Services dba Bakersfield Homeless Center	CA	97,000
Beyond Shelter	CA	141,910
Bill Wilson Center	CA	548,476
Bill Wilson Center	CA	237,230
Bill Wilson Center	CA	303,562
Bonita House, Inc	CA	33,080
Buckelew Programs	CA	196,698
Buckelew Programs	CA	66,659
Buckelew Programs	CA	164,490
Buckelew Programs	CA	53,436
Buckelew Programs	CA	170,040
Buckelew Programs	CA	27,476
Building Opportunities for Self-Sufficiency	CA	736,155
Building Opportunities for Self-Sufficiency	CA	114,997
Building Opportunities for Self-Sufficiency	CA	164,038
Building Opportunities for Self-Sufficiency	CA	274,259
Building Opportunities for Self-Sufficiency	CA	74,500
Building Opportunities for Self-Sufficiency	CA	185,727
Building Opportunities for Self-Sufficiency	CA	96,147

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Butte County Dept. of Behavioral Health	CA	65,656
Butte County Dept. of Behavioral Health	CA	26,835
California Council for Veterans Affairs, Inc	CA	136,216
California Veterans Assistance Foundation, Inc	CA	271,459
Caminar	CA	60,725
Caminar	CA	48,547
Caminar	CA	25,000
Catholic Charities	CA	33,333
Catholic Charities CYO	CA	138,794
Catholic Charities of Santa Clara County	CA	351,351
Catholic Charities of Santa Clara County	CA	420,880
Catholic Charities of Santa Clara County	CA	459,444
Catholic Charities of Santa Clara County	CA	378,173
Catholic Charities of the Diocese of Santa Rosa	CA	74,963
Catholic Charities of the Diocese of Santa Rosa	CA	80,424
Center for Domestic Peace	CA	64,540
Center for Domestic Peace	CA	55,642
Center for Human Rights and Constitutional Law, Inc	CA	134,943
Center for Human Services	CA	77,500
Center for Human Services	CA	42,879
Center for Human Services	CA	90,682
Center Point, Inc	CA	42,210
Center Point, Inc	CA	479,316
Central California Family Crisis Center, Inc	CA	94,373
Central City Lutheran Mission	CA	75,046
Central Coast HIV/AIDS Services	CA	129,312
Champions Recovery Alternative Programs, Inc	CA	106,314
Children's Crisis Center of Stanislaus County, Inc	CA	90,000
City and County of San Francisco	CA	83,892
City and County of San Francisco	CA	1,003,320
City and County of San Francisco	CA	646,584
City and County of San Francisco	CA	54,792
City and County of San Francisco	CA	405,888
City and County of San Francisco	CA	326,832
City and County of San Francisco	CA	544,044
City and County of San Francisco	CA	584,712
City and County of San Francisco	CA	960,180
City and County of San Francisco	CA	167,220
City and County of San Francisco	CA	368,765
City and County of San Francisco	CA	918,528
City and County of San Francisco	CA	125,849
City and County of San Francisco	CA	133,194
City and County of San Francisco	CA	752,787
City and County of San Francisco	CA	111,480
City and County of San Francisco	CA	356,083
City and County of San Francisco	CA	300,385
City and County of San Francisco	CA	352,051
City and County of San Francisco	CA	74,661
City and County of San Francisco	CA	324,384
City and County of San Francisco	CA	222,960
City and County of San Francisco	CA	891,840
City and County of San Francisco	CA	178,200
City and County of San Francisco	CA	327,747
City and County of San Francisco	CA	103,470
City and County of San Francisco	CA	1,114,800
City and County of San Francisco	CA	731,472
City and County of San Francisco	CA	232,146
City and County of San Francisco	CA	1,160,895
City and County of San Francisco	CA	268,078
City and County of San Francisco	CA	113,436
City and County of San Francisco	CA	662,940
City and County of San Francisco	CA	944,783
City and County of San Francisco	CA	377,713
City and County of San Francisco	CA	130,729
City and County of San Francisco	CA	200,664
City and County of San Francisco	CA	89,136
City and County of San Francisco	CA	177,146
City and County of San Francisco	CA	86,844
City and County of San Francisco	CA	238,255
City and County of San Francisco, Department of Public Health	CA	677,348
City and County of San Francisco, Department of Public Health	CA	503,963
City of Berkeley	CA	127,344

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
City of Berkeley	CA	123,900
City of Berkeley	CA	1,964,016
City of Berkeley	CA	457,908
City of Davis	CA	47,326
City of Davis	CA	106,752
City of Fremont	CA	269,790
City of Glendale/Glendale Housing Authority	CA	21,420
City of Glendale/Glendale Housing Authority	CA	93,000
City of Glendale/Glendale Housing Authority	CA	295,524
City of Glendale/Glendale Housing Authority	CA	181,966
City of Glendale/Glendale Housing Authority	CA	41,724
City of Glendale/Glendale Housing Authority	CA	333,581
City of Glendale/Glendale Housing Authority	CA	217,292
City of Glendale/Glendale Housing Authority	CA	74,624
City of Glendale/Glendale Housing Authority	CA	152,904
City of Glendale/Glendale Housing Authority	CA	753,330
City of Glendale/Glendale Housing Authority	CA	153,802
City of Glendale/Glendale Housing Authority	CA	161,340
City of Long Beach	CA	102,363
City of Long Beach	CA	132,884
City of Long Beach	CA	650,823
City of Long Beach	CA	285,838
City of Long Beach	CA	244,998
City of Long Beach	CA	105,870
City of Long Beach	CA	311,881
City of Long Beach	CA	222,721
City of Long Beach	CA	102,327
City of Long Beach	CA	378,202
City of Long Beach	CA	46,998
City of Long Beach	CA	241,279
City of Long Beach	CA	351,508
City of Long Beach	CA	165,122
City of Long Beach	CA	446,880
City of Long Beach	CA	347,700
City of Long Beach	CA	143,696
City of Long Beach	CA	50,017
City of Long Beach	CA	196,623
City of Long Beach	CA	284,097
City of Long Beach	CA	350,396
City of Long Beach	CA	343,145
City of Long Beach	CA	256,340
City of Long Beach	CA	102,379
City of Long Beach	CA	369,024
City of Long Beach	CA	218,639
City of Long Beach	CA	103,788
City of Long Beach	CA	182,128
City of Long Beach	CA	45,178
City of Long Beach	CA	52,209
City of Long Beach	CA	50,085
City of Long Beach	CA	220,638
City of Long Beach	CA	166,896
City of Oakland	CA	1,829,618
City of Oakland	CA	259,824
City of Oakland	CA	245,146
City of Oakland	CA	699,770
City of Oceanside	CA	146,702
City of Oxnard	CA	55,384
City of Oxnard	CA	129,515
City of Oxnard	CA	13,490
City of Pomona	CA	162,154
City of Pomona Housing Authority	CA	965,052
City of Santa Monica Housing Authority	CA	1,741,632
City of Santa Monica Housing Authority	CA	491,791
City of Santa Monica Housing Authority	CA	380,556
City of Santa Monica Housing Authority	CA	77,868
City of Woodland	CA	177,343
Clinica Sierra Vista, Inc	CA	93,903
Coalition of Homeless Services Providers	CA	70,875
Colette's Children's Home	CA	163,898
Colette's Children's Home	CA	163,898
Colette's Children's Home	CA	137,882
Colette's Children's Home	CA	127,309

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Colette's Children's Home	CA	157,278
Committee on the Shelterless	CA	75,000
Committee on the Shelterless	CA	29,744
Committee on the Shelterless	CA	110,300
Committee on the Shelterless	CA	16,000
Committee on the Shelterless	CA	78,359
Community Action Agency of Butte County, Inc	CA	53,946
Community Action Agency of Butte County, Inc	CA	105,000
Community Action Agency of Butte County, Inc	CA	45,880
Community Action of Napa Valley	CA	27,531
Community Action Partnership of Madera Shunammite Place	CA	175,107
Community Action Partnership of San Bernardino County	CA	250,158
Community Action Partnership of Sonoma County	CA	40,624
Community Action Partnership of Sonoma County	CA	107,000
Community Awareness & Treatment Services, Inc	CA	344,497
Community Development Commission of Mendocino County	CA	46,608
Community Development Commission of Mendocino County	CA	1,391,700
Community Housing and Shelter Services	CA	95,313
Community Housing and Shelter Services	CA	88,247
Community Housing and Shelter Services	CA	68,341
Community Housing Partnership	CA	155,836
Community HousingWorks	CA	63,000
Community HousingWorks	CA	104,559
Community HousingWorks	CA	43,557
Community Human Services	CA	128,133
Community Resource Center	CA	55,000
Community Services & Employment Training, Inc	CA	569,203
Community Support Network	CA	40,842
Community Technology Alliance	CA	151,926
Community Technology Alliance	CA	89,985
Community Technology Alliance	CA	303,716
Community Working Group	CA	43,100
Compass Family Services	CA	291,909
Contra Costa Health Services	CA	138,517
Contra Costa Health Services	CA	283,096
Contra Costa Health Services	CA	501,273
Contra Costa Health Services	CA	261,505
Contra Costa Health Services	CA	173,377
Contra Costa Health Services	CA	172,153
CORA	CA	225,375
County of Los Angeles Department of Children and Family Services	CA	197,621
County of Los Angeles Department of Children and Family Services	CA	89,062
County of Los Angeles Department of Children and Family Services	CA	384,676
County of Los Angeles Department of Children and Family Services	CA	274,400
County of Los Angeles, Housing Authority	CA	138,036
County of Los Angeles, Housing Authority	CA	1,453,536
County of Los Angeles, Housing Authority	CA	2,939,760
County of Los Angeles, Housing Authority	CA	180,804
County of Los Angeles, Housing Authority	CA	434,100
County of Los Angeles, Housing Authority	CA	1,980,120
County of Los Angeles, Housing Authority	CA	464,664
County of Los Angeles, Housing Authority	CA	1,599,108
County of Los Angeles, Housing Authority	CA	735,756
County of Los Angeles, Housing Authority	CA	346,896
County of Los Angeles, Housing Authority	CA	549,504
County of Los Angeles, Housing Authority	CA	1,599,420
County of Los Angeles, Housing Authority	CA	262,644
County of Los Angeles, Housing Authority	CA	1,738,500
County of Los Angeles, Housing Authority	CA	665,364
County of Los Angeles, Housing Authority	CA	184,512
County of Los Angeles, Housing Authority	CA	331,980
County of Los Angeles, Housing Authority	CA	1,248,252
County of Los Angeles, Housing Authority	CA	285,072
County of Los Angeles, Housing Authority	CA	312,720
County of Los Angeles, Housing Authority	CA	321,168
County of Napa	CA	19,950
County of Napa	CA	125,794
County of Napa	CA	13,500
County of Nevada	CA	109,244
County of Sacramento Housing Authority	CA	4,096,320
County of Sacramento Housing Authority	CA	158,976
County of San Diego	CA	201,264

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
County of San Diego	CA	146,256
County of San Diego	CA	599,268
County of San Diego	CA	159,768
County of San Luis Obispo	CA	55,000
County of San Luis Obispo	CA	110,263
County of San Luis Obispo	CA	60,000
County of San Luis Obispo	CA	211,395
County of San Luis Obispo	CA	473,981
County of San Luis Obispo	CA	48,091
County of Santa Cruz Health Services Agency	CA	67,559
County of Santa Cruz Health Services Agency	CA	361,339
County of Ventura Human Services Agency	CA	49,085
County of Ventura Human Services Agency	CA	163,795
County of Ventura Human Services Agency	CA	217,276
County of Ventura Human Services Agency	CA	31,214
Covenant House California	CA	129,736
Crisis House, Inc	CA	445,011
Crisis House, Inc	CA	189,081
Department of Human Assistance	CA	81,746
Department of Human Assistance	CA	154,345
Department of Human Assistance	CA	312,328
Department of Human Assistance	CA	178,849
Department of Human Assistance	CA	154,110
Department of Human Assistance	CA	100,396
Department of Human Assistance	CA	275,838
Department of Human Assistance	CA	256,032
Department of Human Assistance	CA	316,033
Department of Human Assistance	CA	499,037
Department of Human Assistance	CA	362,022
Department of Human Assistance	CA	327,869
Department of Human Assistance	CA	99,959
Department of Human Assistance	CA	128,148
Department of Human Assistance	CA	497,726
Department of Human Assistance	CA	229,107
Department of Human Assistance	CA	259,830
Department of Human Assistance	CA	226,000
Department of Human Assistance	CA	312,138
Department of Human Assistance	CA	89,932
Department of Human Assistance	CA	3,061,636
Department of Human Assistance	CA	123,496
Department of Human Assistance	CA	314,738
Department of Human Assistance	CA	102,107
Department of Human Assistance	CA	110,250
Department of Human Assistance	CA	398,509
Department of Human Assistance	CA	187,714
Domestic Violence Solutions for Santa Barbara County	CA	76,219
Eden Investments, Inc	CA	79,240
El Dorado County Human Services—Community Services Division	CA	13,339
Eli Home Second Step	CA	524,275
Emergency Housing Consortium of Santa Clara County	CA	53,747
Emergency Housing Consortium of Santa Clara County	CA	93,866
Emergency Housing Consortium of Santa Clara County	CA	252,722
Episcopal Community Services	CA	509,328
Episcopal Community Services	CA	557,110
Fairfield Suisun Community Action Council	CA	62,816
Fairfield Suisun Community Action Council	CA	186,290
Faithworks Community Coalition	CA	17,823
Families Forward	CA	132,941
Families Forward	CA	73,819
Families Forward	CA	425,000
Families In Transition of Santa Cruz County, Inc	CA	181,158
Families In Transition of Santa Cruz County, Inc	CA	182,448
Family Assistance Ministries	CA	122,388
Family Services of Tulare County	CA	80,342
Family Supportive Housing, Inc	CA	97,368
Family Supportive Housing, Inc	CA	211,231
Family Supportive Housing, Inc	CA	46,036
Family Supportive Housing, Inc	CA	201,927
Filipino American Service Group, Inc	CA	190,449
Flood Bakersfield Ministries, Inc	CA	101,997
Ford Street Project	CA	73,816
Frazee Community Center	CA	26,250

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Fred Finch Youth Center	CA	651,460
Fresno County Economic Opportunities Commission	CA	707,880
Fresno County Economic Opportunities Commission	CA	288,978
Fresno County Economic Opportunities Commission	CA	180,569
Fresno County Economic Opportunities Commission	CA	585,863
Friendship Shelter, Inc	CA	68,136
Fullerton Interfaith Emergency Service	CA	252,000
Garden Park Apartments Community (GPAC)	CA	219,516
Generate Hope	CA	200,000
Global One Development Center	CA	391,125
Goodwill One Stop	CA	863,257
Gramercy Housing Group	CA	210,960
Greater Bakersfield Legal Assistance, Inc	CA	120,044
Greater Richmond Interfaith Program	CA	95,372
Greater Richmond Interfaith Program	CA	73,424
Harbor Interfaith Services, Inc	CA	127,673
Homeless Services Center	CA	142,591
Homes For Life Foundation	CA	72,067
Homes For Life Foundation	CA	337,589
Homeward Bound of Marin	CA	326,216
Homeward Bound of Marin	CA	197,531
Homeward Bound of Marin	CA	50,148
Homeward Bound of Marin	CA	31,153
Homeward Bound of Marin	CA	15,394
House of Prayer Gospel Outreach Ministries, Inc	CA	317,770
Housing Authority City of Fresno	CA	135,000
Housing Authority City of Fresno	CA	622,752
Housing Authority City of Fresno HMIS Expansion	CA	75,000
Housing Authority City of Fresno Shelter Plus Care I	CA	168,348
Housing Authority City of Fresno Shelter Plus Care III	CA	302,232
Housing Authority of Contra Costa County	CA	56,784
Housing Authority of Contra Costa County	CA	428,508
Housing Authority of Contra Costa County	CA	3,090,048
Housing Authority of Contra Costa County	CA	218,196
Housing Authority of the City of Los Angeles	CA	230,640
Housing Authority of the City of Los Angeles	CA	467,868
Housing Authority of the City of Los Angeles	CA	582,936
Housing Authority of the City of Los Angeles	CA	328,392
Housing Authority of the City of Los Angeles	CA	230,640
Housing Authority of the City of Los Angeles	CA	161,448
Housing Authority of the City of Los Angeles	CA	973,560
Housing Authority of the City of Los Angeles	CA	2,257,728
Housing Authority of the City of Los Angeles	CA	444,888
Housing Authority of the City of Los Angeles	CA	150,612
Housing Authority of the City of Los Angeles	CA	330,168
Housing Authority of the City of Los Angeles	CA	1,886,136
Housing Authority of the City of Los Angeles	CA	155,736
Housing Authority of the City of Los Angeles	CA	1,753,176
Housing Authority of the City of Los Angeles	CA	55,632
Housing Authority of the City of Los Angeles	CA	334,428
Housing Authority of the City of Los Angeles	CA	4,503,792
Housing Authority of the City of Los Angeles	CA	2,379,300
Housing Authority of the City of Los Angeles	CA	800,232
Housing Authority of the City of Los Angeles	CA	1,808,040
Housing Authority of the City of Los Angeles	CA	304,872
Housing Authority of the City of Los Angeles	CA	542,004
Housing Authority of the City of Los Angeles	CA	495,876
Housing Authority of the City of Los Angeles	CA	359,352
Housing Authority of the City of Los Angeles	CA	222,528
Housing Authority of the City of Los Angeles	CA	388,380
Housing Authority of the City of Los Angeles	CA	922,560
Housing Authority of the City of Los Angeles	CA	1,441,500
Housing Authority of the City of Los Angeles	CA	518,940
Housing Authority of the City of Los Angeles	CA	283,980
Housing Authority of the City of Los Angeles	CA	1,390,800
Housing Authority of the City of Los Angeles	CA	667,584
Housing Authority of the City of Los Angeles	CA	1,361,616
Housing Authority of the City of Los Angeles	CA	1,326,180
Housing Authority of the City of Los Angeles	CA	938,556
Housing Authority of the City of Napa	CA	24,144
Housing Authority of the City of Napa	CA	13,715
Housing Authority of the City of Napa	CA	60,360

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Housing Authority of the City of San Buenaventura	CA	119,652
Housing Authority of the City of Santa Barbara	CA	257,520
Housing Authority of the City of Santa Barbara	CA	621,384
Housing Authority of the County of Butte	CA	26,748
Housing Authority of the County of Butte	CA	96,504
Housing Authority of the County of Kern	CA	473,700
Housing Authority of the County of Kern	CA	273,948
Housing Authority of the County of Kern	CA	500,040
Housing Authority of the County of Kern	CA	294,048
Housing Authority of the County of Kern	CA	416,580
Housing Authority of the County of Kern	CA	1,517,820
Housing Authority of the County of Marin	CA	948,432
Housing Authority of the County of Marin	CA	54,792
Housing Authority of the County of Merced	CA	273,600
Housing Authority of the County of Monterey	CA	367,867
Housing Authority of the County of Monterey	CA	173,712
Housing Authority of the County of San Bernardino	CA	364,740
Housing Authority of the County of San Bernardino	CA	935,040
Housing Authority of the County of San Bernardino	CA	1,928,520
Housing Authority of the County of San Mateo	CA	54,792
Housing Authority of the County of San Mateo	CA	163,416
Housing Authority of the County of San Mateo	CA	1,606,284
Housing Authority of the County of San Mateo	CA	54,792
Housing Authority of the County of San Mateo	CA	1,085,472
Housing Authority of the County of San Mateo	CA	763,433
Housing Authority of the County of Santa Clara	CA	3,068,100
Housing Authority of the County of Santa Clara	CA	268,740
Housing Authority of the County of Santa Cruz	CA	417,504
Housing Authority of the County of Santa Cruz	CA	13,848
Housing Authority of the County of Santa Cruz	CA	56,000
Housing Authority of the County of Stanislaus	CA	243,744
Housing Authority of the County of Stanislaus	CA	592,620
Housing Authority of the County of Stanislaus	CA	145,440
Housing Authority of the County of Stanislaus	CA	174,160
Housing Authority of the County of Stanislaus	CA	126,720
Human Options, Inc	CA	30,793
Human Options, Inc	CA	111,122
Humboldt County	CA	82,353
Illumination Foundation	CA	213,188
Immanuel Housing Inc	CA	76,192
Inland Counties Legal Services, Inc	CA	54,531
Inland Counties Legal Services, Inc	CA	38,395
Inland Temporary Homes	CA	424,835
Inland Temporary Homes	CA	69,401
InnVision the Way Home	CA	163,719
InnVision the Way Home	CA	88,714
InnVision the Way Home	CA	98,408
InnVision the Way Home	CA	164,635
InnVision the Way Home	CA	348,831
InnVision the Way Home	CA	28,530
InnVision the Way Home	CA	228,335
InnVision the Way Home	CA	135,740
InnVision the Way Home	CA	69,226
InnVision the Way Home	CA	131,928
Intercommunity Child Guidance Center dba The Whole Child	CA	165,207
Interfaith Shelter Network	CA	44,536
Interfaith Shelter Network	CA	24,780
Interfaith Shelter Network	CA	61,134
Interim, Inc	CA	97,407
Interim, Inc	CA	138,168
Interval House	CA	73,268
Jewish Family Service of Los Angeles	CA	180,498
JWCH Institute, Inc	CA	308,999
Kern County Mental Health	CA	74,592
Kern County Mental Health	CA	82,050
Kings United Way	CA	101,920
L.A. Family Housing	CA	355,664
L.A. Family Housing	CA	363,659
Larkin Street Youth Services	CA	109,463
Life Community Development	CA	299,289
LifeLong Medical Care	CA	539,398
Los Angeles Homeless Services Authority	CA	570,870

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Los Angeles Homeless Services Authority	CA	168,843
Los Angeles Homeless Services Authority	CA	223,929
Los Angeles Homeless Services Authority	CA	200,258
Los Angeles Homeless Services Authority	CA	282,429
Los Angeles Homeless Services Authority	CA	157,436
Los Angeles Homeless Services Authority	CA	199,999
Los Angeles Homeless Services Authority	CA	287,114
Los Angeles Homeless Services Authority	CA	59,052
Los Angeles Homeless Services Authority	CA	201,506
Los Angeles Homeless Services Authority	CA	140,466
Los Angeles Homeless Services Authority	CA	364,882
Los Angeles Homeless Services Authority	CA	381,940
Los Angeles Homeless Services Authority	CA	151,802
Los Angeles Homeless Services Authority	CA	169,419
Los Angeles Homeless Services Authority	CA	149,706
Los Angeles Homeless Services Authority	CA	385,943
Los Angeles Homeless Services Authority	CA	220,461
Los Angeles Homeless Services Authority	CA	149,846
Los Angeles Homeless Services Authority	CA	362,250
Los Angeles Homeless Services Authority	CA	110,824
Los Angeles Homeless Services Authority	CA	223,552
Los Angeles Homeless Services Authority	CA	196,350
Los Angeles Homeless Services Authority	CA	177,929
Los Angeles Homeless Services Authority	CA	182,955
Los Angeles Homeless Services Authority	CA	246,780
Los Angeles Homeless Services Authority	CA	24,331
Los Angeles Homeless Services Authority	CA	400,000
Los Angeles Homeless Services Authority	CA	63,687
Los Angeles Homeless Services Authority	CA	157,706
Los Angeles Homeless Services Authority	CA	573,405
Los Angeles Homeless Services Authority	CA	258,248
Los Angeles Homeless Services Authority	CA	94,295
Los Angeles Homeless Services Authority	CA	198,507
Los Angeles Homeless Services Authority	CA	140,300
Los Angeles Homeless Services Authority	CA	134,592
Los Angeles Homeless Services Authority	CA	344,504
Los Angeles Homeless Services Authority	CA	156,635
Los Angeles Homeless Services Authority	CA	147,972
Los Angeles Homeless Services Authority	CA	263,401
Los Angeles Homeless Services Authority	CA	71,796
Los Angeles Homeless Services Authority	CA	248,942
Los Angeles Homeless Services Authority	CA	206,461
Los Angeles Homeless Services Authority	CA	96,975
Los Angeles Homeless Services Authority	CA	143,432
Los Angeles Homeless Services Authority	CA	259,701
Los Angeles Homeless Services Authority	CA	106,479
Los Angeles Homeless Services Authority	CA	112,450
Los Angeles Homeless Services Authority	CA	210,433
Los Angeles Homeless Services Authority	CA	83,913
Los Angeles Homeless Services Authority	CA	193,880
Los Angeles Homeless Services Authority	CA	137,485
Los Angeles Homeless Services Authority	CA	70,031
Los Angeles Homeless Services Authority	CA	50,225
Los Angeles Homeless Services Authority	CA	154,997
Los Angeles Homeless Services Authority	CA	161,539
Los Angeles Homeless Services Authority	CA	385,943
Los Angeles Homeless Services Authority	CA	97,677
Los Angeles Homeless Services Authority	CA	93,310
Los Angeles Homeless Services Authority	CA	178,238
Los Angeles Homeless Services Authority	CA	337,805
Los Angeles Homeless Services Authority	CA	262,085
Los Angeles Homeless Services Authority	CA	162,775
Los Angeles Homeless Services Authority	CA	118,346
Los Angeles Homeless Services Authority	CA	34,999
Los Angeles Homeless Services Authority	CA	119,280
Los Angeles Homeless Services Authority	CA	244,623
Los Angeles Homeless Services Authority	CA	629,647
Los Angeles Homeless Services Authority	CA	209,799
Los Angeles Homeless Services Authority	CA	286,999
Los Angeles Homeless Services Authority	CA	51,771
Los Angeles Homeless Services Authority	CA	489,638
Los Angeles Homeless Services Authority	CA	125,824

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Los Angeles Homeless Services Authority	CA	225,355
Los Angeles Homeless Services Authority	CA	89,094
Los Angeles Homeless Services Authority	CA	241,135
Los Angeles Homeless Services Authority	CA	387,581
Los Angeles Homeless Services Authority	CA	256,710
Los Angeles Homeless Services Authority	CA	92,217
Los Angeles Homeless Services Authority	CA	131,286
Los Angeles Homeless Services Authority	CA	121,874
Los Angeles Homeless Services Authority	CA	331,546
Los Angeles Homeless Services Authority	CA	282,734
Los Angeles Homeless Services Authority	CA	267,828
Los Angeles Homeless Services Authority	CA	189,000
Los Angeles Homeless Services Authority	CA	476,401
Los Angeles Homeless Services Authority	CA	249,999
Los Angeles Homeless Services Authority	CA	54,498
Los Angeles Homeless Services Authority	CA	120,164
Los Angeles Homeless Services Authority	CA	76,059
Los Angeles Homeless Services Authority	CA	249,361
Los Angeles Homeless Services Authority	CA	366,345
Los Angeles Homeless Services Authority	CA	159,179
Los Angeles Homeless Services Authority	CA	130,971
Los Angeles Homeless Services Authority	CA	402,558
Los Angeles Homeless Services Authority	CA	113,971
Los Angeles Homeless Services Authority	CA	66,685
Los Angeles Homeless Services Authority	CA	253,423
Los Angeles Homeless Services Authority	CA	63,655
Los Angeles Homeless Services Authority	CA	349,666
Los Angeles Homeless Services Authority	CA	198,095
Los Angeles Homeless Services Authority	CA	259,875
Los Angeles Youth Network	CA	40,528
Many Mansions a California Non Profit Corporation	CA	61,600
Many Mansions a California Non Profit Corporation	CA	59,911
Many Mansions a California Non Profit Corporation	CA	60,952
Many Mansions a California Non Profit Corporation	CA	39,998
Marjaree Mason Center, Inc	CA	65,482
Marjaree Mason Center, Inc	CA	287,840
Marjaree Mason Center, Inc	CA	108,086
Mary Lind Recovery Centers	CA	442,317
Mary Sheets	CA	34,125
Mendocino County Health and Human Services Agency	CA	200,412
Mendocino County Health and Human Services Agency	CA	28,532
Mendocino County Health and Human Services Agency	CA	130,736
Mental Health Association of San Mateo County	CA	73,271
Mental Health Association of San Mateo County	CA	39,530
Mental Health Systems Inc	CA	287,042
Mental Health Systems Inc	CA	74,843
Mental Health Systems Inc	CA	273,283
Merced County Community Action Agency	CA	81,163
Merced County Mental Health	CA	128,063
Mercy House Living Centers	CA	393,689
Mercy House Living Centers	CA	90,240
Mercy House Living Centers	CA	118,000
NAMI Tuolumne County	CA	15,478
NAMI Tuolumne County	CA	45,641
New Directions, Inc	CA	574,640
New Economics for Women	CA	155,254
New Hope Village, Inc	CA	66,675
North Coast Substance Abuse Council, Inc	CA	109,727
North County Interfaith Council, Inc	CA	64,214
North County Interfaith Council, Inc	CA	82,129
North County Interfaith Council, Inc	CA	43,588
North County Interfaith Council, Inc	CA	42,370
North County Interfaith Council, Inc	CA	346,689
North County Interfaith Council, Inc	CA	103,415
North County Solutions for Change	CA	783,158
North County Solutions for Change	CA	26,661
Northern Valley Catholic Social Service, Inc	CA	91,096
Northern Valley Catholic Social Service, Inc	CA	92,080
Northern Valley Catholic Social Service, Inc	CA	129,868
OC Partnership	CA	433,263
OC Partnership	CA	57,043
Ocean Park Community Center (OPCC)	CA	305,938

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Operation Dignty, Inc	CA	55,392
Orange Coast Interfaith Shelter	CA	283,129
Orange County Housing Authority	CA	426,648
Orange County Housing Authority	CA	3,233,916
Orange County Housing Authority	CA	524,424
Orange County Housing Authority	CA	1,050,864
Orange County Housing Authority	CA	996,480
Orange County Housing Authority	CA	649,872
Orange County Housing Authority	CA	281,280
Orange County Housing Authority	CA	727,608
Orange County Housing Authority	CA	571,176
Pacific Clinics	CA	960,122
Pajaro Valley Shelter Services	CA	13,623
PATH (People Assisting the Homeless)	CA	100,275
PATH (People Assisting the Homeless)	CA	610,000
PATH (People Assisting the Homeless)	CA	114,529
PATH (People Assisting the Homeless)	CA	209,161
PCDC-Applicant	CA	137,754
PCDC-Applicant	CA	163,700
PCDC-Applicant	CA	106,095
PCDC-Applicant	CA	122,097
PCDC-Applicant	CA	724,944
PCDC-Applicant	CA	115,320
PCDC-Applicant	CA	121,404
PCDC-Applicant	CA	53,256
PCDC-Applicant	CA	155,416
PCDC-Applicant	CA	55,632
PCDC-Applicant	CA	43,724
PCDC-Applicant	CA	235,695
Penny Lane Centers	CA	174,969
Placer County HHS Adult System of Care	CA	61,260
Placer County HHS Adult System of Care	CA	290,412
Placer County HHS Adult System of Care	CA	299,927
Placer Women's Center dba PEACE for Families	CA	217,898
Poor and the Homeless (PATH)__Final 2011	CA	111,173
Poverello House	CA	354,169
Project Home Again	CA	367,063
Project Understanding	CA	53,642
Rainbow Services, Ltd	CA	255,012
Redwood Community Action Agency	CA	118,074
Redwood Community Action Agency	CA	38,359
Regional Task Force on the Homeless Inc	CA	108,914
Regional Task Force on the Homeless Inc	CA	134,000
Regional Task Force on the Homeless Inc	CA	222,007
Regional Task Force on the Homeless Inc	CA	89,798
Renaissance Christian Center	CA	99,000
Resources for Community Development	CA	70,187
Resources for Community Development	CA	75,528
Resources for Independent Living	CA	97,876
Reynaissance Family Center	CA	41,650
Riverside City & County Proj Applicant	CA	80,591
Riverside City & County Proj Applicant	CA	218,484
Riverside City & County Proj Applicant	CA	59,440
Riverside City & County Proj Applicant	CA	325,277
Riverside City & County Proj Applicant	CA	216,871
Riverside City & County Proj Applicant	CA	233,015
Riverside City & County Proj Applicant	CA	646,847
Riverside City & County Proj Applicant	CA	24,134
Riverside City & County Proj Applicant	CA	533,405
Riverside City & County Proj Applicant	CA	275,000
Riverside City & County Proj Applicant	CA	523,800
Riverside City & County Proj Applicant	CA	408,234
Riverside City & County Proj Applicant	CA	135,756
Riverside City & County Proj Applicant	CA	72,654
Riverside City & County Proj Applicant	CA	260,498
Riverside City & County Proj Applicant	CA	200,277
Riverside City & County Proj Applicant	CA	350,857
Riverside City & County Proj Applicant	CA	218,000
Riverside City & County Proj Applicant	CA	476,070
Riverside City & County Proj Applicant	CA	42,192
Riverside City & County Proj Applicant	CA	117,127
Riverside City & County Proj Applicant	CA	136,166

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Riverside City & County Proj Applicant	CA	525,000
Riverside City & County Proj Applicant	CA	89,373
Riverside City & County Proj Applicant	CA	374,016
Riverside City & County Proj Applicant	CA	119,486
Rubicon Programs Inc	CA	191,195
Rubicon Programs Inc	CA	654,229
Rubicon Programs Inc	CA	44,013
Rubicon Programs Inc	CA	1,018,766
Rubicon Programs Inc	CA	94,500
Rubicon Programs Inc	CA	204,120
Saint Vincent de Paul Society of San Francisco	CA	131,153
Salvation Army	CA	102,008
Samaritan House	CA	105,000
San Benito, County of	CA	207,966
San Diego Housing Commission	CA	132,288
San Diego Housing Commission	CA	1,006,224
San Diego Housing Commission	CA	270,000
San Diego Housing Commission	CA	212,400
San Diego Housing Commission	CA	405,360
San Diego Housing Commission	CA	357,912
San Diego Youth Services	CA	87,571
San Francisco Network Ministries Housing Corporation	CA	70,006
San Joaquin County CoC Exhibit 2	CA	1,549,848
San Joaquin County CoC Exhibit 2	CA	141,253
San Joaquin County CoC Exhibit 2	CA	255,328
San Joaquin County CoC Exhibit 2	CA	206,157
San Joaquin County CoC Exhibit 2	CA	490,911
San Joaquin County CoC Exhibit 2	CA	398,821
San Joaquin County CoC Exhibit 2	CA	410,664
San Joaquin County CoC Exhibit 2	CA	231,595
San Joaquin County CoC Exhibit 2	CA	354,644
San Joaquin County CoC Exhibit 2	CA	373,488
SANTA BARBARA COMMUNITY HOUSING CORP	CA	99,444
Santa Barbara County—ADMHS	CA	115,315
Santa Barbara County Housing and Community Development	CA	125,189
Santa Barbara County Housing and Community Development	CA	102,809
Santa Barbara County Housing and Community Development	CA	160,585
Santa Barbara County Housing and Community Development	CA	17,850
Santa Clara Unified School District	CA	200,534
Santa Clara Valley Health & Hospital System—MHD	CA	723,114
Santa Clara Valley Health & Hospital System—MHD	CA	351,150
Santa Clara Valley Health & Hospital System—MHD	CA	102,992
Santa Clara Valley Health & Hospital System—MHD	CA	514,196
Santa Cruz Community Counseling Center	CA	15,353
Santa Cruz Community Counseling Center	CA	41,540
Serra Ancillary Care Corp dba The Serra Project	CA	303,173
Serra Ancillary Care Corp dba The Serra Project	CA	326,848
Service League of San Mateo County	CA	44,996
Serving People in Need	CA	403,208
Shelter Network of San Mateo County	CA	52,500
Shelter Network of San Mateo County	CA	494,788
Shelter Network of San Mateo County	CA	215,000
Shelter Network of San Mateo County	CA	381,471
Shelter Network of San Mateo County	CA	131,250
Shelter Network of San Mateo County	CA	104,895
Shelter Network of San Mateo County	CA	74,078
Shelter Network of San Mateo County	CA	225,750
Shelter Network of San Mateo County	CA	131,250
Shelter Outreach Plus	CA	166,599
Shelter Outreach Plus	CA	115,999
Shelter Outreach Plus	CA	121,832
Shelter, Inc of Contra Costa County	CA	80,797
Shelter, Inc of Contra Costa County	CA	272,508
Shelter, Inc of Contra Costa County	CA	676,523
Shelter, Inc of Contra Costa County	CA	393,705
Shields For Families	CA	90,395
Sierra Saving Grace Homeless Project	CA	76,953
Single Room Occupancy (SRO) Housing Corporation	CA	92,610
Single Room Occupancy (SRO) Housing Corporation	CA	369,601
Single Room Occupancy (SRO) Housing Corporation	CA	279,510
Social Advocates for Youth	CA	40,000
Solano County Health & Social Services	CA	80,502

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Solano County Health & Social Services	CA	109,925
Solano County Health & Social Services	CA	102,317
Solano County Health & Social Services	CA	199,246
Sonoma County Community Development Commission	CA	82,800
Sonoma County Community Development Commission	CA	196,776
Sonoma County Community Development Commission	CA	135,329
Sonoma County Community Development Commission	CA	67,176
Sonoma County Community Development Commission	CA	723,648
South Bay Community Services, Inc	CA	96,832
South Bay Community Services, Inc	CA	86,951
South Bay Community Services, Inc	CA	96,843
South Central Health & Rehabilitation Program	CA	225,479
South County Housing Corporation	CA	91,011
South County Outreach	CA	50,191
South County Outreach	CA	175,959
Southern California Alcohol and Drug Programs, Inc	CA	380,345
Southern California Alcohol and Drug Programs, Inc—Angel Step Too	CA	355,942
St. Joseph Center	CA	47,246
St. Joseph's Family Center	CA	287,217
St. Joseph's Family Center	CA	364,804
St. Vincent de Paul Village, Inc	CA	513,712
St. Vincent de Paul Village, Inc	CA	45,099
St. Vincent de Paul Village, Inc	CA	402,182
St. Vincent de Paul Village, Inc	CA	890,000
St. Vincent de Paul Village, Inc	CA	619,024
St. Vincent de Paul Village, Inc	CA	1,699,096
STAND! For Families Free of Violence	CA	75,571
Stanislaus Community Assistance Project	CA	190,017
Stanislaus Community Assistance Project	CA	269,056
Stanislaus Community Assistance Project	CA	156,929
Stanislaus Community Assistance Project	CA	118,333
Step Up on Second Street, Inc	CA	126,727
Su Casa ~ Ending Domestic Violence	CA	52,463
Swords to Plowshares Veterans Rights Organization	CA	230,181
Swords to Plowshares Veterans Rights Organization	CA	251,665
Tarzana Treatment Centers, Inc	CA	188,491
Testimonial Community Love Center	CA	136,887
The Association For Community Housing Solutions (TACHS)	CA	73,500
The Association For Community Housing Solutions (TACHS)	CA	113,400
the john henry foundation	CA	146,369
The Los Angeles Gay and Lesbian Community Services Center	CA	367,493
The Resource Connection	CA	78,948
The Salvation Army	CA	426,301
The Salvation Army	CA	158,521
The Salvation Army (Watsonville)	CA	83,137
The Salvation Army SC Division Glendale Nancy Painter House	CA	86,437
The Salvation Army SC Division Los Angeles	CA	360,500
The Salvation Army SC Division Los Angeles	CA	221,485
The Salvation Army SC Division Los Angeles	CA	172,089
The Salvation Army SC Division Los Angeles	CA	276,039
The Salvation Army SC Division Los Angeles	CA	174,133
The Salvation Army SC Division Los Angeles	CA	360,500
The Salvation Army SC Division Los Angeles	CA	169,948
The Salvation Army SC Division Los Angeles	CA	218,221
The Salvation Army SC Division Ventura TLC	CA	204,637
The Salvation Army, Grass Valley Corps	CA	40,000
The Salvation Army, Modesto	CA	100,000
Time For Change Foundation	CA	348,598
Toby's House	CA	119,545
Transition House	CA	61,763
Transition House	CA	55,792
TRANSITIONAL HOMELESS FAMILY SHELTER	CA	87,833
Transitional Living and Community Support, Inc	CA	305,666
Transitional Living and Community Support, Inc	CA	256,849
Transitional Living and Community Support, Inc	CA	246,855
Transitional Living and Community Support, Inc	CA	335,725
Transitional Living and Community Support, Inc	CA	165,403
Transitional Living and Community Support, Inc	CA	72,384
Tuolumne County Human Services Agency	CA	29,617
Turning Point Community Programs	CA	97,292
Turning Point Community Programs	CA	114,165
Turning Point Foundation	CA	249,999

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Turning Point Foundation	CA	31,361
Turning Point Foundation	CA	26,075
Turning Point Foundation	CA	35,410
Turning Point of Central California, Inc	CA	424,116
Turning Point of Central California, Inc	CA	524,585
Turning Point of Central California, Inc	CA	74,602
Turning Point of Central California, Inc	CA	117,277
Turning Point of Central California, Inc	CA	174,276
Turning Point of Central California, Inc	CA	173,564
United Christian Centers of The Greater Sacramento Area, Inc	CA	46,527
United Friends of the Children	CA	295,657
United States Veterans Initiative-Inglewood	CA	289,795
United States Veterans Initiative-Inland Empire	CA	1,031,955
United Way of Tulare County	CA	91,545
United Way of Ventura County	CA	44,541
United Way of Ventura County	CA	44,541
Upward Bound House	CA	281,424
Vallejo Lord's Fellowship A/G	CA	42,600
Vallejo Lord's Fellowship A/G	CA	33,112
Valley Teen Ranch	CA	30,048
Venice Community Housing Corporation	CA	81,170
Venice Family Clinic	CA	284,842
Ventura County Behavioral Health Department	CA	201,876
Ventura County Behavioral Health Department	CA	40,644
Veterans First	CA	213,187
Veterans First	CA	159,700
Veterans First	CA	254,804
Veterans First	CA	211,664
Veterans Transition Center	CA	81,010
Veterans Transition Center	CA	194,525
Victor Valley Domestic Violence, Inc	CA	283,537
Vietnam Veterans of California	CA	83,107
Vietnam Veterans of San Diego	CA	209,600
Vietnam Veterans of San Diego	CA	202,850
Volunteers of America Southwest CA	CA	301,164
Volunteers of America Southwest CA	CA	298,453
We Care Program—Turlock	CA	95,702
Weingart Center Association	CA	314,478
Weingart Center Association	CA	170,760
West Valley Community Services of Santa Clara County, Inc	CA	82,533
WestCare California, Inc	CA	663,583
Whiteside Manor, Inc	CA	884,051
WISEPlace	CA	100,593
WomanHaven, Inc	CA	169,864
Women's Daytime Drop-In Center	CA	68,975
Women's Transitional Living Center, Inc	CA	74,559
Women's Transitional Living Center, Inc	CA	42,083
YMCA of Metropolitan Los Angeles	CA	177,486
YMCA of San Diego County	CA	178,739
Yolo Community Care Continuum	CA	84,423
YWCA of Central Orange County	CA	93,880
YWCA of San Diego County	CA	553,691
YWCA Sonoma County	CA	52,500
Boulder Housing Partners	CO	274,260
Boulder Housing Partners	CO	29,903
Catholic Charities and Community Services of the Archdiocese of Denver	CO	59,267
City of Colorado Springs	CO	35,940
City of Colorado Springs	CO	66,267
City of Colorado Springs	CO	165,216
Colorado Coalition for the Homeless	CO	619,334
Colorado Coalition for the Homeless	CO	479,236
Colorado Coalition for the Homeless	CO	137,292
Colorado Coalition for the Homeless	CO	526,250
Colorado Coalition for the Homeless	CO	78,500
Colorado Coalition for the Homeless	CO	457,654
Colorado Coalition for the Homeless	CO	132,768
Colorado Coalition for the Homeless	CO	319,609
Colorado Coalition for the Homeless	CO	437,248
Colorado Coalition for the Homeless	CO	48,548
Colorado Coalition for the Homeless	CO	289,760
Colorado Coalition for the Homeless	CO	19,415
Colorado Coalition for the Homeless	CO	413,642

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Colorado Coalition for the Homeless	CO	690,000
Colorado Coalition for the Homeless	CO	19,151
Colorado Coalition for the Homeless	CO	60,529
Colorado Coalition for the Homeless	CO	507,627
Colorado Coalition for the Homeless	CO	108,293
Colorado Coalition for the Homeless	CO	85,521
Colorado Coalition for the Homeless	CO	228,382
Colorado Coalition for the Homeless	CO	40,320
Colorado Coalition for the Homeless	CO	84,135
Colorado Coalition for the Homeless	CO	114,994
Colorado Coalition for the Homeless	CO	146,856
Colorado Coalition for the Homeless	CO	341,335
Colorado Coalition for the Homeless	CO	73,821
Colorado Coalition for the Homeless	CO	117,967
Colorado Coalition for the Homeless	CO	107,439
Colorado Coalition for the Homeless	CO	109,944
Colorado Coalition for the Homeless	CO	91,065
Colorado Coalition for the Homeless	CO	276,339
Colorado Coalition for the Homeless	CO	198,187
Colorado Coalition for the Homeless	CO	182,725
Colorado Coalition for the Homeless	CO	210,430
Colorado Coalition for the Homeless	CO	132,363
Colorado Coalition for the Homeless	CO	184,889
Colorado Division of Housing	CO	2,530,164
Colorado Division of Housing	CO	360,960
Colorado Division of Housing	CO	464,856
Colorado Springs Housing Authority	CO	93,444
Community Housing Services, Inc	CO	970,595
Del Norte NDC	CO	131,136
Denver Department of Human Services	CO	101,520
Denver Department of Human Services	CO	152,280
Denver Department of Human Services	CO	259,920
Denver Department of Human Services	CO	66,816
Denver Department of Human Services	CO	134,496
Denver Department of Human Services	CO	302,592
Denver Department of Human Services	CO	346,860
Denver Department of Human Services	CO	423,564
Denver Department of Human Services	CO	101,520
Denver Department of Human Services	CO	33,840
Denver Department of Human Services	CO	169,200
Denver Department of Human Services	CO	844,080
Denver Department of Human Services	CO	120,708
Denver Options Inc	CO	25,000
Denver Options Inc	CO	154,936
Family Tree, Inc	CO	397,061
Family Tree, Inc	CO	80,085
Fort Collins Housing Authority	CO	258,980
Grand Valley Catholic Outreach, Inc	CO	99,477
Grand Valley Catholic Outreach, Inc	CO	84,165
Grand Valley Catholic Outreach, Inc	CO	97,151
Greccio Housing	CO	64,315
Greeley Center for Independence, Inc	CO	30,893
Housing Solutions for the Southwest	CO	19,008
Larimer Center for Mental Health	CO	54,827
North Range Behavioral Health	CO	109,543
Partners In Housing	CO	47,998
Partners In Housing	CO	32,510
Partners In Housing	CO	24,149
Partners In Housing	CO	88,784
Partners In Housing	CO	90,330
Partners In Housing	CO	50,710
Partners In Housing	CO	81,838
Pikes Peak United Way	CO	196,776
Posada, Inc	CO	249,900
St. Francis Center	CO	146,666
The Salvation Army, a California corporation	CO	107,000
The Salvation Army, a California corporation	CO	59,333
The Salvation Army, a California corporation	CO	19,050
Third Way Center	CO	116,538
Urban Peak Denver	CO	104,160
Volunteers of America Colorado Branch	CO	298,484
Volunteers of America Colorado Branch	CO	166,245

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Volunteers of America Colorado Branch	CO	514,783
Alliance for Living	CT	75,678
Alliance for Living	CT	34,311
Alliance for Living	CT	34,083
Applied Behavioral Rehabilitation Institute, Inc	CT	99,878
Association of Religious Communities	CT	73,489
Bethsaida Community, Inc	CT	86,984
Bethsaida Community, Inc	CT	87,528
Birmingham Group Health Services	CT	133,633
Birmingham Group Health Services	CT	116,928
Catholic Charities of Fairfield County, Inc	CT	202,514
Catholic Charities of Fairfield County, Inc	CT	381,026
Christian Community Action, Inc	CT	200,025
Chrysalis Center, Inc	CT	211,747
Columbus House, Inc	CT	195,521
Columbus House, Inc	CT	111,132
Columbus House, Inc	CT	133,000
Columbus House, Inc	CT	30,902
Community Health Resources	CT	140,018
Community Health Resources	CT	107,184
Community Mental Health Affiliates	CT	197,940
Community Renewal Team, Inc (CRT)	CT	202,885
Community Renewal Team, Inc (CRT)	CT	369,918
Community Renewal Team, Inc (CRT)	CT	576,997
Community Renewal Team, Inc (CRT)	CT	207,117
Community Renewal Team, Inc (CRT)	CT	475,913
Connecticut Coalition to End Homelessness	CT	33,089
Connecticut Coalition to End Homelessness	CT	58,065
Connecticut Coalition to End Homelessness	CT	49,999
Connecticut Coalition to End Homelessness	CT	55,860
Connecticut Department of Mental Health and Addiction Services	CT	195,216
Connecticut Department of Mental Health and Addiction Services	CT	152,820
Connecticut Department of Mental Health and Addiction Services	CT	114,080
Connecticut Department of Mental Health and Addiction Services	CT	192,000
Connecticut Department of Mental Health and Addiction Services	CT	75,600
Connecticut Department of Mental Health and Addiction Services	CT	120,128
Connecticut Department of Mental Health and Addiction Services	CT	129,324
Connecticut Department of Mental Health and Addiction Services	CT	107,424
Connecticut Department of Mental Health and Addiction Services	CT	300,300
Connecticut Department of Mental Health and Addiction Services	CT	226,656
Connecticut Department of Mental Health and Addiction Services	CT	177,828
Connecticut Department of Mental Health and Addiction Services	CT	157,140
Connecticut Department of Mental Health and Addiction Services	CT	1,382,916
Connecticut Department of Mental Health and Addiction Services	CT	193,572
Connecticut Department of Mental Health and Addiction Services	CT	213,379
Connecticut Department of Mental Health and Addiction Services	CT	209,340
Connecticut Department of Mental Health and Addiction Services	CT	270,939
Connecticut Department of Mental Health and Addiction Services	CT	75,600
Connecticut Department of Mental Health and Addiction Services	CT	343,032
Connecticut Department of Mental Health and Addiction Services	CT	153,972
Connecticut Department of Mental Health and Addiction Services	CT	170,160
Connecticut Department of Mental Health and Addiction Services	CT	1,919,928
Connecticut Department of Mental Health and Addiction Services	CT	430,920
Connecticut Department of Mental Health and Addiction Services	CT	163,008
Connecticut Department of Mental Health and Addiction Services	CT	14,292
Connecticut Department of Mental Health and Addiction Services	CT	129,792
Connecticut Department of Mental Health and Addiction Services	CT	89,532
Connecticut Department of Mental Health and Addiction Services	CT	237,344
Connecticut Department of Mental Health and Addiction Services	CT	128,520
Connecticut Department of Mental Health and Addiction Services	CT	80,568
Connecticut Department of Mental Health and Addiction Services	CT	51,048
Connecticut Department of Mental Health and Addiction Services	CT	1,696,584
Connecticut Department of Mental Health and Addiction Services	CT	100,887
Connecticut Department of Mental Health and Addiction Services	CT	489,744
Connecticut Department of Mental Health and Addiction Services	CT	216,468
Connecticut Department of Mental Health and Addiction Services	CT	474,516
Connecticut Department of Mental Health and Addiction Services	CT	181,272
Connecticut Department of Mental Health and Addiction Services	CT	513,180
Connecticut Department of Mental Health and Addiction Services	CT	140,880
Connecticut Department of Mental Health and Addiction Services	CT	30,240
Connecticut Department of Mental Health and Addiction Services	CT	80,568
Connecticut Department of Mental Health and Addiction Services	CT	416,863

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Connecticut Department of Mental Health and Addiction Services	CT	201,912
Connecticut Department of Mental Health and Addiction Services	CT	547,692
Connecticut Department of Mental Health and Addiction Services	CT	61,128
CREDO Housing Development Corporation Inc	CT	56,358
CT Women's Consortium, Inc	CT	173,249
CTE Inc	CT	132,882
Emerge, Inc	CT	44,890
Family and Children's Agency	CT	146,176
Friendship Service Center of New Britain, Inc	CT	31,658
Friendship Service Center of New Britain, Inc	CT	49,596
Friendship Service Center of New Britain, Inc	CT	210,007
Friendship Service Center of New Britain, Inc	CT	48,136
Friendship Service Center of New Britain, Inc	CT	48,059
Friendship Service Center of New Britain, Inc	CT	384,203
Friendship Service Center of New Britain, Inc	CT	87,721
Hall-Brooke Behavioral Health Services	CT	938,078
Hall-Brooke Behavioral Health Services	CT	200,406
Hall-Brooke Behavioral Health Services	CT	309,029
Harbor Health Services, Inc	CT	62,084
Harbor Health Services, Inc	CT	16,461
Holy Family Home and Shelter, Inc	CT	125,631
Housing Authority of the City of Danbury	CT	214,380
Housing Authority of the City of Danbury	CT	142,920
Housing Authority of the City of Waterbury	CT	277,356
Housing Authority of the City of Waterbury	CT	190,344
Housing Authority of the City of Waterbury	CT	92,664
Housing Authority of the City of Waterbury	CT	242,760
Immaculate Conception Shelter & Housing Corporation	CT	98,000
Immaculate Conception Shelter & Housing Corporation	CT	602,466
InterCommunity Mental Health Group Inc	CT	224,057
Interfaith Housing Association of Westport/Weston, Inc	CT	51,288
KILLINGLY HOUSING AUTHORITY	CT	49,740
Laurel House, Inc	CT	109,405
Laurel House, Inc	CT	40,278
Laurel House, Inc	CT	19,703
Liberation Programs, Inc	CT	179,626
Liberty Community Services, Inc	CT	94,352
Liberty Community Services, Inc	CT	292,500
Liberty Community Services, Inc	CT	1,049,464
Mercy Housing and Shelter Corporation	CT	241,190
Mercy Housing and Shelter Corporation	CT	97,757
Micah Housing, Inc	CT	147,410
Mid Fairfield AIDS Project, Inc	CT	123,200
Mid Fairfield AIDS Project, Inc	CT	24,700
Mid Fairfield AIDS Project, Inc	CT	24,748
Mutual Housing Association of Southwestern Connecticut, Inc	CT	165,900
My Sisters' Place, Inc	CT	249,999
New London Homeless Hospitality Center, Inc	CT	32,520
New Opportunities, Inc	CT	39,285
New Opportunities, Inc	CT	374,784
Norwalk Emergency Shelter, Inc	CT	47,830
Norwalk Housing Authority	CT	169,800
Operation Hope of Fairfield, Inc	CT	95,855
Prudence Crandall Center, Inc	CT	187,950
Prudence Crandall Center, Inc	CT	184,999
Prudence Crandall Center, Inc	CT	147,288
Putnam Housing Authority	CT	59,688
Recovery Network of Programs, Inc	CT	261,196
ReFocus Outreach Ministry, Inc	CT	188,191
ReFocus Outreach Ministry, Inc	CT	143,220
Shelter for the Homeless, Inc	CT	19,835
Shelter for the Homeless, Inc	CT	84,051
South Park Inn, Inc	CT	284,288
St. Luke's Community Services, Inc	CT	19,838
St. Luke's Community Services, Inc	CT	398,715
St. Luke's Community Services, Inc	CT	19,724
St. Philip House	CT	165,569
St. Vincent DePaul Mission of Bristol, Inc	CT	321,830
St. Vincent DePaul Mission of Bristol, Inc	CT	27,018
St. Vincent DePaul Mission of Waterbury, Inc	CT	293,325
St. Vincent DePaul Place, Middletown	CT	11,879
St. Vincent DePaul Place, Middletown	CT	112,303

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
St. Vincent DePaul Place, Middletown	CT	11,894
Thames River Community Service Inc	CT	195,983
The Connection, Inc	CT	137,094
The Salvation Army, a New York Corporation	CT	73,150
The Thames Valley Council for Community Action, Inc	CT	673,047
Torrington Community Housing Corporation	CT	95,735
Torrington Housing Authority	CT	162,000
Torrington Housing Authority	CT	75,600
United Way of Coastal Fairfield County	CT	39,999
United Way of Coastal Fairfield County	CT	113,654
Windham Regional Community Council	CT	140,145
Windham Regional Community Council	CT	279,758
Women's Center of Southeastern Connecticut, Inc	CT	50,584
Youth Continuum	CT	304,160
YWCA of the Hartford Region, Inc	CT	166,666
Catholic Charities of the Archdiocese of Washington, DC	DC	432,844
Coalition for the Homeless	DC	171,453
Community Connections, Inc	DC	98,751
Community Connections, Inc	DC	106,863
Community Family Life Services	DC	140,205
District of Columbia CoC	DC	100,905
District of Columbia CoC	DC	899,866
District of Columbia CoC	DC	148,924
District of Columbia CoC	DC	109,725
District of Columbia CoC	DC	414,028
District of Columbia CoC	DC	110,674
District of Columbia CoC	DC	239,506
District of Columbia CoC	DC	622,091
District of Columbia CoC	DC	257,260
District of Columbia CoC	DC	132,300
District of Columbia CoC	DC	592,184
District of Columbia CoC	DC	78,342
District of Columbia CoC	DC	117,600
District of Columbia CoC	DC	275,106
District of Columbia CoC	DC	188,312
District of Columbia CoC	DC	149,203
District of Columbia CoC	DC	245,421
District of Columbia CoC	DC	141,214
District of Columbia CoC	DC	181,025
District of Columbia CoC	DC	75,000
District of Columbia CoC	DC	285,457
District of Columbia CoC	DC	102,199
District of Columbia CoC	DC	141,366
District of Columbia CoC	DC	143,742
District of Columbia CoC	DC	211,621
District of Columbia CoC	DC	144,758
District of Columbia CoC	DC	350,173
District of Columbia CoC	DC	123,530
District of Columbia CoC	DC	189,000
District of Columbia CoC	DC	121,727
District of Columbia CoC	DC	204,747
District of Columbia CoC	DC	150,000
District of Columbia CoC	DC	477,676
District of Columbia CoC	DC	134,834
District of Columbia CoC	DC	86,003
District of Columbia CoC	DC	430,837
District of Columbia CoC	DC	165,819
District of Columbia CoC	DC	420,000
District of Columbia CoC	DC	39,375
District of Columbia CoC	DC	425,773
District of Columbia CoC	DC	201,038
District of Columbia CoC	DC	955,500
District of Columbia CoC	DC	541,313
District of Columbia Department of Health HIV/AIDS Administration	DC	337,752
District of Columbia Department of Health HIV/AIDS Administration	DC	254,976
District of Columbia Department of Human Services	DC	938,784
District of Columbia Department of Human Services	DC	3,234,924
Families Forward, Inc	DC	207,041
Families Forward, Inc	DC	234,862
Hannah House	DC	148,115
House of Ruth	DC	321,806
House of Ruth	DC	144,083

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
House of Ruth	DC	114,586
House of Ruth	DC	84,383
Pathways to Housing DC	DC	514,025
Sasha Bruce Youthwork, Inc	DC	129,593
Sasha Bruce Youthwork, Inc	DC	189,057
Sasha Bruce Youthwork, Inc	DC	67,628
SOME, Inc	DC	323,673
SOME, Inc	DC	513,940
SOME, Inc	DC	101,333
The Harbor Light Center	DC	475,935
Transitional Housing Corporation	DC	127,720
Connections Community Support Programs Inc	DE	212,970
Connections Community Support Programs Inc	DE	145,572
Connections Community Support Programs Inc	DE	152,421
Connections Community Support Programs Inc	DE	539,231
Connections Community Support Programs Inc	DE	149,429
Connections Community Support Programs Inc	DE	399,128
Connections Community Support Programs Inc	DE	228,512
Connections Community Support Programs Inc	DE	298,324
Connections Community Support Programs Inc	DE	145,580
Connections Community Support Programs Inc	DE	300,557
Connections Community Support Programs Inc	DE	249,240
DHSS/Div. Substance Abuse and Mental Health	DE	128,049
DHSS/Div. Substance Abuse and Mental Health	DE	26,596
Homeless Planning Council of Delaware	DE	95,000
The Ministry of Caring Inc	DE	374,174
The Ministry of Caring Inc	DE	212,357
The Ministry of Caring Inc	DE	200,408
The Ministry of Caring Inc	DE	145,034
The Ministry of Caring Inc	DE	129,874
The Ministry of Caring Inc	DE	45,612
The Ministry of Caring Inc	DE	66,467
The Ministry of Caring Inc	DE	647,696
West End Neighborhood House	DE	252,207
YWCA Delaware Inc	DE	323,967
2-1-1 Brevard, Inc	FL	76,751
211 palm beach/treasure coast	FL	155,077
2-1-1 Tampa Bay Cares, Inc	FL	100,452
2-1-1 Tampa Bay Cares, Inc	FL	172,454
A.H. of Monroe County, Inc (AIDS Help)	FL	23,900
Ace Opportunities, Inc	FL	111,495
Adopt-A-Family of the Palm Beaches, Inc	FL	207,038
Adopt-A-Family of the Palm Beaches, Inc	FL	207,811
Agency for Community Treatment Services, Inc (ACTS)	FL	403,035
Agency for Community Treatment Services, Inc (ACTS)	FL	133,334
Agency for Community Treatment Services, Inc (ACTS)	FL	171,597
Agency for Community Treatment Services, Inc (ACTS)	FL	50,400
Agency for Community Treatment Services, Inc (ACTS)	FL	114,483
Agency for Community Treatment Services, Inc (ACTS)	FL	182,305
Agency for Community Treatment Services, Inc (ACTS)	FL	246,327
Agency for Community Treatment Services, Inc (ACTS)	FL	93,181
Agency for Community Treatment Services, Inc (ACTS)	FL	168,190
Aid to Victims of Domestic Abuse, Inc	FL	106,540
Alachua County Housing Authority	FL	8,965
Alachua County Housing Authority	FL	80,569
Alpha House of Pinellas County	FL	69,888
Alpha House of Tampa, Inc	FL	229,051
Another Way, Inc	FL	23,689
Another Way, Inc	FL	27,244
Boley Centers, Inc	FL	133,928
Boley Centers, Inc	FL	64,344
Boley Centers, Inc	FL	77,362
Boley Centers, Inc	FL	356,438
Boley Centers, Inc	FL	253,778
Boley Centers, Inc	FL	468,792
Boley Centers, Inc	FL	147,459
Boley Centers, Inc	FL	82,554
Boley Centers, Inc	FL	142,143
Boley Centers, Inc	FL	581,560
Boley Centers, Inc	FL	183,840
Brookwood Florida-Central, Inc	FL	98,430
Broward County Board of County Commissioners	FL	964,262

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Broward County Board of County Commissioners	FL	1,161,180
Broward County Board of County Commissioners	FL	413,424
Broward County Board of County Commissioners	FL	877,344
Broward County Board of County Commissioners	FL	252,132
Broward County Board of County Commissioners	FL	272,688
Broward County Board of County Commissioners	FL	245,237
Broward County Board of County Commissioners	FL	288,229
Broward County Board of County Commissioners	FL	948,025
Broward County Board of County Commissioners	FL	421,488
Broward County Board of County Commissioners	FL	284,042
Broward County Board of County Commissioners	FL	346,049
Broward County Board of County Commissioners	FL	246,891
Broward County Board of County Commissioners	FL	388,548
Broward County Housing Authority	FL	1,302,132
Capital City Youth Services, Inc	FL	165,727
Carrfour Supportive Housing	FL	409,479
CASA (Community Action Stops Abuse, Inc)	FL	241,031
Catholic Charities Diocese of St. Petersburg, Inc	FL	169,927
Catholic Charities Housing, Inc	FL	300,895
Catholic Charities of the Archdiocese of Miami, Inc	FL	172,516
Catholic Charities, Diocese of Venice, Inc	FL	120,137
Catholic Charities, Diocese of Venice, Inc	FL	79,166
Charlotte County Homeless Coalition, Inc	FL	26,707
Charlotte County Homeless Coalition, Inc	FL	40,333
Charlotte County Homeless Coalition, Inc	FL	49,395
Children's Home Society of Florida	FL	129,156
Citrus County Housing Services	FL	130,560
City of Bradenton	FL	150,876
Clara White Mission, Inc	FL	132,038
Coalition for the Homeless of Pasco County, Inc	FL	33,806
Coalition for the Homeless of Pasco County, Inc	FL	20,000
Coalition for the Hungry and Homeless of Brevard County, Inc	FL	4,810
Coalition for the Hungry and Homeless of Brevard County, Inc	FL	171,054
Coalition for the Hungry and Homeless of Brevard County, Inc	FL	137,327
Coalition for the Hungry and Homeless of Brevard County, Inc	FL	151,788
Coalition for the Hungry and Homeless of Brevard County, Inc	FL	230,453
Columbia, Hamilton, Lafayette, Suwannee Counties CoC	FL	32,146
Community Connections of Jacksonville, Inc	FL	228,950
Community Connections of Jacksonville, Inc	FL	162,380
Community Connections of Jacksonville, Inc	FL	532,794
Covenant House Florida	FL	185,329
Crosswinds Youth Services, Inc	FL	88,088
Directions for Mental Health, Inc	FL	137,761
Domestic Abuse Council, Inc	FL	62,815
Domestic Abuse Council, Inc	FL	125,488
Domestic Abuse Council, Inc	FL	70,498
Emergency Services and Homeless Coalition of Jacksonville, Inc	FL	64,374
Emergency Services and Homeless Coalition of Jacksonville, Inc	FL	75,042
Emergency Services and Homeless Coalition of Jacksonville, Inc	FL	463,275
Escarosa Coalition on the Homeless, Inc	FL	108,273
Escarosa Coalition on the Homeless, Inc	FL	18,892
Escarosa Coalition on the Homeless, Inc	FL	31,342
ESHC of St. Johns County	FL	62,790
ESHC of St. Johns County	FL	55,864
ESHC of St. Johns County	FL	89,610
Family Renew Community, Inc	FL	19,045
Family Renew Community, Inc	FL	52,980
FL-504 Project	FL	54,566
FL-504 Project	FL	85,286
Flagler Ecumenical Social Service Center, Inc dba Family Life Center	FL	73,167
Florida Keys Outreach Coalition	FL	175,879
Florida Keys Outreach Coalition	FL	28,071
Fort Walton Beach, Okaloosa Walton Counties Continuum of Care	FL	197,249
Fort Walton Beach, Okaloosa Walton Counties Continuum of Care	FL	61,853
Fort Walton Beach, Okaloosa Walton Counties Continuum of Care	FL	34,146
Fort Walton Beach, Okaloosa Walton Counties Continuum of Care	FL	327,898
Ft Myers/Cape Coral/Lee County CoC	FL	119,722
Ft Myers/Cape Coral/Lee County CoC	FL	13,125
Ft Myers/Cape Coral/Lee County CoC	FL	74,292
Ft Myers/Cape Coral/Lee County CoC	FL	1,286,206
Ft Myers/Cape Coral/Lee County CoC	FL	122,604
Ft Myers/Cape Coral/Lee County CoC	FL	180,510

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Ft Myers/Cape Coral/Lee County CoC	FL	68,748
Ft Myers/Cape Coral/Lee County CoC	FL	89,668
Ft Myers/Cape Coral/Lee County CoC	FL	32,777
Ft Myers/Cape Coral/Lee County CoC	FL	52,978
Ft Myers/Cape Coral/Lee County CoC	FL	89,733
Ft Myers/Cape Coral/Lee County CoC	FL	100,404
Gainesville Housing Authority	FL	143,220
Gainesville Housing Authority	FL	87,912
Gateway Community Services, Inc	FL	54,727
Gateway Community Services, Inc	FL	61,705
Goodwill of North Florida	FL	284,588
Gulfstream Goodwill Industries, Inc	FL	134,036
Gulfstream Goodwill Industries, Inc	FL	410,548
Gulfstream Goodwill Industries, Inc	FL	990,218
Haven Recovery Center, Inc	FL	60,249
Haven Recovery Center, Inc	FL	171,920
Haven Recovery Center, Inc	FL	191,250
Haven Recovery Center, Inc	FL	129,273
Haven Recovery Center, Inc	FL	23,012
Haven Recovery Center, Inc	FL	45,858
Highlands County Coalition for the Homeless, Inc	FL	33,344
Homeless Coalition of Hillsborough County, Inc	FL	278,843
Homeless Coalition of Hillsborough County, Inc	FL	44,191
Homeless Coalition of Hillsborough County, Inc	FL	513,702
Homeless Coalition of Polk County, Inc	FL	116,531
Homeless Emergency Project, Inc	FL	60,850
Homeless Emergency Project, Inc	FL	71,000
Homeless Emergency Project, Inc	FL	33,101
Homeless Services Network of Central Florida	FL	283,455
Homeless Services Network of Central Florida	FL	118,324
Homeless Services Network of Central Florida	FL	92,809
Homeless Services Network of Central Florida	FL	123,134
Homeless Services Network of Central Florida	FL	136,832
Homeless Services Network of Central Florida	FL	94,852
Homeless Services Network of Central Florida	FL	123,553
Homeless Services Network of Central Florida	FL	78,352
Homeless Services Network of Central Florida	FL	363,480
Homeless Services Network of Central Florida	FL	121,949
Homeless Services Network of Central Florida	FL	48,999
Homeless Services Network of Central Florida	FL	168,345
Homeless Services Network of Central Florida	FL	52,500
Homeless Services Network of Central Florida	FL	210,000
Homeless Services Network of Central Florida	FL	81,885
Homeless Services Network of Central Florida	FL	42,105
Homeless Services Network of Central Florida	FL	118,542
Homeless Services Network of Central Florida	FL	175,988
Homeless Services Network of Central Florida	FL	98,043
Homeless Services Network of Central Florida	FL	37,203
Homeless Services Network of Central Florida	FL	96,448
Homeless Services Network of Central Florida	FL	120,298
Homeless Services Network of Central Florida	FL	172,647
Homeless Services Network of Central Florida	FL	61,950
Homeless Services Network of Central Florida	FL	181,989
Homeless Services Network of Central Florida	FL	185,600
Homeless Services Network of Central Florida	FL	51,747
Homeless Services Network of Central Florida	FL	124,388
Homeless Services Network of Central Florida	FL	156,661
Homeless Services Network of Central Florida	FL	269,745
Homeless Services Network of Central Florida	FL	147,787
Homeless Services Network of Central Florida	FL	92,302
Homeless Services Network of Central Florida	FL	127,839
Homeless Services Network of Central Florida	FL	84,630
HOPE Family Services, Inc	FL	25,862
HOPE Family Services, Inc	FL	67,680
Housing Authority of the City of Tampa	FL	175,056
Housing Authority of the City of Tampa	FL	168,360
Housing Authority of the City of Tampa	FL	183,840
Housing Partnership, Inc	FL	62,587
I.M. Sulzbacher Center for the Homeless, Inc	FL	237,169
I.M. Sulzbacher Center for the Homeless, Inc	FL	157,460
Indian River County Board of Commissioners	FL	153,444
Indian River County Board of Commissioners	FL	25,856

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Indian River County Board of Commissioners	FL	104,988
Indian River County Board of Commissioners	FL	58,000
Indian River County Board of Commissioners	FL	36,177
Indian River County Board of Commissioners	FL	69,048
Indian River County Board of Commissioners	FL	88,836
Indian River County Board of Commissioners	FL	70,063
Interfaith Ministries	FL	146,632
Jackie Richardson	FL	98,849
Jackie Richardson	FL	105,199
Jacksonville Housing Authority	FL	354,600
Jacksonville Housing Authority	FL	189,024
Jerome Golden Center for Behavioral Health, Inc	FL	137,615
Jerome Golden Center for Behavioral Health, Inc	FL	386,104
Jerome Golden Center for Behavioral Health, Inc	FL	132,255
Lakeview Center Incorporated	FL	307,887
Lakeview Center Incorporated	FL	105,777
Lakeview Center Incorporated	FL	158,701
LifeStream Behavioral Center	FL	62,160
Loaves & Fishes Soup Kitchen, Inc	FL	248,672
Martin County Board of Commissioners	FL	104,640
Martin County Board of Commissioners	FL	97,548
Martin County Board of Commissioners	FL	107,004
Mental Health Care, Inc	FL	199,500
Mental Health Care, Inc	FL	295,333
Mental Health Care, Inc	FL	839,791
Mental Health Care, Inc	FL	241,377
Mental Health Resource Center, Inc	FL	252,317
Meridian Behavioral Healthcare, Inc	FL	80,569
Meridian Behavioral Healthcare, Inc	FL	63,359
Miami-Dade County	FL	118,393
Miami-Dade County	FL	321,509
Miami-Dade County	FL	151,582
Miami-Dade County	FL	923,833
Miami-Dade County	FL	363,478
Miami-Dade County	FL	34,188
Miami-Dade County	FL	425,391
Miami-Dade County	FL	216,216
Miami-Dade County	FL	79,479
Miami-Dade County	FL	389,996
Miami-Dade County	FL	174,998
Miami-Dade County	FL	737,089
Miami-Dade County	FL	289,224
Miami-Dade County	FL	292,660
Miami-Dade County	FL	339,721
Miami-Dade County	FL	712,327
Miami-Dade County	FL	63,993
Miami-Dade County	FL	528,062
Miami-Dade County	FL	108,612
Miami-Dade County	FL	714,079
Miami-Dade County	FL	189,300
Miami-Dade County	FL	347,128
Miami-Dade County	FL	219,942
Miami-Dade County	FL	534,832
Miami-Dade County	FL	138,789
Miami-Dade County	FL	256,812
Miami-Dade County	FL	296,020
Miami-Dade County	FL	85,677
Miami-Dade County	FL	411,588
Miami-Dade County	FL	154,980
Miami-Dade County	FL	273,807
Miami-Dade County	FL	177,066
Miami-Dade County	FL	313,121
Miami-Dade County	FL	221,184
Miami-Dade County	FL	336,002
Miami-Dade County	FL	12,075
Miami-Dade County	FL	394,999
Miami-Dade County	FL	192,664
Miami-Dade County	FL	348,233
Miami-Dade County	FL	278,100
Miami-Dade County	FL	113,661
Miami-Dade County	FL	178,171
Miami-Dade County	FL	1,770,156

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Miami-Dade County	FL	106,992
Miami-Dade County	FL	756,756
Miami-Dade County	FL	162,929
Miami-Dade County	FL	124,621
Miami-Dade County	FL	111,240
Miami-Dade County	FL	434,726
Miami-Dade County	FL	46,964
Miami-Dade County	FL	125,000
Miami-Dade County	FL	852,655
Miami-Dade County	FL	251,071
Miami-Dade County	FL	33,957
Miami-Dade County	FL	892,989
Miami-Dade County	FL	421,296
Miami-Dade County	FL	338,376
Miami-Dade County	FL	150,685
Miami-Dade County	FL	540,540
Miami-Dade County	FL	639,348
Miami-Dade County	FL	158,095
Miami-Dade County	FL	129,138
Miami-Dade County	FL	265,248
Miami-Dade County	FL	158,448
Miami-Dade County	FL	53,112
Miami-Dade County	FL	348,014
Miami-Dade County	FL	215,001
Miami-Dade County	FL	149,891
Miami-Dade County	FL	84,000
Miami-Dade County	FL	40,533
Miami-Dade County	FL	687,505
Miami-Dade County	FL	357,790
Miami-Dade County	FL	445,464
Miami-Dade County	FL	469,380
Miami-Dade County	FL	311,678
Miami-Dade County	FL	376,666
Miami-Dade County	FL	333,720
Miami-Dade County	FL	124,996
Miami-Dade County	FL	879,311
Miami-Dade County	FL	222,480
Miami-Dade County	FL	262,174
Miami-Dade County	FL	1,231,524
Miami-Dade County	FL	57,668
Miami-Dade County	FL	580,020
Miami-Dade County	FL	169,798
Mid-Florida Homeless Coalition, Inc	FL	78,143
Monroe Association for Retarded Citizens, Inc	FL	102,268
Naples/Collier County CoC	FL	104,645
Ocala/Marion County CoC	FL	21,646
Ocala/Marion County CoC	FL	62,160
Ocala/Marion County CoC	FL	58,999
Orange County Government	FL	127,764
Orange County Government	FL	245,700
Orange County Government	FL	245,700
Osceola County Government	FL	400,140
Palm Beach County Board of County Commissioners	FL	370,176
Palm Beach County Board of County Commissioners	FL	442,158
Panama City/Bay, Jackson Counties Projects	FL	45,222
Pasco County Housing Authority	FL	294,960
Peace River Center for Personal Development, Inc	FL	184,688
Peace River Center for Personal Development, Inc	FL	99,574
Peaceful Paths Domestic Abuse Network, Inc	FL	46,500
Peaceful Paths Domestic Abuse Network, Inc	FL	84,974
Project Return, Inc	FL	153,956
Punta Gorda Housing Authority	FL	104,208
Religious Community Services	FL	110,054
River Region Human Services	FL	258,775
River Region Human Services	FL	140,025
Sarasota/Bradenton/Sarasota, Manatee Counties CoC	FL	75,691
SAWCC, Inc	FL	113,000
Seminole County Government	FL	235,872
SMA Behavioral Health Services, Inc	FL	45,198
St. Francis House, Inc	FL	79,800
St. Lucie County Board of County Commissioners	FL	141,888
St. Lucie County Board of County Commissioners	FL	289,680

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
St. Lucie County Board of County Commissioners	FL	142,452
St. Matthew's House, Inc	FL	113,116
Talbot House Ministries of Lakeland, Inc	FL	255,925
Talbot House Ministries of Lakeland, Inc	FL	47,374
Tallahassee/Leon County CoC	FL	345,538
Tallahassee/Leon County CoC	FL	71,379
Tallahassee/Leon County CoC	FL	311,104
Tallahassee/Leon County CoC	FL	76,231
Tallahassee/Leon County CoC	FL	73,215
The Center for Independent Living of North Florida, Inc, dba Ability1st	FL	156,078
The House of Israel, Inc	FL	118,939
The Lord's Place, Inc	FL	131,171
The Lord's Place, Inc	FL	182,984
The Lord's Place, Inc	FL	283,023
The Neighborhood Center of West Volusia	FL	100,000
The Salvation Army, a Georgia Corporation, for The Salvation Army of Sarasota	FL	170,432
The Salvation Army, a Georgia Corporation, for The Salvation Army, Tampa, FL	FL	244,745
The Salvation Army, a Georgia Corporation, for The Salvation Army, Tampa, FL	FL	144,467
The Salvation Army, a Georgia Corporation for The Salvation Army of Palm Beach County	FL	233,735
The Salvation Army, a Georgia Corporation, for The Salvation Army of Daytona Beach, FL	FL	71,045
The Salvation Army, a Georgia Corporation, for The Salvation Army of Lakeland, FL	FL	127,780
The Salvation Army, a Georgia Corporation, for The Salvation Army of Ocala, FL	FL	107,625
The Salvation Army, Fort Lauderdale	FL	603,641
The Spring of Tampa Bay, Inc	FL	177,557
Three Rivers Legal Services, Inc	FL	21,000
Tri-County Human Services, Inc	FL	76,052
Tri-County Human Services, Inc	FL	76,199
Volunteers of America of Florida, Inc	FL	344,110
Volunteers of America of Florida, Inc	FL	354,510
Volunteers of America of Florida, Inc	FL	698,113
Volunteers of America of Florida, Inc	FL	382,628
Volunteers of America of Florida, Inc	FL	125,789
Volunteers of America of Florida, Inc	FL	358,313
Volunteers of America of Florida, Inc	FL	217,549
WestCare GulfCoast-Florida, Inc	FL	273,000
Wilson House	FL	96,337
Young Women's Christian Association of Tampa Bay, Inc	FL	176,237
YWCA of Palm Beach County	FL	229,547
ACC Dept. of Human and Economic Development	GA	28,752
ACC Dept. of Human and Economic Development	GA	77,068
ACC Dept. of Human and Economic Development	GA	26,712
ACC Dept. of Human and Economic Development	GA	105,991
ACC Dept. of Human and Economic Development	GA	55,008
ACC Dept. of Human and Economic Development	GA	56,834
Action Ministries, Inc	GA	308,908
Action Ministries, Inc	GA	486,342
Action Ministries, Inc	GA	70,000
Action Ministries, Inc	GA	75,651
Advantage Behavioral Health Systems	GA	167,095
Asian American Resource Center	GA	157,408
Atlanta Center for Self Sufficiency, Inc	GA	60,344
Augusta Coc	GA	181,027
Buckhead Christian Ministry	GA	82,800
Calvary Refuge Center, Inc	GA	203,326
CaringWorks, Inc	GA	377,210
Chatham-Savannah Authority for the Homeless	GA	402,917
Citizens Against Violence, Inc	GA	265,464
City of Albany	GA	116,217
City of Augusta, Georgia	GA	34,545
City of Hinesville	GA	64,929
City of Savannah, Georgia	GA	574,560
Cobb Community Collaborative, Inc	GA	30,000
Colquitt County Serenity House Project, Inc	GA	198,902
Community Advanced Practice Nurses, Inc	GA	46,423
Community Advanced Practice Nurses, Inc	GA	18,517
Community Advanced Practice Nurses, Inc	GA	39,039
CSRA Economic Opportunity Authority, Inc	GA	122,198
Dalton-Whitfield Community Development Corporation	GA	31,058
DeKalb CSB	GA	193,732
Douglas County Community Services Board	GA	105,639
Economic Opportunity Authority for Savannah-Chatham County Area, Inc	GA	220,500
Families First, Inc	GA	172,492

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Fulton County Board of Commissioners	GA	211,368
Fulton County Board of Commissioners	GA	373,951
Fulton County Board of Commissioners	GA	405,000
Fulton County Board of Commissioners	GA	300,000
Fulton County Board of Commissioners	GA	686,487
Furniture Bank of Metro Atlanta, Inc	GA	70,009
Gateway Center	GA	157,728
Gateway Community Service Board	GA	282,000
Gateway Community Service Board	GA	340,247
Genesis Shelter, Inc	GA	136,500
Georgia Law Center on Homelessness & Poverty, Inc	GA	295,200
Georgia Coalition Against Domestic Violence	GA	91,072
Georgia Coalition Against Domestic Violence	GA	342,584
Georgia Housing & Finance Authority	GA	426,228
Georgia Housing & Finance Authority	GA	419,628
Georgia Housing & Finance Authority	GA	202,080
Georgia Housing & Finance Authority	GA	171,672
Georgia Housing & Finance Authority	GA	651,000
Georgia Housing & Finance Authority	GA	262,788
Georgia Housing & Finance Authority	GA	168,648
Georgia Housing & Finance Authority	GA	277,560
Georgia Housing & Finance Authority	GA	224,040
Georgia Housing & Finance Authority	GA	159,528
Georgia Housing & Finance Authority	GA	179,016
Georgia Housing & Finance Authority	GA	234,864
Georgia Housing & Finance Authority	GA	684,000
Georgia Housing & Finance Authority	GA	206,472
Georgia Housing & Finance Authority	GA	454,200
Georgia Housing & Finance Authority	GA	89,916
Georgia Housing & Finance Authority	GA	167,688
Georgia Housing & Finance Authority	GA	167,760
Georgia Housing & Finance Authority	GA	32,160
Georgia Housing & Finance Authority	GA	161,436
Georgia Housing & Finance Authority	GA	231,792
Georgia Housing & Finance Authority	GA	182,748
Georgia Housing & Finance Authority	GA	314,400
Georgia Housing & Finance Authority	GA	126,780
Georgia Housing & Finance Authority	GA	167,832
Georgia Housing & Finance Authority	GA	548,136
Georgia Housing & Finance Authority	GA	148,224
Georgia Housing & Finance Authority	GA	74,556
Georgia Housing & Finance Authority	GA	137,520
Georgia Housing & Finance Authority	GA	74,484
Georgia Housing & Finance Authority	GA	347,088
Georgia Housing & Finance Authority	GA	113,184
Georgia Housing & Finance Authority	GA	315,948
Georgia Housing & Finance Authority	GA	119,856
Georgia Housing & Finance Authority	GA	87,000
Georgia Housing & Finance Authority	GA	72,924
Georgia Housing & Finance Authority	GA	94,944
Georgia Housing & Finance Authority	GA	198,480
Georgia Housing & Finance Authority	GA	1,103,040
Georgia Housing & Finance Authority	GA	94,764
Georgia Housing & Finance Authority	GA	209,556
Georgia Housing & Finance Authority	GA	295,788
Georgia Housing & Finance Authority	GA	331,068
Georgia Housing & Finance Authority	GA	162,540
Georgia Housing & Finance Authority	GA	434,472
Georgia Housing & Finance Authority	GA	441,960
Georgia Housing & Finance Authority	GA	785,400
Georgia Housing & Finance Authority	GA	264,756
Georgia Housing & Finance Authority	GA	110,208
Goodwill Industries of Middle Georgia, Inc	GA	89,761
Goodwill Industries of Middle Georgia, Inc	GA	148,066
Goodwill Industries of Middle Georgia, Inc	GA	110,310
Greenbriar Children's Center, Inc	GA	398,424
Gwinnett Housing Resource Partnership, Inc dba: The IMPACT! Group	GA	183,928
Gwinnett Housing Resource Partnership, Inc dba: The IMPACT! Group	GA	73,447
Gwinnett Housing Resource Partnership, Inc dba: The IMPACT! Group	GA	146,895
Hodac, Inc	GA	42,891
Hope House, Inc	GA	58,842
Housing Authority of Savannah	GA	1,140,504

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Housing Initiative of North Fulton	GA	23,632
Initiative for Affordable Housing, Inc	GA	321,418
Jerusalem House, Inc	GA	193,704
Loaves & Fishes Ministry of Macon, Inc	GA	97,429
Lowndes Associated Ministries to People, Inc	GA	145,917
Lowndes Associated Ministries to People, Inc	GA	140,571
Macon-Bibb Economic Opportunity Council, Inc	GA	94,500
Macon-Bibb Economic Opportunity Council, Inc	GA	99,750
Maranatha Outreach	GA	60,178
Marietta Housing Authority	GA	116,304
Marietta Housing Authority	GA	218,016
Mary Hall Freedom House, Inc	GA	292,265
Mary Hall Freedom House, Inc	GA	424,000
Mary Hall Freedom House, Inc	GA	287,254
MUST Ministries	GA	35,000
MUST Ministries	GA	133,900
MUST Ministries	GA	70,560
MUST Ministries	GA	35,280
New Horizons Community Service Board	GA	45,122
Open Door Community House, Inc	GA	267,745
Our House, Inc	GA	47,235
Progressive Redevelopment, Inc	GA	563,245
Rainbow Village, Inc	GA	226,295
S.H.A.R.E. House, Inc	GA	128,396
Saint Joseph's Mercy Care Services, Inc	GA	36,823
South Georgia Coalition to End Homelessness	GA	71,034
South Georgia Coalition to End Homelessness	GA	248,500
St. Jude's Recovery Center	GA	278,342
St. Jude's Recovery Center	GA	449,604
Stewart Community Home, Inc	GA	285,619
Supportive Housing Program	GA	35,000
The Center for Family Resources	GA	96,700
The Center for Family Resources	GA	450,489
The Center for Family Resources	GA	194,061
The Center for Family Resources	GA	85,323
The Extension, Inc	GA	104,654
The House of TIME	GA	106,756
The House of TIME	GA	347,079
The Quilt Youth Transitional Service, Inc	GA	417,933
Travelers Aid of Metropolitan Atlanta, Inc	GA	56,556
Travelers Aid of Metropolitan Atlanta, Inc	GA	156,541
Travelers Aid of Metropolitan Atlanta, Inc	GA	56,378
Travelers Aid of Metropolitan Atlanta, Inc	GA	367,317
Trinity Community Ministries	GA	195,968
Union Mission, Inc	GA	218,875
Union Mission, Inc	GA	169,381
Union Mission, Inc	GA	166,436
YWCA of Northwest Georgia	GA	173,053
Zion Hill Community Development Corporation	GA	233,210
Zion Keepers, Inc	GA	171,332
Zion Keepers, Inc	GA	50,693
Government of Guam/Guam Housing & Urban Renewal Authority	GU	123,000
Government of Guam/Guam Housing & Urban Renewal Authority	GU	28,224
Government of Guam/Guam Housing & Urban Renewal Authority	GU	123,100
Government of Guam/Guam Housing & Urban Renewal Authority	GU	171,852
Government of Guam/Guam Housing & Urban Renewal Authority	GU	313,363
Government of Guam/Guam Housing & Urban Renewal Authority	GU	125,415
Government of Guam/Guam Housing & Urban Renewal Authority	GU	161,448
Government of Guam/Guam Housing & Urban Renewal Authority	GU	79,082
Alternative Structures International	HI	147,175
Child and Family Service	HI	84,488
Gregory House Programs	HI	363,080
Hale Kipa, Inc	HI	136,000
Hawaii Department of Human Services	HI	61,440
Hawaii Department of Human Services	HI	41,160
Hawaii Department of Human Services	HI	77,536
Hawaii Department of Human Services	HI	90,180
Hawaii Department of Human Services	HI	605,124
Hawaii Department of Human Services	HI	31,131
Hawaii Department of Human Services	HI	489,048
Hawaii Department of Human Services	HI	496,404
Hawaii Department of Human Services	HI	140,388

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Hawaii Department of Human Services	HI	147,540
Hawaii Department of Human Services	HI	115,628
Hawaii Department of Human Services	HI	74,304
Honolulu CoC—Applicant	HI	133,607
Honolulu CoC—Applicant	HI	68,000
Honolulu CoC—Applicant	HI	1,646,868
Honolulu CoC—Applicant	HI	2,055,900
Honolulu CoC—Applicant	HI	1,306,512
Honolulu CoC—Applicant	HI	185,147
Honolulu CoC—Applicant	HI	518,700
Honolulu CoC—Applicant	HI	23,072
Housing Solutions, Inc	HI	55,132
Ka Hale A Ke Ola Homeless Resource Centers, Inc	HI	91,717
Ka Hale A Ke Ola Homeless Resource Centers, Inc	HI	46,245
Legal Aid Society of Hawaii	HI	64,669
Mental Health Kokua	HI	876,273
Parents and Children Together Ohia Shelter	HI	29,015
Steadfast Housing Development Corporation	HI	36,384
Steadfast Housing Development Corporation	HI	207,198
Steadfast Housing Development Corporation	HI	36,960
Steadfast Housing Development Corporation	HI	27,874
Steadfast Housing Development Corporation	HI	33,384
Steadfast Housing Development Corporation	HI	32,924
Steadfast Housing Development Corporation	HI	29,653
Steadfast Housing Development Corporation	HI	31,598
The Salvation Army ATS	HI	289,302
The Salvation Army Family Treatment Services	HI	183,498
United States Veterans Initiative	HI	341,263
United States Veterans Initiative	HI	142,282
Area Substance Abuse Council, dba. New Directions	IA	104,223
Cedar Valley Friends of the Family	IA	256,767
Center for Siouxland	IA	128,168
Center for Siouxland	IA	107,362
City of Des Moines	IA	289,732
City of Des Moines	IA	240,960
City of Des Moines	IA	288,266
City of Des Moines	IA	256,108
City of Des Moines	IA	99,390
City of Des Moines	IA	110,250
City of Des Moines	IA	76,136
City of Des Moines	IA	227,468
City of Des Moines	IA	251,580
City of Des Moines	IA	30,265
City of Des Moines	IA	818,676
City of Des Moines	IA	85,000
City of Des Moines	IA	176,516
City of Dubuque	IA	93,528
City of Sioux City	IA	113,452
Community Action Agency of Siouxland	IA	137,239
Community Corrections Improvement Association	IA	72,187
Community Housing Initiatives, Inc	IA	136,201
Community Housing Initiatives, Inc	IA	380,865
Crisis Intervention & Advocacy Center	IA	158,918
Crisis Intervention Services	IA	36,166
Crittenton Center	IA	184,527
Family Resources, Inc	IA	38,946
Family Resources, Inc	IA	39,525
Hawkeye Area Community Action Program, Inc	IA	26,749
Hawkeye Area Community Action Program, Inc	IA	213,827
Hawkeye Area Community Action Program, Inc	IA	466,174
Hillcrest Family Services	IA	71,538
Humility of Mary Housing, Inc	IA	37,549
Humility of Mary Shelter, Inc	IA	220,000
Humility of Mary Shelter, Inc	IA	492,000
Humility of Mary Shelter, Inc	IA	155,000
Humility of Mary Shelter, Inc	IA	68,880
Iowa Institute for Community Alliances	IA	12,600
Iowa Institute for Community Alliances	IA	252,979
Iowa Institute for Community Alliances	IA	87,150
Iowa Institute for Community Alliances	IA	29,749
Manasseh House	IA	78,828
Mason City Housing Authority	IA	107,364

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Northern Lights Alliance for the Homeless, Inc	IA	38,713
Opening Doors	IA	42,221
Project Concern	IA	31,570
Shelter House Community Shelter and Transition Services	IA	448,318
The Salvation Army	IA	148,666
The Salvation Army	IA	110,210
Youth and Shelter Services	IA	191,096
Youth and Shelter Services	IA	129,733
YWCA Clinton	IA	49,232
Ada County Housing Authority	ID	541,169
Ada County Housing Authority	ID	177,192
Boise City Housing Authority	ID	18,410
Boise City Housing Authority	ID	7,696
Boise City Housing Authority	ID	64,514
IHFA Project	ID	64,795
IHFA Project	ID	60,924
IHFA Project	ID	111,395
IHFA Project	ID	72,183
IHFA Project	ID	72,715
IHFA Project	ID	47,700
IHFA Project	ID	42,315
IHFA Project	ID	23,390
IHFA Project	ID	81,450
IHFA Project	ID	78,236
IHFA Project	ID	63,559
IHFA Project	ID	98,524
IHFA Project	ID	47,370
IHFA Project	ID	69,050
IHFA Project	ID	39,797
IHFA Project	ID	28,844
IHFA Project	ID	92,180
IHFA Project	ID	86,997
IHFA Project	ID	111,260
IHFA Project	ID	70,446
IHFA Project	ID	106,988
IHFA Project	ID	78,049
IHFA Project	ID	147,743
IHFA Project	ID	44,602
IHFA Project	ID	302,244
IHFA Project	ID	77,950
IHFA Project	ID	71,208
IHFA Project	ID	125,632
IHFA Project	ID	76,135
IHFA Project	ID	179,886
IHFA Project	ID	54,854
IHFA Project	ID	29,141
IHFA Project	ID	109,740
IHFA Project	ID	53,450
Supportive Housing and Innovative Partnerships	ID	19,572
Women's and Children's Alliance	ID	113,450
A Safe Haven Foundation	IL	87,284
A Safe Haven Foundation	IL	329,711
A Safe Haven Foundation	IL	344,365
A Safe Haven Foundation	IL	52,447
A Safe Haven Foundation	IL	212,378
Abundant Faith Ministry	IL	20,090
Abundant Faith Ministry	IL	13,738
Affordable Housing Preservation Foundation 51st Street Y	IL	77,553
AIDS Foundation of Chicago	IL	994,996
AIDS Foundation of Chicago	IL	336,539
AIDS Foundation of Chicago	IL	2,140,276
Alexian Brothers Bonaventure House	IL	160,847
Alliance to End Homelessness in Suburban Cook County	IL	227,684
Ambassadors for Christ	IL	38,616
Anna Bixby Women's Center	IL	114,539
Anna Bixby Women's Center	IL	77,105
Apna Ghar, Inc	IL	123,087
B.C.M.W. Community Services	IL	19,597
B.C.M.W. Community Services	IL	147,871
Beacon Therapeutic Diagnostic and Treatment Center	IL	983,922
Bethany for Children & Families	IL	375,018
Bethany Place	IL	187,012

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Bethany Place	IL	48,641
Bethany Place	IL	51,955
Bethel Human Resources Corp	IL	184,231
Breakthrough Urban Ministries, Inc	IL	139,650
Breakthrough Urban Ministries, Inc	IL	151,775
Breakthrough Urban Ministries, Inc	IL	45,360
Bridge Communities, Inc	IL	111,376
C.E.F.S. Economic Opportunity Corporation	IL	133,350
C.E.F.S. Economic Opportunity Corporation	IL	199,675
C.E.F.S. Economic Opportunity Corporation	IL	96,721
Call for Help	IL	527,382
Casa Central	IL	434,437
Casa Central	IL	383,904
Cathedral Shelter of Chicago	IL	53,122
Cathedral Shelter of Chicago	IL	35,332
Catholic Charities	IL	468,552
Catholic Charities	IL	195,753
Catholic Charities	IL	1,693,872
Catholic Charities	IL	140,000
Catholic Charities	IL	187,128
Catholic Charities	IL	107,100
Catholic Charities	IL	36,313
Catholic Charities	IL	731,105
Catholic Charities	IL	89,379
Catholic Charities	IL	194,713
Catholic Charities, Diocese of Joliet	IL	754,500
Catholic Charities, Diocese of Joliet	IL	70,000
Catholic Charities, Diocese of Joliet	IL	122,586
Catholic Charities, Diocese of Joliet	IL	417,484
Catholic Charities, Diocese of Joliet	IL	53,138
Catholic Charities, Diocese of Joliet	IL	216,230
Catholic Charities, Diocese of Joliet	IL	842,965
CDBG Operations Corporation	IL	86,486
CDBG Operations Corporation	IL	96,687
CDBG Operations Corporation	IL	344,907
CEDA Bloom-Rich	IL	231,678
CEDA Northwest Self-Help Center, Inc	IL	144,873
CEDA Northwest Self-Help Center, Inc	IL	162,947
Center for Housing and Health	IL	1,962,434
Champaign County—Champaign County Regional Planning Commission	IL	380,256
Champaign County—Champaign County Regional Planning Commission	IL	40,920
Champaign County—Champaign County Regional Planning Commission	IL	6,231
Chestnut Health Systems	IL	133,052
Chestnut Health Systems, Inc	IL	575,674
Chestnut Health Systems, Inc	IL	107,896
Chestnut Health Systems, Inc	IL	269,203
Chestnut Health Systems, Inc	IL	283,300
Chicago Department of Family & Support Services	IL	328,296
Chicago Department of Family & Support Services	IL	134,100
Chicago Department of Family & Support Services	IL	402,480
Chicago Department of Family & Support Services	IL	106,140
Chicago Department of Family & Support Services	IL	265,836
Chicago Department of Family & Support Services	IL	446,844
Chicago Department of Family & Support Services	IL	318,498
Chicago Department of Family & Support Services	IL	287,628
Chicago Department of Family & Support Services	IL	235,392
Chicago Department of Family & Support Services	IL	245,868
Chicago Department of Family & Support Services	IL	102,360
Chicago Department of Family & Support Services	IL	587,484
Chicago Department of Family & Support Services	IL	474,540
Chicago Department of Family & Support Services	IL	255,564
Chicago Department of Family & Support Services	IL	268,200
Chicago Department of Family & Support Services	IL	504,312
Chicago Department of Family & Support Services	IL	261,960
Chicago Department of Family & Support Services	IL	268,200
Chicago Department of Family & Support Services	IL	447,000
Chicago Department of Family & Support Services	IL	312,900
Chicago Department of Family & Support Services	IL	44,700
Chicago Department of Family & Support Services	IL	395,088
Chicago Department of Family & Support Services	IL	42,156
Chicago Department of Family & Support Services	IL	191,244
Chicago Department of Family & Support Services	IL	164,844

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Chicago Department of Family & Support Services	IL	652,620
Chicago Department of Family & Support Services	IL	591,840
Chicago Department of Family & Support Services	IL	341,796
Chicago Department of Family & Support Services	IL	201,240
Chicago Department of Family & Support Services	IL	358,260
Chicago Department of Family & Support Services	IL	391,488
Chicago Department of Family & Support Services	IL	268,200
Chicago Department of Family & Support Services	IL	42,156
Chicago Department of Family & Support Services	IL	429,120
Chicago Department of Family & Support Services	IL	647,532
Chicago Department of Family & Support Services	IL	268,200
Chicago Department of Family & Support Services	IL	727,284
Chicago Department of Family & Support Services	IL	259,392
Chicago House and Social Service Agency	IL	40,639
Chicago House and Social Service Agency	IL	243,653
Chicago Low-Income Housing Trust Fund	IL	178,145
Children's Home + Aid	IL	38,650
Christian Care	IL	78,750
Christian Community Health Center	IL	191,489
Christian Community Health Center	IL	2,127,900
Christian Family Ministries, The Lamb's Fold Center for Women and Children	IL	33,250
City of Bloomington	IL	23,700
City of Bloomington	IL	23,082
City of Bloomington	IL	5,217
City of Bloomington	IL	139,046
City of Bloomington	IL	19,367
City of Bloomington	IL	130,914
City of Urbana	IL	196,879
Community and Economic Development Association of Cook County, Inc	IL	265,875
Community Crisis Center	IL	30,135
Community Crisis Center	IL	66,500
Community Mental Health Council, Inc	IL	128,453
Community Mental Health Council, Inc	IL	97,391
Community Mental Health Council, Inc	IL	66,007
Community Mental Health Council, Inc	IL	123,736
Community Mental Health Council, Inc	IL	73,013
Community Supportive Living Systems, Inc	IL	201,120
Connections for Abused Women and Their Children	IL	23,695
Connections for the Homeless, Inc	IL	112,560
Connections for the Homeless, Inc	IL	71,526
Connections for the Homeless, Inc	IL	106,975
Connections for the Homeless, Inc	IL	187,847
Connections for the Homeless, Inc	IL	22,869
Connections for the Homeless, Inc	IL	117,197
Connections for the Homeless, Inc	IL	94,535
Connections for the Homeless, Inc	IL	43,682
Connections for the Homeless, Inc	IL	60,000
Cornerstone Community Outreach	IL	79,017
Cornerstone Community Outreach	IL	44,037
Cornerstone Community Outreach	IL	132,224
Cornerstone Services, Inc	IL	1,702,441
Cornerstone Services, Inc	IL	115,071
Cornerstone Services, Inc	IL	24,948
Cornerstone Services, Inc	IL	25,476
County of Morgan dba Morgan County MCS Community Services	IL	75,994
Crosspoint Human Services	IL	137,789
Deborah's Place	IL	417,076
Deborah's Place	IL	188,064
Deborah's Place	IL	330,293
Deborah's Place	IL	150,144
Decatur Housing Authority	IL	132,924
Decatur Housing Authority	IL	16,711
Decatur Housing Authority	IL	45,696
DeLaCerda House, Inc	IL	56,429
Delta Center	IL	19,338
Dove, Inc	IL	34,536
Dove, Inc	IL	329,047
Dove, Inc	IL	156,326
Dove, Inc	IL	74,828
Dove, Inc	IL	16,941
Dove, Inc	IL	35,747
Dove, Inc	IL	17,103

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
DuPage County Community Services	IL	151,667
DuPage County Community Services	IL	35,550
DuPage County Health Department	IL	573,994
DuPage County Health Department	IL	51,920
DuPage County Health Department	IL	249,444
DuPage P.A.D.S., Inc	IL	401,348
DuPage P.A.D.S., Inc	IL	123,472
DuPage P.A.D.S., Inc	IL	201,957
DuPage P.A.D.S., Inc	IL	26,950
East St. Louis Housing Authority	IL	342,096
Ecker Center for Mental Health	IL	164,930
Ecker Center for Mental Health	IL	173,302
EdgeAlliance	IL	366,108
Embarras River Basin Agency, Inc	IL	252,920
Embarras River Basin Agency, Inc	IL	154,722
Exhibit 2 Project CoC	IL	164,108
Exhibit 2 Project CoC	IL	573,552
Exhibit 2 Project CoC	IL	122,904
Exhibit 2 Project CoC	IL	116,440
Exhibit 2 Project CoC	IL	93,079
Exhibit 2 Project CoC	IL	27,312
Exhibit 2 Project CoC	IL	39,947
Exhibit 2 Project CoC	IL	102,993
Exhibit 2 Project CoC	IL	33,764
Exhibit 2 Project CoC	IL	148,126
Facing Forward to End Homelessness	IL	286,841
Facing Forward to End Homelessness	IL	240,091
Family Rescue	IL	58,165
Family Rescue	IL	571,732
FEATHERFIST	IL	129,817
FEATHERFIST	IL	141,395
FEATHERFIST	IL	300,843
FEATHERFIST	IL	517,459
FEATHERFIST	IL	259,219
FEATHERFIST	IL	221,315
FEATHERFIST	IL	112,483
FEATHERFIST	IL	264,173
FEATHERFIST	IL	114,300
FEATHERFIST	IL	298,232
Fifth Street Renaissance	IL	36,191
Fifth Street Renaissance	IL	24,150
Fifth Street Renaissance	IL	17,464
Fifth Street Renaissance	IL	17,466
Freedom House	IL	62,000
Freeport Area Church Cooperative	IL	178,563
Freeport Area Church Cooperative	IL	57,109
Good Samaritan House of Granite City, Inc	IL	154,355
Good Samaritan Ministries-A Project of the Carbondale Interfaith Council	IL	74,212
Goodwill Home for Veterans	IL	167,696
Healthcare Alternative Systems, Inc	IL	197,711
Heartland Health Outreach, Inc	IL	126,332
Heartland Health Outreach, Inc	IL	320,269
Heartland Health Outreach, Inc	IL	169,845
Heartland Health Outreach, Inc	IL	270,101
Heartland Health Outreach, Inc	IL	100,629
Heartland Health Outreach, Inc	IL	357,170
Heartland Health Outreach, Inc	IL	484,722
Heartland Health Outreach, Inc	IL	948,721
Heartland Human Care Services, Inc	IL	41,668
Heartland Human Care Services, Inc	IL	254,948
Heartland Human Care Services, Inc	IL	1,534,722
Heartland Human Care Services, Inc	IL	1,162,457
Heartland Human Care Services, Inc	IL	316,829
Heartland Human Care Services, Inc	IL	507,826
Helping Hands of Springfield Inc	IL	17,466
Helping Hands of Springfield Inc	IL	116,964
Home of the Sparrow, Inc	IL	27,064
Home of the Sparrow, Inc	IL	54,600
Hope Haven of DeKalb County, Inc	IL	98,374
Hope Haven of DeKalb County, Inc	IL	95,268
HOPE of East Central Illinois	IL	77,552
Housing Authority of the County of Cook	IL	157,320

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Housing Authority of the County of Cook	IL	363,132
Housing Authority of the County of DeKalb	IL	388,776
Housing Authority of the County of DeKalb	IL	13,704
Housing Opportunities for Women, Inc	IL	167,813
Housing Opportunities for Women, Inc	IL	286,520
Housing Opportunities for Women, Inc	IL	190,181
Housing Opportunities for Women, Inc	IL	464,308
Housing Opportunities for Women, Inc	IL	64,920
Housing Opportunity Development Corporation	IL	17,750
Housing Opportunity Development Corporation	IL	47,391
Housing Options for the Mentally Ill	IL	83,560
Housing Options for the Mentally Ill	IL	112,962
Housing Options for the Mentally Ill	IL	120,413
Hull House Association/Emerge Program	IL	378,229
Human Resources Development Institute, Inc (HRDI)	IL	427,768
Human Service Center	IL	131,597
Human Service Center	IL	75,668
Illinois Department of Veterans Affairs	IL	115,588
Illinois Valley Economic Development Corporation	IL	103,084
Inspiration Corporation	IL	199,224
Inspiration Corporation	IL	40,258
Inspiration Corporation	IL	85,667
Inspiration Corporation	IL	323,235
Inspiration Corporation	IL	83,462
Inspiration Corporation	IL	111,182
Interdependent Living Solutions Center	IL	156,964
Interfaith House	IL	364,719
I-PLUS	IL	22,069
I-PLUS	IL	12,805
Iroquois-Kankakee Regional Office of Education #32	IL	53,550
Jeannie Shelton	IL	104,141
Kane County, Illinois	IL	109,853
La Casa Norte	IL	295,292
La Casa Norte	IL	90,982
Lake County	IL	95,648
Lake County	IL	46,274
Lake County	IL	42,290
Lake County	IL	51,180
Lake County	IL	184,940
Lake County	IL	137,331
Lake County	IL	45,507
Lake County	IL	58,184
Lake County	IL	82,766
Lake County	IL	110,250
Lake County	IL	314,556
Latin United Community Housing Association	IL	32,130
Lazarus House	IL	31,997
Lazarus House	IL	63,927
Lazarus House	IL	31,996
Lazarus House	IL	54,331
Light The Way, Inc	IL	173,387
Lincoln Park Community Shelter	IL	212,111
M.E.R.C.Y. Communities, Inc	IL	83,190
M.E.R.C.Y. Communities, Inc	IL	169,614
Madison County	IL	197,568
Madison County	IL	308,320
Madison County	IL	28,224
Madison County HMIS	IL	41,362
Matthew House Inc	IL	316,768
Matthew House Inc	IL	204,750
Matthew House Inc	IL	223,993
Matthew House Inc	IL	123,866
McDermott Center	IL	58,026
Mental Health Center of Champaign County, Inc	IL	43,043
Mental Health Center of Champaign County, Inc	IL	185,543
Mercy Housing Lakefront	IL	259,631
Mercy Housing Lakefront	IL	125,546
Mercy Housing Lakefront	IL	368,430
Mercy Housing Lakefront	IL	61,950
Mercy Housing Lakefront	IL	187,833
Mid Central Community Action, Inc	IL	32,917
Ministers United Against Human Suffering	IL	50,000

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
NCO YOUTH & FAMILY SERVICES	IL	202,584
Near West Side Community Development Corporation	IL	97,781
New Foundation Center, Inc. (formerly WilPower, Inc.)	IL	277,596
New Foundation Center, Inc. (formerly WilPower, Inc.)	IL	170,245
New Moms Inc	IL	245,039
North Side Housing and Supportive Services, Inc	IL	76,381
North Side Housing and Supportive Services, Inc	IL	61,271
North Side Housing and Supportive Services, Inc	IL	105,900
North Side Housing and Supportive Services, Inc	IL	112,120
Northwestern Memorial Hospital	IL	301,910
Northwestern Memorial Hospital	IL	217,518
Northwestern Memorial Hospital	IL	153,844
PADS Lake County, Inc	IL	226,376
PADS to HOPE, Inc	IL	183,665
Peoria Housing Authority	IL	168,480
Peoria Opportunities Foundation	IL	246,505
Pillars Community Services	IL	521,332
Pillars Community Services	IL	477,060
Pillars Community Services	IL	24,115
Pillars Community Services	IL	110,000
Pillars Community Services	IL	31,177
Pioneer Center for Human Services	IL	105,000
Pioneer Center for Human Services	IL	231,548
Pioneer Center for Human Services	IL	261,821
Polish American Association	IL	50,904
Prairie State Legal Services, Inc	IL	68,780
Prairie State Legal Services, Inc	IL	50,000
Project NOW, Inc	IL	127,942
Project NOW, Inc	IL	58,712
Project NOW, Inc	IL	119,444
Public Action to Deliver Shelter, Inc	IL	234,302
Public Action to Deliver Shelter, Inc	IL	96,090
Renaissance Social Services, Inc	IL	133,970
Renaissance Social Services, Inc	IL	372,982
Rock Island Housing Authority	IL	50,016
Sarah's Circle	IL	103,563
Sarah's Circle	IL	66,463
Shields Township	IL	153,540
Shields Township	IL	92,124
Single Room Housing Assistance Corp	IL	488,047
Single Room Housing Assistance Corp	IL	421,988
Single Room Housing Assistance Corp	IL	365,000
South Side Office of Concern	IL	14,962
South Side Office of Concern	IL	52,977
South Suburban Family Shelter	IL	281,957
South Suburban PADS	IL	284,574
Southern Illinois Coalition for the Homeless	IL	84,702
Southern Illinois Coalition for the Homeless	IL	50,878
Southern Illinois Coalition for the Homeless	IL	60,511
Springfield Housing Authority	IL	50,388
St Leonards	IL	42,525
St. Clair County	IL	50,000
St. Clair County	IL	169,439
St. Clair County	IL	176,448
St. Clair County	IL	38,280
St. Clair County	IL	296,496
Stopping Woman Abuse Now	IL	71,640
Stopping Woman Abuse Now	IL	71,828
Stopping Woman Abuse Now	IL	53,788
Supportive Services Development Corporation	IL	124,000
Teen Living Programs	IL	189,334
Teen Living Programs	IL	128,373
The Center for Prevention of Abuse	IL	172,759
The Center for Women in Transition	IL	8,963
The Center of Concern	IL	130,534
The Eagle's Nest of St. Clair County	IL	54,465
The Inner Voice, Inc	IL	298,237
The Inner Voice, Inc	IL	362,611
The Inner Voice, Inc	IL	331,601
The Inner Voice, Inc	IL	76,484
The Inner Voice, Inc	IL	196,062
The Interfaith Housing Development Corporation of Chicago	IL	189,000

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
The Interfaith Housing Development Corporation of Chicago	IL	77,301
The Larkin Center	IL	300,575
The Night Ministry	IL	74,260
The Night Ministry	IL	144,391
The Renaissance Collaborative	IL	166,006
The Salvation Army of Kankakee County	IL	109,927
The Women's Center	IL	29,308
The Women's Center	IL	21,300
Thresholds Inc	IL	78,489
Thresholds Inc	IL	162,687
Thresholds Inc	IL	351,158
Thresholds Inc	IL	243,889
Thresholds Inc	IL	199,489
Thresholds Inc	IL	403,605
Thresholds Inc	IL	152,825
Thresholds Inc	IL	78,489
Thresholds Inc	IL	403,199
Together We Cope	IL	124,837
Together We Cope	IL	190,517
Transitional Living Services	IL	47,245
Transitional Living Services	IL	25,762
Tri-County Opportunities Council	IL	62,150
Trilogy Inc	IL	237,109
Trinity Services, Inc	IL	253,317
Unity Parenting & Counseling Inc	IL	420,453
Unity Parenting & Counseling Inc	IL	121,688
Unity Parenting & Counseling Inc	IL	497,620
Unity Parenting & Counseling Inc	IL	175,025
Urban Family & Community Centers d/b/a Primo Center for Women and Children	IL	255,302
WellSpring Resources	IL	281,693
West Suburban PADS	IL	844,532
Western Illinois Regional Council—Community Action Agency	IL	54,906
WINGS PROGRAM, INC	IL	44,693
WINGS PROGRAM, INC	IL	84,968
WINGS PROGRAM, INC	IL	100,120
WINGS PROGRAM, INC	IL	43,402
WINGS PROGRAM, INC	IL	124,554
WINGS PROGRAM, INC	IL	89,874
Young Men's Christian Association	IL	231,259
Young Men's Christian Association	IL	59,645
Young Men's Christian Association of Chicago/YMCA Network	IL	225,546
Your Family Resource Connection	IL	137,743
Youth Service Bureau	IL	91,899
Youth Services Network	IL	250,469
YWCA of Quincy	IL	56,795
YWCA of Quincy	IL	331,349
YWCA of Quincy	IL	26,000
YWCA of Quincy	IL	135,631
YWCA Peoria IL	IL	92,912
YWCA Peoria IL	IL	214,530
YWCA Peoria IL	IL	196,215
A Better Way Services, Inc	IN	149,617
AIDS Ministries/AIDS Assist of North Indiana, Inc	IN	100,703
AIDS Ministries/AIDS Assist of North Indiana, Inc	IN	35,558
Alternatives Incorporated of Madison County	IN	102,317
Amethyst House, Inc	IN	87,054
Aurora, Inc	IN	191,835
Aurora, Inc	IN	1,161,655
Blue River Services, Inc	IN	44,778
Blue River Services, Inc	IN	51,135
Bridges Community Services, Inc	IN	171,652
Bridges Community Services, Inc	IN	218,556
Cedars HOPE Inc I	IN	35,700
Cedars HOPE Inc I	IN	86,380
Center for the Homeless	IN	33,272
Center for the Homeless	IN	77,778
Center for the Homeless	IN	25,902
Center for the Homeless	IN	122,445
Center for the Homeless	IN	135,662
Center for the Homeless	IN	89,636
Center for the Homeless	IN	192,593
Centerstone of Indiana	IN	41,063

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Centerstone of Indiana	IN	253,931
Centerstone of Indiana	IN	37,968
City of Bloomington, Indiana	IN	65,292
City of Indianapolis	IN	267,300
City of Indianapolis	IN	121,132
City of Indianapolis	IN	317,016
City of Indianapolis	IN	120,768
City of Indianapolis	IN	160,200
City of Indianapolis	IN	150,960
City of Indianapolis	IN	150,859
City of Indianapolis	IN	71,352
City of Indianapolis	IN	66,192
City of Indianapolis	IN	75,480
City of Indianapolis	IN	100,461
City of Indianapolis	IN	149,868
City of Indianapolis	IN	105,409
City of Indianapolis	IN	121,233
City of Indianapolis	IN	114,752
City of Indianapolis	IN	140,292
City of Indianapolis	IN	122,160
City of Indianapolis	IN	1,427,100
City of Indianapolis	IN	75,480
City of Indianapolis	IN	159,925
City of Indianapolis	IN	377,400
City of Indianapolis	IN	188,700
City of Indianapolis	IN	84,199
City of South Bend, Indiana	IN	272,448
Community Mental Health Center, Inc	IN	57,052
Community Mental Health Center, Inc	IN	83,084
Community Mental Health Center, Inc	IN	107,425
Community Mental Health Center, Inc	IN	156,767
Community Mental Health Center, Inc	IN	302,374
Community Mental Health Center, Inc	IN	167,505
Council on Domestic Abuse, Inc	IN	87,743
CRWorks, Inc	IN	140,836
ECHO Housing Corporation	IN	97,001
ECHO Housing Corporation	IN	231,495
Edgewater Systems For Balanced Living	IN	119,022
Evansville Goodwill Industries, Inc	IN	220,133
Family Crisis Shelter	IN	60,558
Family Service Association of Howard County, Inc	IN	110,858
Family Services of Elkhart County, Inc	IN	46,856
Fort Wayne Women's Bureau, Inc	IN	89,775
Gary Commission for Women	IN	138,066
Genesis Outreach, Inc	IN	42,000
Hope House, Inc	IN	133,678
Hope House, Inc	IN	64,890
Housing Opportunities Inc	IN	82,601
Housing Opportunities Inc	IN	84,484
Housing Opportunities Inc	IN	49,450
Housing Opportunities Inc	IN	83,167
Housing Opportunities Inc	IN	82,734
Human Services, Inc	IN	36,588
Human Services, Inc	IN	108,084
Indiana Housing and Community Development Authority	IN	608,400
Indiana Housing and Community Development Authority	IN	182,208
Indiana Housing and Community Development Authority	IN	53,664
Indiana Housing and Community Development Authority	IN	98,880
Indiana Housing and Community Development Authority	IN	121,680
Indiana Housing and Community Development Authority	IN	306,600
Indiana Housing and Community Development Authority	IN	69,600
Indiana Housing and Community Development Authority	IN	75,318
Indiana Housing and Community Development Authority	IN	363,998
Indiana Housing and Community Development Authority	IN	111,204
Indiana Housing and Community Development Authority	IN	290,760
Indiana Housing and Community Development Authority	IN	284,160
Indiana Housing and Community Development Authority	IN	98,352
Indiana Housing and Community Development Authority	IN	44,088
Indiana Housing and Community Development Authority	IN	610,860
Indiana Housing and Community Development Authority	IN	473,052
Indiana Housing and Community Development Authority	IN	273,300
Indiana Housing and Community Development Authority	IN	420,240

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Interfaith Mission, Inc d/b/a The Lighthouse	IN	45,500
Kosciusko County Shelter for Abuse	IN	37,556
Lafayette Transitional Housing Center, Inc	IN	104,186
Lafayette Transitional Housing Center, Inc	IN	75,337
Lafayette Transitional Housing Center, Inc	IN	73,893
Life Treatment Centers	IN	70,293
Life Treatment Centers	IN	323,429
LifeSpring, Inc	IN	235,570
Martha's House, Inc	IN	133,793
Mental Health Association in Vigo County	IN	69,475
Middle Way House, Incorporated	IN	171,093
Oaklawn Psychiatric Center, Inc	IN	57,148
Oaklawn Psychiatric Center, Inc	IN	112,000
Pathfinder Services, Inc	IN	144,478
Salvation Army	IN	279,594
Shalom Community Center, Inc	IN	1,002,552
St. Elizabeth Catholic Charities	IN	187,231
Stepping Stones, Inc	IN	78,748
The Center for Women and Families	IN	223,144
The Stepping Stone Shelter For Women, Incorporated	IN	183,456
United Caring Shelters, Inc	IN	60,424
Vincent Village, Inc	IN	52,944
Vincent Village, Inc	IN	48,451
Vincent Village, Inc	IN	89,788
YWCA North Central Indiana	IN	65,000
YWCA North Central Indiana	IN	55,130
YWCA of Evansville, IN Inc	IN	86,865
Catholic Charities of Northeast Kansas, Inc	KS	29,524
Catholic Charities of Northeast Kansas, Inc	KS	100,971
Catholic Social Service	KS	188,987
CLASS LTD	KS	179,015
Community Action, Inc	KS	171,550
County of Sedgwick	KS	279,523
County of Sedgwick	KS	41,946
Cowley County Safe Homes, Inc	KS	133,332
Cowley County Safe Homes, Inc	KS	245,335
Hillcrest Transitional Housing of Wyandotte County	KS	99,919
Homeless Task Force CoC	KS	1,359,216
Inter-Faith Ministries Wichita, Inc	KS	56,420
Inter-Faith Ministries Wichita, Inc	KS	43,050
Inter-Faith Ministries Wichita, Inc	KS	106,656
Inter-Faith Ministries Wichita, Inc	KS	138,198
Johnson County Human Services	KS	32,700
Johnson County Human Services	KS	7,884
Johnson County Mental Health Center	KS	94,608
Kansas Housing Resources Corporation	KS	133,000
Kansas Legal Services	KS	190,607
Lawrence-Douglas County Housing Authority	KS	87,729
Manhattan Emergency Shelter, Inc	KS	204,656
Manhattan Emergency Shelter, Inc	KS	151,639
Mental Health America of the Heartland	KS	104,045
Mental Health America of the Heartland	KS	95,587
Mid America Assistance Coalition	KS	18,666
Mid Kansas CAP Inc	KS	58,259
Mid Kansas CAP Inc	KS	157,500
My Father's House Community Services, Inc	KS	215,670
NEK-CAP, INC	KS	160,360
New Beginnings, Inc	KS	125,716
Plumb Place	KS	80,007
Prairie View Inc	KS	136,090
SAFEHOME, Inc	KS	57,568
Salina Housing Authority	KS	81,900
Sedgwick County Housing Department	KS	29,340
Sedgwick County Housing Department	KS	704,604
The Kansas City Metropolitan Lutheran Ministry	KS	132,978
The Kansas City Metropolitan Lutheran Ministry	KS	150,000
The Salvation Army	KS	333,333
The Salvation Army	KS	61,866
The Salvation Army	KS	61,460
The Salvation Army	KS	133,628
The Salvation Army	KS	48,877
The Salvation Army	KS	131,176

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Topeka/Shawnee County CoC	KS	87,200
Unified Government of Wyandotte County/KCK	KS	55,235
Unified Government of Wyandotte County/KCK	KS	89,945
Unified Government of Wyandotte County/KCK	KS	53,961
Unified Government of Wyandotte County/KCK	KS	29,565
United Methodist Open Door, Inc	KS	80,804
United Methodist Open Door, Inc	KS	84,377
United Methodist Open Door, Inc	KS	56,238
United Way of the Plains	KS	86,663
United Way of the Plains	KS	49,498
USD 500 Kansas City Kansas Public Schools	KS	22,660
Valeo Behavioral Health Care, Inc	KS	109,491
Wichita Children's Home	KS	102,566
Wichita Children's Home	KS	166,028
Wyandot Center for Community Behavioral Healthcare	KS	63,551
Bellewood Presbyterian Home for Children	KY	88,327
Bellewood Presbyterian Home for Children	KY	143,478
Bluegrass Regional Mental Health-Mental Retardation Board, Inc	KY	165,268
Center for Independent Living Options, Inc	KY	128,999
Choices, Inc	KY	70,497
Chrysalis House, Inc	KY	219,154
Chrysalis House, Inc	KY	85,595
Chrysalis House, Inc	KY	52,931
Coalition for the Homeless, Inc	KY	5,332
Coalition for the Homeless, Inc	KY	122,311
Community Action Council for Lexington-Fayette, Bourbon, Harrison, and Nicholas Counties	KY	65,129
Daniel Pitino Shelter, Inc	KY	266,039
Family Health Centers, Inc	KY	255,146
Father Maloney's Boys' Haven, Inc	KY	169,846
Home of the Innocents	KY	88,844
Hope Center, Inc	KY	269,334
Hope Center, Inc	KY	166,667
House of Ruth, Inc	KY	152,709
House of Ruth, Inc	KY	137,694
Jefferson Street Baptist Center, Inc	KY	69,983
Kentucky Housing Corporation	KY	278,472
Kentucky Housing Corporation	KY	249,804
Kentucky Housing Corporation	KY	52,920
Kentucky Housing Corporation	KY	10,414
Kentucky Housing Corporation	KY	166,039
Kentucky Housing Corporation	KY	83,363
Kentucky Housing Corporation	KY	88,664
Kentucky Housing Corporation	KY	150,359
Kentucky Housing Corporation	KY	196,860
Kentucky Housing Corporation	KY	277,702
Kentucky Housing Corporation	KY	30,169
Kentucky Housing Corporation	KY	80,646
Kentucky Housing Corporation	KY	101,510
Kentucky Housing Corporation	KY	247,800
Kentucky Housing Corporation	KY	35,694
Kentucky Housing Corporation	KY	78,641
Kentucky Housing Corporation	KY	190,000
Kentucky Housing Corporation	KY	126,055
Kentucky Housing Corporation	KY	277,614
Kentucky Housing Corporation	KY	176,760
Kentucky Housing Corporation	KY	279,095
Kentucky Housing Corporation	KY	171,615
Kentucky Housing Corporation	KY	77,312
Kentucky Housing Corporation	KY	93,688
Kentucky Housing Corporation	KY	194,216
Kentucky Housing Corporation	KY	23,568
Kentucky Housing Corporation	KY	163,800
Kentucky Housing Corporation	KY	50,392
Kentucky Housing Corporation	KY	163,560
Kentucky Housing Corporation	KY	40,341
Kentucky Housing Corporation	KY	189,262
Kentucky Housing Corporation	KY	94,234
Kentucky Housing Corporation	KY	479,860
Kentucky Housing Corporation	KY	629,293
Kentucky Housing Corporation	KY	455,593
Kentucky Housing Corporation	KY	222,440
Kentucky Housing Corporation	KY	61,404

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Kentucky Housing Corporation	KY	161,946
Kentucky Housing Corporation	KY	333,323
Kentucky Housing Corporation	KY	63,580
Kentucky Housing Corporation	KY	29,485
Kentucky Housing Corporation	KY	113,724
Kentucky Housing Corporation	KY	539,471
Kentucky Housing Corporation	KY	105,184
Kentucky Housing Corporation	KY	200,108
Kentucky Housing Corporation	KY	618,877
Kentucky Housing Corporation	KY	66,500
Kentucky Housing Corporation	KY	168,191
Kentucky Housing Corporation	KY	225,438
Kentucky Housing Corporation	KY	25,727
Kentucky Housing Corporation	KY	85,303
Lexington-Fayette Urban County Housing Authority	KY	196,320
Louisville/Jefferson County Metro Government	KY	38,249
Louisville/Jefferson County Metro Government	KY	1,713,732
Louisville/Jefferson County Metro Government	KY	36,672
Louisville/Jefferson County Metro Government	KY	28,224
Louisville/Jefferson County Metro Government	KY	83,760
Louisville/Jefferson County Metro Government	KY	32,088
Louisville/Jefferson County Metro Government	KY	66,012
New Beginnings Bluegrass Inc	KY	53,492
New Directions Housing Corporation	KY	58,245
Owensboro Area Shelter, Information & Services, Inc (OASIS, Inc)	KY	515,225
Schizophrenia Foundation, KY.	KY	28,054
Schizophrenia Foundation, KY.	KY	211,649
Schizophrenia Foundation, KY.	KY	21,000
Seven Counties Services, Inc	KY	93,060
Society of St. Vincent de Paul	KY	115,516
Society of St. Vincent de Paul	KY	137,938
Society of St. Vincent de Paul	KY	420,699
Society of St. Vincent de Paul	KY	427,747
The Center for Women and Families	KY	33,581
The Center for Women and Families	KY	49,875
The Salvation Army Southern Territory Headquarters	KY	119,999
Transitions, Inc	KY	82,545
Transitions, Inc	KY	8,767
Transitions, Inc	KY	79,363
Transitions, Inc	KY	236,770
Transitions, Inc	KY	162,503
Volunteers of America of Kentucky, Inc	KY	164,045
Volunteers of America of Kentucky, Inc	KY	128,390
Volunteers of America of Kentucky, Inc	KY	371,611
Volunteers of America of Kentucky, Inc	KY	246,682
Wayside Christian Mission	KY	81,902
Wayside Christian Mission	KY	25,575
Wayside Christian Mission	KY	103,369
Welcome House of No. KY, Inc	KY	469,348
Acadiana C.A.R.E.S., Inc	LA	102,837
Acadiana C.A.R.E.S., Inc	LA	233,216
Acadiana C.A.R.E.S., Inc	LA	146,178
Acadiana C.A.R.E.S., Inc	LA	215,017
Acadiana C.A.R.E.S., Inc	LA	59,583
Acadiana C.A.R.E.S., Inc	LA	21,000
Acadiana Outreach Center, Inc	LA	136,941
Acadiana Outreach Center, Inc	LA	129,868
Acadiana Outreach Center, Inc	LA	49,290
ASSIST Agency	LA	97,520
Bridge House Corporation	LA	197,189
Caddo Parish School Board	LA	85,073
Calcasieu Parish Police Jury Housing Department	LA	58,284
Capital Area Alliance for the Homeless	LA	58,692
Catholic Charities Archdiocese of New Orleans	LA	126,524
Catholic Charities Archdiocese of New Orleans	LA	93,595
Catholic Charities Archdiocese of New Orleans	LA	101,734
Cenla Chemical Dependency Council, Inc	LA	208,278
Central La. Homeless Coalition Ex. 2 Applicant	LA	58,244
Church United for Community Development	LA	24,698
Church United for Community Development	LA	105,305
City of Baton Rouge & Parish of East Baton Rouge	LA	83,727
City of Baton Rouge & Parish of East Baton Rouge	LA	46,292

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
City of Baton Rouge & Parish of East Baton Rouge	LA	20,458
City of Baton Rouge & Parish of East Baton Rouge	LA	97,334
City of Baton Rouge & Parish of East Baton Rouge	LA	144,868
City of Baton Rouge & Parish of East Baton Rouge	LA	177,563
City of Baton Rouge & Parish of East Baton Rouge	LA	85,599
City of Baton Rouge & Parish of East Baton Rouge	LA	197,204
City of Baton Rouge & Parish of East Baton Rouge	LA	86,461
City of Baton Rouge & Parish of East Baton Rouge	LA	63,418
City of Baton Rouge & Parish of East Baton Rouge	LA	39,900
City of Baton Rouge & Parish of East Baton Rouge	LA	63,661
City of Baton Rouge & Parish of East Baton Rouge	LA	93,164
City of New Orleans—Office of Planning & Development	LA	585,972
Community Directions, Inc	LA	72,905
Community Directions, Inc	LA	66,940
Community Support Programs, Inc	LA	263,208
Community Support Programs, Inc	LA	291,418
Community Support Programs, Inc	LA	301,902
COUNCIL ALCOHOLISM/DRUG ABUSE OF NW LA	LA	252,159
Covenant House	LA	144,622
Covenant House	LA	79,735
Elisha Ministries	LA	85,123
Elisha Ministries	LA	102,695
Faith House, Inc	LA	67,998
First Evangelist Housing and Community Development Corporation	LA	150,000
Gulf Coast Teaching Family Services	LA	135,657
Gulf Coast Teaching Family Services, Inc	LA	199,932
Gulf Coast Teaching Family Services, Inc	LA	134,360
Gulf Coast Teaching Family Services, Inc	LA	170,722
Gulf Coast Teaching Family Services, Inc	LA	100,153
Hammond Housing Authority	LA	180,870
Holy Cross Episcopal Church	LA	33,944
Hope House of Central Louisiana, Inc	LA	129,084
Housing Authority of the City of Bossier City, Louisiana	LA	213,908
Housing Authority of the City of Bossier City, Louisiana	LA	381,888
Housing Authority of the City of Bossier City, Louisiana	LA	58,752
Housing Authority of the City of Sulphur	LA	144,336
Iberia Homeless Shelter Inc	LA	33,040
Inner City Revitalization Corp	LA	33,333
Jefferson Parish Department of Community Development	LA	350,880
Jefferson Parish Human Services Authority	LA	281,336
LAEHCY	LA	62,092
Lafayette Catholic Service Centers, Inc	LA	30,975
Lafayette Catholic Service Centers, Inc	LA	336,712
Lafayette Catholic Service Centers, Inc	LA	35,401
Lafayette Catholic Service Centers, Inc	LA	35,087
Lafayette Catholic Service Centers, Inc	LA	100,533
Lake Charles Housing Authority	LA	92,400
Metropolitan Center for Women and Children, Inc	LA	113,344
Metropolitan Human Services District	LA	1,195,188
Monroe Housing Authority	LA	145,824
NAMI New Orleans	LA	157,093
Our House, Inc	LA	57,447
Philadelphia Center	LA	176,400
Providence House	LA	91,535
Providence House	LA	161,481
Rays of Sonshine	LA	149,737
Responsibility House, Inc	LA	136,221
Responsibility House, Inc	LA	208,528
Shreveport SRO, Inc dba Centerpoint Community Services	LA	62,133
Shreveport SRO, Inc dba Centerpoint Community Services	LA	125,200
Southeast Louisiana State Hospital	LA	166,497
Southeast Louisiana State Hospital	LA	80,134
Southeast Louisiana State Hospital	LA	68,431
Southeast Louisiana State Hospital	LA	163,257
Southeast Spouse Abuse Program	LA	147,993
Southeast Spouse Abuse Program	LA	87,978
Southeastern Louisiana University	LA	148,109
St. Martin, Iberia, Lafayette Community Action Agency (SMILE)	LA	31,911
St. Mary Community Action Committee Association	LA	64,496
St. Mary Community Action Committee Association	LA	73,420
St. Tammany Parish Government	LA	94,405
START Corporation	LA	224,584

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
START Corporation	LA	162,787
START Corporation	LA	161,192
START Corporation	LA	111,860
The Wellspring Alliance for Families, Inc	LA	80,209
The Wellspring Alliance for Families, Inc	LA	260,685
The Wellspring Alliance for Families, Inc	LA	91,725
The Wellspring Alliance for Families, Inc	LA	160,032
The Wellspring Alliance for Families, Inc	LA	72,858
UNITY of Greater New Orleans	LA	479,078
UNITY of Greater New Orleans	LA	78,893
UNITY of Greater New Orleans	LA	217,498
UNITY of Greater New Orleans	LA	906,748
UNITY of Greater New Orleans	LA	570,084
UNITY of Greater New Orleans	LA	99,238
UNITY of Greater New Orleans	LA	109,842
UNITY of Greater New Orleans	LA	86,297
UNITY of Greater New Orleans	LA	203,776
UNITY of Greater New Orleans	LA	306,647
UNITY of Greater New Orleans	LA	160,537
UNITY of Greater New Orleans	LA	134,683
UNITY of Greater New Orleans	LA	557,632
UNITY of Greater New Orleans	LA	210,151
UNITY of Greater New Orleans	LA	489,656
UNITY of Greater New Orleans	LA	34,125
UNITY of Greater New Orleans	LA	380,884
UNITY of Greater New Orleans	LA	490,057
UNITY of Greater New Orleans	LA	208,645
UNITY of Greater New Orleans	LA	148,711
UNITY of Greater New Orleans	LA	166,902
UNITY of Greater New Orleans	LA	50,999
UNITY of Greater New Orleans	LA	515,262
UNITY of Greater New Orleans	LA	128,907
UNITY of Greater New Orleans	LA	173,250
UNITY of Greater New Orleans	LA	312,105
UNITY of Greater New Orleans	LA	502,142
UNITY of Greater New Orleans	LA	480,201
UNITY of Greater New Orleans	LA	121,819
UNITY of Greater New Orleans	LA	162,469
UNITY of Greater New Orleans	LA	460,580
UNITY of Greater New Orleans	LA	666,584
Vernon Community Action Council, Inc	LA	70,092
VOA Cenla	LA	71,671
VOA Rapides	LA	78,720
VOA Rural	LA	63,521
Volunteer Center Southwest Inc	LA	116,483
Volunteers of America—Greater Baton Rouge	LA	122,794
Volunteers of America—Greater Baton Rouge	LA	180,507
Volunteers of America North LA	LA	324,101
Volunteers of America North LA	LA	144,795
Volunteers of America North LA	LA	112,074
Volunteers of America North LA	LA	197,400
Volunteers of America North LA	LA	102,187
Volunteers of America of Greater New Orleans	LA	481,497
Volunteers of America of Greater New Orleans	LA	50,000
Volunteers of America of Greater New Orleans	LA	161,320
Volunteers of America of Greater New Orleans	LA	111,884
Volunteers of America of Greater New Orleans	LA	44,343
Volunteers of America of Greater New Orleans	LA	85,226
Volunteers of America of Greater New Orleans	LA	538,656
Volunteers of America of Greater New Orleans	LA	321,948
Volunteers of America of Greater New Orleans	LA	196,288
Volunteers of America of North Louisiana	LA	96,206
Volunteers of America, Greater Baton Rouge, Inc	LA	173,105
Volunteers of America, Greater Baton Rouge, Inc	LA	59,860
Women Outreaching Women	LA	43,864
Women Outreaching Women	LA	43,327
Action Inc	MA	114,400
Advocates, Inc	MA	168,022
Advocates, Inc	MA	33,438
Advocates, Inc	MA	83,860
Advocates, Inc	MA	169,781
Advocates, Inc	MA	83,860

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Advocates, Inc	MA	117,213
Barnstable Housing Authority	MA	61,524
Barnstable Housing Authority	MA	35,940
Barnstable Housing Authority	MA	392,280
Berkshire Community Action Council	MA	26,700
Berkshire Community Action Council	MA	34,988
Berkshire Community Action Council	MA	12,000
Berkshire Community Action Council	MA	133,190
Brookline Community Mental Health Center	MA	70,797
Brookline Community Mental Health Center	MA	120,771
Brookline Housing Authority	MA	39,552
Cambridge Housing Authority	MA	296,640
CASPAR, Inc	MA	114,450
CASPAR, Inc	MA	39,138
CASPAR, Inc	MA	150,793
CASPAR, Inc	MA	81,498
Catholic Charitable Bureau of the Archdiocese of Boston, Inc	MA	50,972
Catholic Social Services of Fall River, Inc	MA	31,708
Catholic Social Services of Fall River, Inc	MA	119,469
Catholic Social Services of Fall River, Inc	MA	25,811
Central Massachusetts Housing Alliance, Inc	MA	655,822
Central Massachusetts Housing Alliance, Inc	MA	181,250
Central Massachusetts Housing Alliance, Inc	MA	183,708
Central Massachusetts Housing Alliance, Inc	MA	146,490
Central Massachusetts Housing Alliance, Inc	MA	262,500
Central Massachusetts Housing Alliance, Inc	MA	219,247
Central Massachusetts Housing Alliance, Inc	MA	98,786
Central Massachusetts Housing Alliance, Inc	MA	139,119
Central Massachusetts Housing Alliance, Inc	MA	38,850
Central Massachusetts Housing Alliance, Inc	MA	181,325
Central Massachusetts Housing Alliance, Inc	MA	45,734
Central Massachusetts Housing Alliance, Inc	MA	117,667
Central Massachusetts Housing Alliance, Inc	MA	187,189
Central Massachusetts Housing Alliance, Inc	MA	78,601
Central Massachusetts Housing Alliance, Inc	MA	104,999
Central Massachusetts Housing Alliance, Inc	MA	133,416
Central Massachusetts Housing Alliance, Inc	MA	259,536
Central Massachusetts Housing Alliance, Inc	MA	49,700
Central Massachusetts Housing Alliance, Inc	MA	181,431
Citizens for Affordable Housing in Newton Development Organization, Inc	MA	12,616
City of Boston Acting by and through its Public Facilities Commission by DND	MA	32,586
City of Boston Acting by and through its Public Facilities Commission by DND	MA	187,532
City of Boston Acting by and through its Public Facilities Commission by DND	MA	79,869
City of Boston Acting by and through its Public Facilities Commission by DND	MA	530,164
City of Boston Acting by and through its Public Facilities Commission by DND	MA	199,892
City of Boston Acting by and through its Public Facilities Commission by DND	MA	311,311
City of Boston Acting by and through its Public Facilities Commission by DND	MA	44,100
City of Boston Acting by and through its Public Facilities Commission by DND	MA	158,632
City of Boston Acting by and through its Public Facilities Commission by DND	MA	217,233
City of Boston Acting by and through its Public Facilities Commission by DND	MA	1,082,575
City of Boston Acting by and through its Public Facilities Commission by DND	MA	435,278
City of Boston Acting by and through its Public Facilities Commission by DND	MA	197,760
City of Boston Acting by and through its Public Facilities Commission by DND	MA	188,161
City of Boston Acting by and through its Public Facilities Commission by DND	MA	244,529
City of Boston Acting by and through its Public Facilities Commission by DND	MA	1,382,236
City of Boston Acting by and through its Public Facilities Commission by DND	MA	355,968
City of Boston Acting by and through its Public Facilities Commission by DND	MA	118,768
City of Boston Acting by and through its Public Facilities Commission by DND	MA	146,664
City of Boston Acting by and through its Public Facilities Commission by DND	MA	189,034
City of Boston Acting by and through its Public Facilities Commission by DND	MA	632,195
City of Boston Acting by and through its Public Facilities Commission by DND	MA	187,872
City of Boston Acting by and through its Public Facilities Commission by DND	MA	245,814
City of Boston Acting by and through its Public Facilities Commission by DND	MA	317,808
City of Boston Acting by and through its Public Facilities Commission by DND	MA	289,305
City of Boston Acting by and through its Public Facilities Commission by DND	MA	310,453
City of Boston Acting by and through its Public Facilities Commission by DND	MA	67,618
City of Boston Acting by and through its Public Facilities Commission by DND	MA	201,048
City of Boston Acting by and through its Public Facilities Commission by DND	MA	221,669
City of Boston Acting by and through its Public Facilities Commission by DND	MA	37,010
City of Boston Acting by and through its Public Facilities Commission by DND	MA	176,010
City of Boston Acting by and through its Public Facilities Commission by DND	MA	307,434
City of Boston Acting by and through its Public Facilities Commission by DND	MA	43,176

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
City of Boston Acting by and through its Public Facilities Commission by DND	MA	237,312
City of Boston Acting by and through its Public Facilities Commission by DND	MA	394,476
City of Boston Acting by and through its Public Facilities Commission by DND	MA	474,531
City of Boston Acting by and through its Public Facilities Commission by DND	MA	49,392
City of Boston Acting by and through its Public Facilities Commission by DND	MA	197,842
City of Boston Acting by and through its Public Facilities Commission by DND	MA	345,636
City of Boston Acting by and through its Public Facilities Commission by DND	MA	234,780
City of Boston Acting by and through its Public Facilities Commission by DND	MA	510,118
City of Boston Acting by and through its Public Facilities Commission by DND	MA	470,976
City of Boston Acting by and through its Public Facilities Commission by DND	MA	411,215
City of Boston Acting by and through its Public Facilities Commission by DND	MA	56,889
City of Boston Acting by and through its Public Facilities Commission by DND	MA	108,244
City of Boston Acting by and through its Public Facilities Commission by DND	MA	28,350
City of Boston Acting by and through its Public Facilities Commission by DND	MA	310,701
City of Boston Acting by and through its Public Facilities Commission by DND	MA	39,552
City of Boston Acting by and through its Public Facilities Commission by DND	MA	338,088
City of Boston Acting by and through its Public Facilities Commission by DND	MA	131,880
City of Boston Acting by and through its Public Facilities Commission by DND	MA	746,316
City of Boston Acting by and through its Public Facilities Commission by DND	MA	117,331
City of Boston Acting by and through its Public Facilities Commission by DND	MA	227,028
City of Boston Acting by and through its Public Facilities Commission by DND	MA	295,645
City of Boston Acting by and through its Public Facilities Commission by DND	MA	288,363
City of Boston Acting by and through its Public Facilities Commission by DND	MA	230,830
City of Boston Acting by and through its Public Facilities Commission by DND	MA	1,110,192
City of Boston Acting by and through its Public Facilities Commission by DND	MA	1,749,408
City of Boston Acting by and through its Public Facilities Commission by DND	MA	511,402
City of Boston Acting by and through its Public Facilities Commission by DND	MA	775,812
City of Boston Acting by and through its Public Facilities Commission by DND	MA	90,185
City of Boston Acting by and through its Public Facilities Commission by DND	MA	565,500
City of Boston Acting by and through its Public Facilities Commission by DND	MA	206,315
City of Boston Acting by and through its Public Facilities Commission by DND	MA	34,617
City of Boston Acting by and through its Public Facilities Commission by DND	MA	144,288
City of Boston Acting by and through its Public Facilities Commission by DND	MA	231,708
City of Boston Acting by and through its Public Facilities Commission by DND	MA	104,843
City of Boston Acting by and through its Public Facilities Commission by DND	MA	133,369
City of Boston Acting by and through its Public Facilities Commission by DND	MA	56,883
City of Boston Acting by and through its Public Facilities Commission by DND	MA	387,528
City of Boston Acting by and through its Public Facilities Commission by DND	MA	48,442
City of Boston Acting by and through its Public Facilities Commission by DND	MA	55,777
City of Cambridge, Massachusetts	MA	56,541
City of Cambridge, Massachusetts	MA	18,480
City of Cambridge, Massachusetts	MA	81,632
City of Cambridge, Massachusetts	MA	171,142
City of Cambridge, Massachusetts	MA	121,428
City of Cambridge, Massachusetts	MA	125,928
City of Cambridge, Massachusetts	MA	9,916
City of Cambridge, Massachusetts	MA	14,386
City of Cambridge, Massachusetts	MA	32,497
City of Cambridge, Massachusetts	MA	52,605
City of Cambridge, Massachusetts	MA	20,790
City of Cambridge, Massachusetts	MA	33,600
City of Cambridge, Massachusetts	MA	169,649
City of Cambridge, Massachusetts	MA	51,042
City of Cambridge, Massachusetts	MA	60,986
City of Cambridge, Massachusetts	MA	17,724
City of Cambridge, Massachusetts	MA	45,479
City of Cambridge, Massachusetts	MA	438,573
City of Cambridge, Massachusetts	MA	32,640
City of Cambridge, Massachusetts	MA	72,198
City of Cambridge, Massachusetts	MA	81,118
City of Cambridge, Massachusetts	MA	19,527
City of Cambridge, Massachusetts	MA	225,717
City of Cambridge, Massachusetts	MA	81,118
City of Cambridge, Massachusetts	MA	707,545
City of Cambridge, Massachusetts	MA	57,750
City of Cambridge, Massachusetts	MA	165,068
City of Cambridge, Massachusetts	MA	52,295
City of Cambridge, Massachusetts	MA	137,815
City of Cambridge, Massachusetts	MA	58,530
City of Cambridge, Massachusetts	MA	28,946
City of Lawrence	MA	12,416
City of Lawrence	MA	20,895

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
City of Lawrence	MA	53,345
City of Lawrence	MA	14,962
City of Lowell	MA	40,325
City of Lowell	MA	189,283
City of Lowell	MA	67,350
City of Lowell	MA	91,567
City of Lowell	MA	400,894
City of Lowell	MA	79,742
City of New Bedford	MA	96,819
City of New Bedford	MA	159,371
City of New Bedford	MA	29,524
City of New Bedford	MA	298,069
City of New Bedford	MA	272,490
City of New Bedford	MA	245,064
City of New Bedford	MA	187,933
City of New Bedford	MA	97,884
City of New Bedford	MA	265,079
City of New Bedford	MA	198,609
City of Northampton	MA	72,450
City of Northampton	MA	68,079
City of Northampton	MA	80,351
City of Northampton	MA	104,991
City of Northampton	MA	55,493
City of Northampton	MA	177,672
City of Northampton	MA	106,022
City of Northampton	MA	200,529
City of Northampton	MA	100,527
City of Northampton	MA	111,348
City of Northampton	MA	22,312
City of Northampton	MA	51,675
City of Northampton	MA	242,300
City of Northampton	MA	94,500
City of Northampton	MA	80,760
City of Northampton	MA	42,018
City of Quincy, MA	MA	80,390
City of Quincy, MA	MA	195,888
City of Quincy, MA	MA	69,547
City of Quincy, MA	MA	51,345
City of Quincy, MA	MA	350,401
City of Quincy, MA	MA	96,891
City of Quincy, MA	MA	119,952
City of Quincy, MA	MA	946,584
City of Quincy, MA	MA	55,742
City of Quincy, MA	MA	72,588
City of Quincy, MA	MA	506,052
City of Quincy, MA	MA	451,420
City of Quincy, MA	MA	86,509
City of Quincy, MA	MA	101,112
City of Springfield	MA	524,940
City of Springfield	MA	22,255
City of Springfield	MA	217,908
City of Springfield	MA	29,732
City of Springfield	MA	96,694
City of Springfield	MA	80,760
City of Springfield	MA	118,831
City of Springfield	MA	35,419
City of Springfield	MA	152,428
City of Springfield	MA	129,216
City of Springfield	MA	96,912
City of Springfield	MA	195,574
City of Springfield	MA	201,900
City of Worcester, MA	MA	181,582
City of Worcester, MA	MA	647,328
City of Worcester, MA	MA	264,960
City of Worcester, MA	MA	353,375
City of Worcester, MA	MA	468,226
Commonwealth of Massachusetts	MA	689,736
Commonwealth of Massachusetts	MA	70,000
Commonwealth of Massachusetts	MA	47,364
Commonwealth of Massachusetts	MA	560,676
Commonwealth of Massachusetts	MA	126,000
Commonwealth of Massachusetts	MA	509,284

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Commonwealth of Massachusetts	MA	31,500
Commonwealth of Massachusetts	MA	209,880
Commonwealth of Massachusetts	MA	668,185
Commonwealth of Massachusetts	MA	199,137
Commonwealth of Massachusetts	MA	63,689
Commonwealth of Massachusetts	MA	918,583
Commonwealth of Massachusetts	MA	193,752
Commonwealth of Massachusetts	MA	148,380
Commonwealth of Massachusetts	MA	195,236
Commonwealth of Massachusetts	MA	137,976
Commonwealth of Massachusetts	MA	193,624
Commonwealth of Massachusetts	MA	82,656
Commonwealth of Massachusetts	MA	714,605
Commonwealth of Massachusetts	MA	297,312
Commonwealth of Massachusetts	MA	290,616
Commonwealth of Massachusetts	MA	411,336
Commonwealth of Massachusetts	MA	84,000
Commonwealth of Massachusetts	MA	258,788
Commonwealth of Massachusetts	MA	840,720
Commonwealth of Massachusetts	MA	486,803
Commonwealth of Massachusetts	MA	43,020
Community Counseling of Bristol County, Inc	MA	41,269
Community Counseling of Bristol County, Inc	MA	284,094
Community Counseling of Bristol County, Inc	MA	169,022
Community Counseling of Bristol County, Inc	MA	64,821
Community Healthlink, Inc	MA	363,930
Community Healthlink, Inc	MA	246,979
Construct	MA	41,200
Construct	MA	23,971
Duffy Health Center, Inc	MA	32,886
Duffy Health Center, Inc	MA	45,849
Emmaus Inc	MA	250,725
Emmaus Inc	MA	102,100
Emmaus Inc	MA	67,542
Fall River CoC	MA	347,784
Fall River CoC	MA	75,871
Fall River CoC	MA	159,413
Fall River CoC	MA	37,800
Fall River CoC	MA	63,960
Fall River CoC	MA	163,497
Fall River CoC	MA	76,724
Fall River CoC	MA	70,906
Fall River CoC	MA	407,856
Fall River CoC	MA	32,052
Fall River CoC	MA	329,091
Fall River CoC	MA	103,240
Family Life Support Center, Inc	MA	55,300
Family Life Support Center, Inc	MA	136,491
Family Life Support Center, Inc	MA	26,833
Father Bills & MainSpring	MA	102,152
Father Bills & MainSpring	MA	38,329
Father Bills & MainSpring	MA	41,346
Father Bills & MainSpring	MA	162,122
Father Bills & MainSpring	MA	182,895
Father Bills & MainSpring	MA	119,712
Haverhill Housing Authority	MA	65,304
Haverhill Housing Authority	MA	130,608
Heading Home	MA	216,409
Heading Home	MA	131,525
Heading Home	MA	69,869
Heading Home	MA	67,662
Heading Home	MA	71,678
Heading Home	MA	69,399
Heading Home	MA	474,503
Heading Home	MA	69,512
Housing Assistance Corporation	MA	66,431
Housing Assistance Corporation	MA	76,840
Housing Assistance Corporation	MA	76,550
Housing Assistance Corporation	MA	48,206
Housing Families Inc	MA	127,234
Housing For All Corporation	MA	44,200
Just-A-Start	MA	23,100

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Lynn Housing Authority & Neighborhood Development	MA	134,291
Lynn Housing Authority & Neighborhood Development	MA	86,853
Lynn Housing Authority & Neighborhood Development	MA	257,544
Lynn Housing Authority & Neighborhood Development	MA	714,060
Lynn Housing Authority & Neighborhood Development	MA	283,250
Lynn Housing Authority & Neighborhood Development	MA	12,561
Lynn Housing Authority & Neighborhood Development	MA	41,300
Lynn Housing Authority & Neighborhood Development	MA	26,012
Lynn Housing Authority & Neighborhood Development	MA	206,256
Lynn Housing Authority & Neighborhood Development	MA	29,383
Lynn Housing Authority & Neighborhood Development	MA	44,887
Lynn Housing Authority & Neighborhood Development	MA	239,507
lynn shelter	MA	211,146
Malden Housing Authority	MA	139,920
Mass Department of Mental Health	MA	224,160
Merrimack Valley Young Men's Christian Association Inc	MA	80,665
MetroWest Legal Services	MA	48,506
New Hope Inc	MA	92,235
North Shore Community Action Programs, Inc (NSCAP)	MA	31,448
North Shore Community Action Programs, Inc (NSCAP)	MA	142,310
Old Colony Y	MA	86,751
Old Colony Y	MA	90,896
Pine Street Inn, Inc	MA	28,000
Pine Street Inn, Inc	MA	193,132
provincetown housing authority	MA	71,880
Seeds of Hope	MA	88,620
SMOC	MA	116,150
SMOC	MA	102,670
SMOC	MA	79,128
Somerville Community Corporation	MA	9,275
Somerville Community Corporation	MA	176,740
Somerville Community Corporation	MA	16,769
Somerville Homeless Coalition, Inc	MA	163,827
Somerville Homeless Coalition, Inc	MA	40,011
Somerville Homeless Coalition, Inc	MA	407,396
Somerville Homeless Coalition, Inc	MA	230,889
Somerville Homeless Coalition, Inc	MA	131,450
Somerville Homeless Coalition, Inc	MA	194,608
Somerville Housing Authority	MA	130,548
South Coastal Counties Legal Services, Inc	MA	24,937
South Shore Housing Development Corporation	MA	42,000
The Psychological Center	MA	138,734
The Second Step. Inc	MA	65,810
The Second Step. Inc	MA	94,045
The Second Step. Inc	MA	216,473
The Second Step. Inc	MA	63,344
Transition House Inc	MA	14,073
Tri-City Community Action Program	MA	84,205
Tri-City Community Action Program	MA	143,454
Tri-City Community Action Program	MA	175,964
Tri-City Community Action Program	MA	183,961
Turning Point, Inc	MA	218,649
Twin Cities Community Development Corporation	MA	91,018
Veterans Northeast Outreach Center	MA	135,487
Veterans Northeast Outreach Center	MA	163,359
Vinfen Corporation	MA	21,912
Vinfen Corporation	MA	28,954
Vinfen Corporation	MA	43,536
Wayside Youth and Family Support Network, Inc	MA	235,821
YWCA of Greater Lawrence, Inc	MA	187,950
Advocates for Homeless Families, Inc	MD	24,008
AIDS Interfaith Residential Services, Inc	MD	38,800
AIDS Interfaith Residential Services, Inc	MD	147,340
AIDS Interfaith Residential Services, Inc	MD	231,315
AIDS Interfaith Residential Services, Inc	MD	185,039
AIDS Interfaith Residential Services, Inc	MD	107,610
Allegany County Human Resources Development Commission, Inc	MD	32,739
Allegany County Human Resources Development Commission, Inc	MD	68,460
Allegany County Human Resources Development Commission, Inc	MD	66,044
Allegany County Human Resources Development Commission, Inc	MD	14,137
Anne Arundel County, Maryland	MD	56,784
Anne Arundel County, Maryland	MD	171,056

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Anne Arundel County, Maryland	MD	116,613
Anne Arundel County, Maryland	MD	41,597
Anne Arundel County, Maryland	MD	329,983
Anne Arundel County, Maryland	MD	57,225
Anne Arundel County, Maryland	MD	57,107
Anne Arundel County, Maryland	MD	129,499
Anne Arundel County, Maryland	MD	56,658
Anne Arundel County, Maryland	MD	252,273
Anne Arundel County, Maryland	MD	70,786
Anne Arundel County, Maryland	MD	315,679
Anne Arundel County, Maryland	MD	54,548
Associated Catholic Charities, Inc	MD	219,231
Associated Catholic Charities, Inc	MD	79,198
Baltimore County Department of Social Services	MD	15,750
Baltimore County Department of Social Services	MD	80,138
Baltimore County, Maryland Project Applicant	MD	168,914
Baltimore Mental Health Systems, Inc	MD	369,600
Baltimore Mental Health Systems, Inc	MD	159,600
Baltimore Mental Health Systems, Inc	MD	392,200
Baltimore Mental Health Systems, Inc	MD	227,566
Baltimore Mental Health Systems, Inc	MD	252,874
Baltimore Mental Health Systems, Inc	MD	342,117
Baltimore Mental Health Systems, Inc	MD	247,453
Board of County Commissioners of Calvert County, Maryland	MD	18,252
Catholic Charities of the Archdiocese of Washington DC	MD	86,391
Catholic Charities of the Archdiocese of Washington DC	MD	24,245
Catholic Charities of the Archdiocese of Washington DC	MD	76,684
Cecil County Department of Social Services	MD	37,996
City of Frederick	MD	135,536
City of Frederick	MD	65,895
City of Gaithersburg-Wells/Robertson House	MD	128,247
Community Assistance Network	MD	174,593
Community Coalition for Affordable Housing	MD	5,665
Community Coalition for Affordable Housing	MD	5,665
Crossroads Community, Inc	MD	39,019
Crossroads Community, Inc	MD	13,456
Crossroads Community, Inc	MD	13,584
Crossroads Community, Inc	MD	192,763
Cumberland YMCA	MD	70,350
Cumberland YMCA	MD	369,536
Friends for Neighborhood Progress, Inc	MD	47,715
Friends for Neighborhood Progress, Inc	MD	22,418
Garrett County Community Action Committee, Inc (GCCAC)	MD	9,843
Garrett County Community Action Committee, Inc (GCCAC)	MD	5,720
Garrett County Community Action Committee, Inc (GCCAC)	MD	153,305
Garrett County Community Action Committee, Inc (GCCAC)	MD	52,473
Garrett County Community Action Committee, Inc (GCCAC)	MD	12,974
Hagerstown/Washington County CoC	MD	45,839
Harford County, Maryland	MD	10,185
Harford County, Maryland	MD	71,263
Harford County, Maryland	MD	83,944
Harford County, Maryland	MD	48,358
Harford County, Maryland	MD	56,047
Harford County, Maryland	MD	83,975
Harford County, Maryland	MD	9,273
Harford County, Maryland	MD	20,504
Harford County, Maryland	MD	10,585
Harford County, Maryland	MD	89,770
Harford County, Maryland	MD	10,244
Heartly House, Inc	MD	35,074
Housing Authority of St. Mary's County, MD	MD	35,864
Housing Authority of St. Mary's County, MD	MD	174,554
Housing Authority of St. Mary's County, MD	MD	70,633
Housing Authority of St. Mary's County, MD	MD	40,630
Housing Authority of St. Mary's County, MD	MD	17,479
Housing Authority of St. Mary's County, MD	MD	110,360
Housing Authority of St. Mary's County, MD	MD	17,449
Housing Authority of St. Mary's County, MD	MD	11,471
Housing Authority of St. Mary's County, MD	MD	10,574
Housing Authority of St. Mary's County, MD	MD	42,451
Housing Opportunities Commission	MD	79,533
Housing Opportunities Commission	MD	270,912

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Housing Opportunities Commission	MD	673,584
Housing Opportunities Commission	MD	2,307,775
Housing Opportunities Commission	MD	217,406
Howard County Government	MD	52,363
Howard County Government	MD	22,773
Howard County Government	MD	130,335
Howard County Government	MD	70,504
Howard County Government	MD	236,433
Howard County Mental Health Authority	MD	166,788
Human Services Developmental Corporation, Inc	MD	73,776
Human Services Programs of Carroll County, Inc	MD	7,668
Human Services Programs of Carroll County, Inc	MD	42,792
Human Services Programs of Carroll County, Inc	MD	65,402
Human Services Programs of Carroll County, Inc	MD	15,682
Human Services Programs of Carroll County, Inc	MD	44,000
Human Services Programs of Carroll County, Inc	MD	86,135
Human Services Programs of Carroll County, Inc	MD	7,668
INNterim Permanent Housing	MD	248,745
Interfaith Works	MD	279,825
Interfaith Works	MD	235,903
JHP, Inc	MD	228,186
JHP, Inc	MD	136,761
Laurel Advocacy and Referral Services, Inc	MD	185,770
Laurel Advocacy and Referral Services, Inc	MD	158,815
Laurel Advocacy and Referral Services, Inc	MD	47,265
Maryland Department of Health and Mental Hygiene	MD	141,504
Maryland Department of Health and Mental Hygiene	MD	173,988
Maryland Department of Health and Mental Hygiene	MD	107,268
Maryland Department of Health and Mental Hygiene	MD	46,044
Maryland Department of Health and Mental Hygiene	MD	63,156
Maryland Department of Health and Mental Hygiene	MD	224,580
Maryland Department of Health and Mental Hygiene	MD	1,208,916
Maryland Department of Health and Mental Hygiene	MD	161,496
Maryland Department of Health and Mental Hygiene	MD	374,664
Maryland Department of Health and Mental Hygiene	MD	47,808
Maryland Department of Health and Mental Hygiene	MD	119,844
Maryland Department of Health and Mental Hygiene	MD	122,136
Maryland Department of Health and Mental Hygiene	MD	64,200
Maryland Department of Health and Mental Hygiene	MD	279,228
Maryland Department of Health and Mental Hygiene	MD	281,376
Maryland Department of Health and Mental Hygiene	MD	86,844
Maryland Department of Health and Mental Hygiene	MD	599,616
Maryland Department of Health and Mental Hygiene	MD	240,060
Maryland Department of Health and Mental Hygiene	MD	267,864
Mid-Shore Mental Health Systems, Inc	MD	59,306
Mid-Shore Mental Health Systems, Inc	MD	183,792
Montgomery Avenue Womens Center	MD	138,183
Montgomery County Coalition for the Homeless	MD	131,260
Montgomery County Coalition for the Homeless	MD	511,058
Montgomery County Coalition for the Homeless	MD	135,434
Montgomery County Coalition for the Homeless	MD	134,433
Montgomery County Coalition for the Homeless	MD	359,232
Montgomery County Coalition for the Homeless	MD	135,435
Montgomery County Coalition for the Homeless	MD	826,569
National Center for Children and Families	MD	640,658
Nehemiah House, Inc	MD	57,295
People Encouraging People, Inc	MD	157,474
Prince George's County Department of Social Services	MD	382,783
Prince George's County Department of Social Services	MD	116,193
Prince George's County Department of Social Services	MD	1,289,000
Projects—City of Baltimore	MD	307,500
Projects—City of Baltimore	MD	109,032
Projects—City of Baltimore	MD	74,001
Projects—City of Baltimore	MD	1,429,572
Projects—City of Baltimore	MD	1,138,320
Projects—City of Baltimore	MD	55,860
Projects—City of Baltimore	MD	488,651
Projects—City of Baltimore	MD	114,805
Projects—City of Baltimore	MD	251,744
Projects—City of Baltimore	MD	363,849
Projects—City of Baltimore	MD	67,554
Projects—City of Baltimore	MD	235,900

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Projects—City of Baltimore	MD	341,496
Projects—City of Baltimore	MD	59,088
Projects—City of Baltimore	MD	571,680
Projects—City of Baltimore	MD	175,124
Projects—City of Baltimore	MD	1,846,680
Projects—City of Baltimore	MD	31,137
Projects—City of Baltimore	MD	1,421,238
Projects—City of Baltimore	MD	63,125
Projects—City of Baltimore	MD	173,250
Projects—City of Baltimore	MD	107,116
Projects—City of Baltimore	MD	307,500
Projects—City of Baltimore	MD	704,886
Projects—City of Baltimore	MD	308,504
Projects—City of Baltimore	MD	165,152
Projects—City of Baltimore	MD	356,030
Projects—City of Baltimore	MD	611,913
Projects—City of Baltimore	MD	55,347
Projects—City of Baltimore	MD	297,461
Projects—City of Baltimore	MD	113,832
Projects—City of Baltimore	MD	225,528
Projects—City of Baltimore	MD	155,548
Projects—City of Baltimore	MD	1,490,580
Projects—City of Baltimore	MD	32,983
Projects—City of Baltimore	MD	46,235
Projects—City of Baltimore	MD	102,062
Projects—City of Baltimore	MD	291,244
Projects—City of Baltimore	MD	853,740
Projects—City of Baltimore	MD	132,948
Projects—City of Baltimore	MD	98,780
Projects—City of Baltimore	MD	41,149
Projects—City of Baltimore	MD	584,306
Projects—City of Baltimore	MD	397,793
Projects—City of Baltimore	MD	45,378
Projects—City of Baltimore	MD	214,025
Projects—City of Baltimore	MD	110,700
Projects—City of Baltimore	MD	132,144
Projects—City of Baltimore	MD	38,127
Projects—City of Baltimore	MD	118,176
Projects—City of Baltimore	MD	23,520
Projects—City of Baltimore	MD	204,000
Projects—City of Baltimore	MD	246,000
Projects—City of Baltimore	MD	49,200
Projects—City of Baltimore	MD	335,087
Projects—City of Baltimore	MD	113,461
Projects—City of Baltimore	MD	97,356
Projects—City of Baltimore	MD	58,776
Projects—City of Baltimore	MD	976,056
Projects—City of Baltimore	MD	43,579
Projects—City of Baltimore	MD	73,069
Projects—City of Baltimore	MD	34,341
Projects—City of Baltimore	MD	69,258
Projects—City of Baltimore	MD	35,343
Projects—City of Baltimore	MD	100,044
Projects—City of Baltimore	MD	100,247
Projects—City of Baltimore	MD	205,926
Projects—City of Baltimore	MD	50,022
Projects—City of Baltimore	MD	166,656
Projects—City of Baltimore	MD	78,750
Prologue, Inc	MD	431,727
Prologue, Inc	MD	105,000
Rehabilitation Systems, Inc	MD	132,958
Rehabilitation Systems, Inc	MD	368,004
Rehabilitation Systems, Inc	MD	234,720
Somerset County Health Department	MD	221,433
Somerset County Health Department	MD	27,622
Somerset County Health Department	MD	14,076
Somerset County Health Department	MD	13,468
Somerset County Health Department	MD	13,866
Somerset County Health Department	MD	13,447
Somerset County Health Department	MD	421,857
United Communities Against Poverty	MD	161,403
United Communities Against Poverty	MD	194,852

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
United Communities Against Poverty	MD	158,919
Volunteers of America Chesapeake, Inc	MD	321,121
Washington County Community Action Council, Inc	MD	198,729
Washington County Community Action Council, Inc	MD	56,367
Avesta Housing Development Corporation	ME	304,266
Bread of Life Ministries, Inc	ME	73,500
Bread of Life Ministries, Inc	ME	12,600
CHCS HUD TPC	ME	18,599
City of Bangor	ME	74,496
City of Bangor	ME	329,292
City of Bangor	ME	36,480
City of Bangor	ME	36,480
City of Bangor	ME	282,156
City of Portland	ME	15,443
City of Portland	ME	70,016
City of Portland	ME	158,125
Community Housing of Maine, Inc	ME	19,635
Counseling Services, Inc	ME	64,410
Hope and Justice Project, Inc	ME	27,251
Hope House/PCHC	ME	9,975
Kennebec Behavioral Health	ME	32,838
LearningWorks	ME	70,652
Maine State Housing Authority	ME	27,969
Maine State Housing Authority	ME	154,959
Maine State Housing Authority	ME	16,758
Maine State Housing Authority	ME	22,715
Maine State Housing Authority	ME	66,431
Maine State Housing Authority	ME	163,800
MAPS/StepUP!	ME	71,355
New Beginnings, Inc	ME	167,116
OHI	ME	27,900
Shaw House	ME	95,550
Shaw House	ME	109,068
State of Maine, Department of Health and Human Services	ME	223,080
State of Maine, Department of Health and Human Services	ME	86,400
State of Maine, Department of Health and Human Services	ME	380,940
State of Maine, Department of Health and Human Services	ME	78,432
State of Maine, Department of Health and Human Services	ME	110,268
State of Maine, Department of Health and Human Services	ME	1,681,032
State of Maine, Department of Health and Human Services	ME	1,540,476
State of Maine, Department of Health and Human Services	ME	222,660
State of Maine, Department of Health and Human Services	ME	392,508
State of Maine, Department of Health and Human Services	ME	1,988,208
State of Maine, Department of Health and Human Services	ME	183,528
Tedford Housing	ME	6,825
Tedford Housing	ME	16,519
Washington County Association for Retarded Citizens	ME	28,927
York County Shelter Programs, Inc	ME	99,174
York County Shelter Programs, Inc	ME	292,038
York County Shelter Programs, Inc	ME	111,127
York County Shelter Programs, Inc	ME	33,238
Youth Alternatives Ingraham, Inc	ME	126,936
Youth Alternatives Ingraham, Inc	ME	307,099
Youth Alternatives Ingraham, Inc	ME	82,356
Alger Marquette Community Action Board	MI	52,207
Alternative Community Living, Inc d/b/a New Passages Behavioral Health & Rehabilitation Services	MI	33,469
Alternative Community Living, Inc d/b/a New Passages Behavioral Health & Rehabilitation Services	MI	36,211
Alternatives For Girls	MI	111,726
Ann Arbor Housing Commission	MI	275,712
Ann Arbor Housing Commission	MI	51,696
Ann Arbor Housing Commission	MI	199,776
Ann Arbor Housing Commission	MI	216,276
Ann Arbor Housing Commission	MI	66,252
Avalon Housing, Inc	MI	83,334
Avalon Housing, Inc	MI	86,534
Bay Area Women's Center	MI	60,483
Bay Area Women's Center	MI	106,488
Branch County Coalition Against Domestic Violence	MI	14,422
Branch County Coalition Against Domestic Violence	MI	20,700
Capital Area Community Services, Inc	MI	93,809
Capital Area Community Services, Inc	MI	106,791
Cass Community Social Services, Inc	MI	257,272

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Cass Community Social Services, Inc	MI	188,724
Cass Community Social Services, Inc	MI	420,000
Catholic Family Services	MI	104,240
Catholic Social Services of Wayne County	MI	181,417
Catholic Social Services of Wayne County	MI	355,618
Center for Women in Transition	MI	81,736
Center for Women in Transition	MI	38,614
Center for Women in Transition	MI	85,795
Center for Women in Transition	MI	23,220
Central Territorial of the Salvation Army	MI	228,488
Central Territorial of the Salvation Army	MI	249,854
Central Territorial of the Salvation Army	MI	231,583
CHARTER COUNTY OF WAYNE	MI	401,246
CHARTER COUNTY OF WAYNE	MI	211,488
CHARTER COUNTY OF WAYNE	MI	293,160
CHARTER COUNTY OF WAYNE	MI	127,813
CHARTER COUNTY OF WAYNE	MI	40,020
CHARTER COUNTY OF WAYNE	MI	112,665
CHARTER COUNTY OF WAYNE	MI	283,980
CHARTER COUNTY OF WAYNE	MI	453,143
City of Lansing Project Applicant	MI	62,842
City of Lansing Project Applicant	MI	385,826
City of Lansing Project Applicant	MI	97,081
City of Lansing Project Applicant	MI	46,115
City of Lansing Project Applicant	MI	24,000
City of Lansing Project Applicant	MI	62,842
City of Lansing Project Applicant	MI	585,090
City of Lansing Project Applicant	MI	39,334
City of Lansing Project Applicant	MI	172,900
City of Lansing Project Applicant	MI	149,999
City of Melvindale	MI	251,124
CMHS of Muskegon County	MI	102,888
CMHS of Muskegon County	MI	21,168
CMHS of Muskegon County	MI	16,598
CMHS of Muskegon County	MI	21,024
Coalition On Temporary Shelter	MI	68,259
Coalition On Temporary Shelter	MI	84,979
Coalition On Temporary Shelter	MI	660,686
Coalition On Temporary Shelter	MI	135,338
Coalition On Temporary Shelter	MI	308,083
Coalition On Temporary Shelter	MI	105,546
Common Ground	MI	132,999
Common Ground	MI	84,546
Common Ground	MI	105,000
Common Ground	MI	82,761
Community & Home Supports, Inc	MI	680,524
Community Action Agency	MI	269,267
Community Action Agency	MI	54,932
Community Action Agency	MI	56,131
Community Action Agency	MI	190,243
Community Care Services	MI	143,119
Community Housing Network, Inc	MI	71,554
Community Housing Network, Inc	MI	267,996
Community Housing Network, Inc	MI	326,432
Community Housing Network, Inc	MI	149,689
Community Housing Network, Inc	MI	144,435
Community Housing Network, Inc	MI	301,080
Community Housing Network, Inc	MI	319,414
Community Housing Network, Inc	MI	161,124
Community Housing Network, Inc	MI	158,908
Community Housing Network, Inc	MI	122,665
Community Housing Network, Inc	MI	212,524
Community Housing Network, Inc	MI	69,737
Community Housing Network, Inc	MI	50,199
Community Housing Network, Inc	MI	49,400
Community Housing Network, Inc	MI	75,441
Community Housing Network, Inc	MI	102,331
Community Housing Network, Inc	MI	206,398
Community Housing Network, Inc	MI	58,180
Community Housing Network, Inc	MI	209,365
Community Housing Network, Inc	MI	168,253
Community Rebuilders	MI	256,080

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Community Rebuilders	MI	607,695
Community Rebuilders	MI	260,310
Community Rebuilders	MI	116,603
Comprehensive Youth Services	MI	29,820
CORY PLACE, INC	MI	136,666
County of Kent	MI	390,984
County of Kent	MI	794,616
County of Kent	MI	141,120
Covenant House Michigan	MI	400,233
Cynthia Haberman	MI	76,987
Cynthia Haberman	MI	12,223
Detroit Central City CMH, Inc	MI	1,009,997
Detroit Rescue Mission Ministries	MI	426,160
Detroit Rescue Mission Ministries	MI	759,593
Detroit Rescue Mission Ministries	MI	406,740
Detroit Rescue Mission Ministries	MI	448,436
Detroit Rescue Mission Ministries	MI	622,667
Detroit Rescue Mission Ministries	MI	220,333
Detroit Rescue Mission Ministries	MI	1,057,721
Detroit Rescue Mission Ministries	MI	394,917
Detroit Rescue Mission Ministries	MI	543,532
Dwelling Place of Grand Rapids, Inc	MI	100,935
Eastern Upper Peninsula Veterans Foundation	MI	115,166
First Step: Western Wayne County Project on Domestic Assault	MI	47,580
First Step: Western Wayne County Project on Domestic Assault	MI	41,657
Foundation for Mental Health—Grand Traverse/Leelanau	MI	42,105
Foundation for Mental Health—Grand Traverse/Leelanau	MI	12,588
Foundation for Mental Health—Grand Traverse/Leelanau	MI	31,500
Foundation for Mental Health—Grand Traverse/Leelanau	MI	60,170
Foundation for Mental Health—Grand Traverse/Leelanau	MI	58,708
Freedom House	MI	383,543
Genesee County Community Action Resource Department	MI	176,616
Genesis Non-Profit Housing Corporation	MI	36,750
Genesis Non-Profit Housing Corporation	MI	32,550
Genesis Non-Profit Housing Corporation	MI	26,250
Good Samaritan Ministries	MI	402,066
Goodwill Industries of Northern Michigan, Inc	MI	51,923
Goodwill Industries of Northern Michigan, Inc—HMIS	MI	25,620
Grand Rapids Housing Commission	MI	226,900
Grand Rapids Housing Commission	MI	118,009
Grand Rapids Housing Commission	MI	120,086
Grand Rapids Housing Commission	MI	121,577
Haven of Rest Ministries	MI	175,166
Haven of Rest Ministries	MI	86,758
Heartside Nonprofit Housing Corporation	MI	63,000
Heartside Nonprofit Housing Corporation	MI	253,687
Heartside Nonprofit Housing Corporation	MI	116,667
Homeless Action Network of Detroit	MI	288,463
Homeless Action Network of Detroit	MI	190,273
Housing Resource Center	MI	84,800
Housing Resources, Inc of Kalamazoo County	MI	65,030
Housing Resources, Inc of Kalamazoo County	MI	120,390
Housing Resources, Inc of Kalamazoo County	MI	317,960
Housing Resources, Inc of Kalamazoo County	MI	77,439
Housing Services for Eaton County	MI	197,007
Housing Services for Eaton County	MI	49,875
Housing Services for Eaton County	MI	14,351
Human Development Commission	MI	244,603
Inner City Christian Federation	MI	38,810
Jewish Vocational Service	MI	653,153
Kalamazoo Community Mental Health & Substance Abuse Services	MI	258,648
Kalamazoo Community Mental Health & Substance Abuse Services	MI	109,113
Kalamazoo Community Mental Health & Substance Abuse Services	MI	51,972
Kalamazoo Community Mental Health & Substance Abuse Services	MI	58,052
Kalamazoo Community Mental Health & Substance Abuse Services	MI	58,079
Kalamazoo Community Mental Health & Substance Abuse Services	MI	38,149
Kalamazoo Community Mental Health & Substance Abuse Services	MI	299,401
Kalamazoo Community Mental Health & Substance Abuse Services	MI	38,803
Kalamazoo County Public Housing Commission	MI	38,136
Lansing Housing Commission Shelter Plus Care Program	MI	258,336
Lenawee Emergency and Affordable Housing Corporation	MI	86,511
Lenawee Emergency and Affordable Housing Corporation	MI	32,780

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Lighthouse of Oakland County, Inc	MI	100,762
Lighthouse of Oakland County, Inc	MI	171,337
Lighthouse of Oakland County, Inc	MI	76,650
Lighthouse of Oakland County, Inc	MI	203,741
Lighthouse of Oakland County, Inc	MI	103,106
Lighthouse of Oakland County, Inc	MI	107,716
Livingston County Community Mental Health Authority	MI	67,553
Livingston County Community Mental Health Authority	MI	66,666
Lutheran Social Services of Wisconsin and Upper Michigan, Inc	MI	104,307
Lutheran Social Services of Wisconsin and Upper Michigan, Inc	MI	89,209
Macomb County Community Mental Health	MI	22,816
Macomb Homeless Coalition	MI	29,919
Macomb Homeless Coalition	MI	28,890
Mariners Inn	MI	289,004
Mariners Inn	MI	105,788
Mariners Inn	MI	243,585
Metro Community Development	MI	21,305
Metro Community Development	MI	89,577
Metro Community Development	MI	205,542
Metro Community Development	MI	62,160
Metro Community Development	MI	50,269
Metro Community Development	MI	124,287
Metro Community Development	MI	28,251
Metro Community Development	MI	24,749
Metro Community Development	MI	76,683
Metro Community Development	MI	322,871
Metro Community Development	MI	247,570
Metro Community Development	MI	105,213
Metro Community Development	MI	66,247
Metro Community Development	MI	60,664
Metro Community Development	MI	61,518
Metro Community Development	MI	230,956
Metro Community Development	MI	342,695
Michigan Ability Partners	MI	41,316
Michigan Ability Partners	MI	51,100
Michigan Ability Partners	MI	403,071
Michigan Department of Community Health	MI	337,344
Michigan Department of Community Health	MI	248,724
Michigan Department of Community Health	MI	464,232
Michigan Department of Community Health	MI	1,000,500
Michigan Department of Community Health	MI	164,532
Michigan Department of Community Health	MI	362,827
Michigan Department of Community Health	MI	177,672
Michigan Department of Community Health	MI	238,820
Michigan Department of Community Health	MI	179,220
Michigan Department of Community Health	MI	2,113,536
Michigan Department of Community Health	MI	214,855
Michigan Department of Community Health	MI	703,649
Michigan Department of Community Health	MI	175,632
Michigan Department of Community Health	MI	681,420
Michigan Department of Community Health	MI	134,208
Michigan Department of Community Health	MI	156,870
Michigan Department of Community Health	MI	334,428
Michigan Department of Human Services	MI	520,814
Michigan Department of Human Services	MI	117,454
Michigan Department of Human Services	MI	952,558
Michigan Department of Human Services	MI	322,507
Michigan Department of Human Services	MI	870,274
Michigan State Housing Development Authority	MI	640,500
Michigan Veterans Foundation	MI	709,836
Monroe County Opportunity Program	MI	102,863
Neighborhood Legal Services Michigan	MI	468,316
Neighborhood Legal Services Michigan	MI	161,116
Neighborhood Legal Services Michigan	MI	335,863
Neighborhood Legal Services Michigan	MI	768,090
Oakland Livingston Human Service Agency	MI	16,080
Oakland Livingston Human Service Agency	MI	11,162
Oakland Livingston Human Service Agency	MI	25,083
Oakland Livingston Human Service Agency	MI	17,158
Oakland Livingston Human Service Agency	MI	8,364
Oakland Livingston Human Service Agency	MI	8,364
Ottawa County Community Mental Health	MI	17,585

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Ottawa County Community Mental Health	MI	31,775
Ottawa County Community Mental Health	MI	15,786
Ottawa County Community Mental Health	MI	96,996
Ottawa County Community Mental Health	MI	218,943
Ozone House, Inc	MI	42,201
Ozone House, Inc	MI	112,157
Peckham, Inc	MI	146,877
Perfecting Community Development Corporation	MI	50,818
Positive Images	MI	700,009
POWER Inc	MI	168,871
Relief After Violent Encounter—Ionia/Montcalm Inc	MI	57,833
S.A.F.E. Place	MI	85,000
Sacred Heart Rehabilitation Center, Inc	MI	194,214
Safe Horizons	MI	214,539
Saginaw County Community Mental Health Authority	MI	201,456
Saginaw County Community Mental Health Authority	MI	67,980
Saginaw County Community Mental Health Authority	MI	117,888
Saginaw County Youth Protection Council	MI	26,998
Saginaw County Youth Protection Council	MI	58,263
Saginaw County Youth Protection Council	MI	81,382
Saginaw County Youth Protection Council	MI	39,892
Saginaw County Youth Protection Council	MI	96,304
Saginaw Housing Commission	MI	75,000
Saginaw Housing Commission	MI	54,512
Saginaw Housing Commission	MI	152,832
Saginaw Housing Commission	MI	46,656
Saginaw Housing Commission	MI	30,900
Saginaw Housing Commission	MI	30,900
Saginaw Housing Commission	MI	30,900
Sault Ste Marie Housing Commission	MI	168,000
Shelter, Inc	MI	44,241
Simon House	MI	88,674
SIREN/Eaton Shelter, Inc	MI	278,739
SOS Community Services	MI	433,994
SOS Community Services	MI	252,455
SOS Community Services	MI	1,182,579
SOS Community Services	MI	395,974
South Oakland Shelter	MI	338,699
Southwest Counseling Solutions, Inc	MI	941,892
Southwest Housing Solutions	MI	202,978
Southwest Housing Solutions	MI	129,539
St. Vincent Catholic Charities	MI	145,149
Staircase Youth Services, Inc	MI	101,963
Summit Pointe	MI	67,936
The Salvation Army Eastern Michigan Division Harbor Light Special Services	MI	466,464
Training and Treatment Innovations	MI	115,054
Training and Treatment Innovations	MI	109,192
Training and Treatment Innovations	MI	150,051
Training and Treatment Innovations	MI	151,532
Training and Treatment Innovations, Inc	MI	118,144
Training and Treatment Innovations, Inc	MI	112,876
Travelers Aid Society of Metropolitan Detroit	MI	222,828
Travelers Aid Society of Metropolitan Detroit	MI	80,655
Travelers Aid Society of Metropolitan Detroit	MI	213,300
Travelers Aid Society of Metropolitan Detroit	MI	867,982
Travelers Aid Society of Metropolitan Detroit	MI	938,985
Underground Railroad, Inc	MI	152,786
Underground Railroad, Inc	MI	82,663
Underground Railroad, Inc	MI	124,683
Underground Railroad, Inc	MI	115,746
United Community Housing Coalition	MI	569,351
United Way of Saginaw County	MI	70,509
Wayne Metropolitan Community Action Agency	MI	369,538
Wayne Metropolitan Community Action Agency	MI	180,530
Wayne Metropolitan Community Action Agency	MI	280,181
Wayne Metropolitan Community Action Agency	MI	119,279
Wayne Metropolitan Community Action Agency	MI	69,468
Wayne Metropolitan Community Action Agency	MI	191,987
Wayne Metropolitan Community Action Agency	MI	81,354
Wayne Metropolitan Community Action Agency	MI	224,256
Wayne Metropolitan Community Action Agency	MI	89,949
Wayne Metropolitan Community Action Agency	MI	102,224

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Wayne, Charter County of	MI	175,143
West Michigan Therapy	MI	45,735
West Michigan Therapy	MI	62,000
West Michigan Therapy	MI	234,168
West Michigan Therapy	MI	13,333
Women Empowering Women	MI	59,219
Women's Resource Center for the Grand Traverse Area	MI	26,496
Women's Resource Center for the Grand Traverse Area	MI	133,875
Women's Resource Center for the Grand Traverse Area	MI	29,517
YWCA West Central Michigan	MI	391,898
Advocates Against Domestic Abuse	MN	12,420
Aeon	MN	236,803
Aeon	MN	77,003
Alliance Housing Inc	MN	206,557
American Indian Community Development Corporation	MN	81,111
American Indian Community Housing Organization	MN	25,481
American Indian Community Housing Organization	MN	12,434
American Indian Community Housing Organization	MN	39,157
American Indian Community Housing Organization	MN	35,022
American Indian Community Housing Organization	MN	20,483
Amherst H. Wilder Foundation	MN	105,410
Amherst H. Wilder Foundation	MN	18,000
Amherst H. Wilder Foundation	MN	25,000
Amherst H. Wilder Foundation	MN	10,000
Amherst H. Wilder Foundation	MN	49,994
Amherst H. Wilder Foundation	MN	5,756
Amherst H. Wilder Foundation	MN	954,260
Amherst H. Wilder Foundation	MN	32,510
Amherst H. Wilder Foundation	MN	28,000
Amherst H. Wilder Foundation	MN	19,999
Amherst H. Wilder Foundation	MN	5,829
Amherst H. Wilder Foundation	MN	20,554
Amherst H. Wilder Foundation	MN	42,649
Amherst H. Wilder Foundation	MN	6,000
Arrowhead Economic Opportunity Agency	MN	20,600
Arrowhead Economic Opportunity Agency	MN	53,552
Arrowhead Economic Opportunity Agency	MN	51,143
Arrowhead Economic Opportunity Agency	MN	26,276
Bi-County Community Action Programs, Inc	MN	19,511
Bi-County Community Action Programs, Inc	MN	65,848
Bi-County Community Action Programs, Inc	MN	16,800
Bi-County Community Action Programs, Inc	MN	78,128
Bi-County Community Action Programs, Inc	MN	33,880
Blue Earth County	MN	129,768
Bluff Country Family Resources	MN	35,332
Breaking Free	MN	93,600
Breaking Free	MN	183,676
Cabrini Partnership	MN	183,077
Carver County CDA	MN	98,472
Catholic Charities of the Archdiocese of St. Paul and Minneapolis	MN	514,133
Catholic Charities St. Paul Minneapolis	MN	309,857
center city housing	MN	39,921
center city housing	MN	143,000
center city housing	MN	41,532
center city housing	MN	78,122
center city housing	MN	61,733
CommonBond Communities	MN	25,000
Community Involvement Programs	MN	25,479
Crookston Housing and Economic Development Authority	MN	48,480
Dakota County	MN	410,844
Dakota County CDA	MN	228,048
East Metro Women's Council	MN	67,814
Elim Transitional Housing, Inc	MN	152,325
Elim Transitional Housing, Inc	MN	30,319
Elim Transitional Housing, Inc	MN	13,983
Elim Transitional Housing, Inc	MN	33,101
Emerge Community Development	MN	573,312
emma norton services	MN	136,212
emma norton services	MN	71,251
Evergreen House, Inc	MN	43,905
Face to Face Health and Counseling Service, Inc	MN	43,308
Freeport West, Inc	MN	242,886

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Freeport West, Inc	MN	412,619
Grant County	MN	109,536
Guild Incorporated	MN	257,611
Heartland Community Action Agency, Inc	MN	58,052
Heartland Community Action Agency, Inc	MN	139,560
Hennepin County	MN	503,868
Hennepin County	MN	347,548
Hennepin County	MN	196,680
Hennepin County HRA	MN	530,880
Homeless Youth Outreach Program	MN	38,638
Housing & Redevelopment Authority of Bemidji	MN	40,872
Housing & Redevelopment Authority of Clay County	MN	200,432
Housing & Redevelopment Authority of Clay County	MN	56,666
Housing & Redevelopment Authority of Clay County	MN	58,872
Housing and Redevelopment Authority In and For the City of Willmar MN	MN	63,744
Housing and Redevelopment Authority In and For the City of Willmar MN	MN	23,705
Housing and Redevelopment Authority In and For the City of Willmar MN	MN	16,920
Housing and Redevelopment Authority of Duluth, MN	MN	108,048
Housing and Redevelopment Authority of Duluth, MN	MN	208,512
Housing and Redevelopment Authority of St. Cloud	MN	196,608
Housing and Redevelopment Authority of St. Cloud	MN	26,688
Housing and Redevelopment Authority of St. Cloud	MN	109,200
Housing Authority of St. Louis Park	MN	117,420
Housing Authority of St. Louis Park	MN	105,288
Housing Authority of St. Louis Park	MN	30,336
Housing Authority of St. Louis Park	MN	62,568
Housing Authority of St. Louis Park	MN	30,336
Hubbard HRA	MN	34,150
HUMAN DEVELOPMENT CENTER	MN	16,417
HUMAN DEVELOPMENT CENTER	MN	74,263
HUMAN DEVELOPMENT CENTER	MN	73,416
Human Services, Inc, in Washington County Minnesota	MN	52,701
Human Services, Inc, in Washington County Minnesota	MN	41,874
Itasca County HRA	MN	58,356
Kootasca Community Action Inc	MN	32,019
Lakes & Prairies Community Action Partnership, Inc	MN	21,376
Lakes & Prairies Community Action Partnership, Inc	MN	21,358
Lakes & Prairies Community Action Partnership, Inc	MN	21,358
Lakes & Prairies Community Action Partnership, Inc	MN	47,697
Lakes and Pines Community Action Council, Inc	MN	121,294
Life House, Inc	MN	19,011
LivingWorks Ventures	MN	55,999
Lutheran Social Service of Minnesota	MN	166,023
Lutheran Social Service of Minnesota	MN	119,464
Lutheran Social Service of Minnesota	MN	47,184
Mental Health Resources, Inc	MN	173,315
Mental Health Resources, Inc	MN	26,402
Mental Health Resources, Inc	MN	359,042
Metropolitan Council, Minnesota	MN	1,881,024
Metropolitan Council, Minnesota	MN	788,808
Metropolitan Council, Minnesota	MN	223,092
Minnesota Assistance Council for Veterans	MN	152,250
Minnesota Assistance Council for Veterans	MN	49,260
Minnesota Assistance Council for Veterans	MN	58,889
Minnesota Assistance Council for Veterans	MN	26,602
Model Cities of St. Paul, Inc	MN	216,857
New Foundations, Inc	MN	298,090
New Pathways, Inc	MN	89,292
New Pathways, Inc	MN	105,265
Northwestern Mental Health Center, Inc	MN	47,400
Northwestern Mental Health Center, Inc	MN	40,046
Olmsted County Community Services	MN	117,816
Olmsted County Housing & Redevelopment Authority	MN	98,880
Olmsted County Housing and Redevelopment Authority	MN	24,720
Otter Tail Wadena Community Action Council, Inc	MN	43,738
Our Saviour's Outreach Ministries	MN	69,905
Partners for Affordable Housing	MN	11,522
People Incorporated	MN	45,641
People Incorporated	MN	64,426
Perspectives, Inc	MN	171,173
Perspectives, Inc	MN	171,499
Plymouth Church Neighborhood Foundation	MN	267,946

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Project for Pride in Living, Inc	MN	128,625
Ramsey County	MN	888,624
Range Mental Health Center	MN	41,312
Range Transitional Housing, Inc	MN	70,500
Range Transitional Housing, Inc	MN	133,317
Range Transitional Housing, Inc	MN	236,828
Range Transitional Housing, Inc	MN	91,432
Red Wing Housing and Redevelopment Authority	MN	86,040
RESOURCE,Inc	MN	583,903
Rice County Housing and Redevelopment Authority	MN	64,620
RS Eden	MN	45,486
RS Eden	MN	149,100
Rum River Health Services, Inc	MN	50,250
Ruths House of Hope Inc	MN	102,494
Ruths House of Hope Inc	MN	17,178
Safe Haven for Youth	MN	26,889
Scott County Human Services	MN	182,748
Scott-Carver-Dakota CAP Agency	MN	119,961
Scott-Carver-Dakota CAP Agency	MN	24,253
Scott-Carver-Dakota CAP Agency	MN	28,419
Scott-Carver-Dakota CAP Agency	MN	23,230
Simpson Housing Services, Inc	MN	143,091
Simpson Housing Services, Inc	MN	74,275
South Metro Human Services	MN	48,297
Southwestern Minnesota Adult Mental Health Consortium	MN	48,000
St. Louis County	MN	215,280
Steele County Transitional Housing	MN	23,751
Supportive Housing and Managed Care Pilot, aka Hearth Connection	MN	69,204
Supportive Housing and Managed Care Pilot, aka Hearth Connection	MN	185,976
Supportive Housing and Managed Care Pilot, aka Hearth Connection	MN	26,724
The Link	MN	50,075
The Salvation Army	MN	333,577
The Salvation Army	MN	45,108
The Salvation Army	MN	88,098
The Salvation Army	MN	31,081
The Salvation Army	MN	121,817
The Salvation Army	MN	85,575
The Salvation Army	MN	246,784
The Salvation Army	MN	145,166
The Salvation Army	MN	145,149
Theresa Living Center	MN	54,912
Theresa Living Center	MN	84,650
Three Rivers Community Action	MN	175,915
Three Rivers Community Action	MN	149,665
Tubman	MN	97,085
Violence Intervention Project	MN	21,249
Virginia HRA	MN	110,664
Virginia HRA	MN	257,220
Volunteers of America of Minnesota	MN	103,477
Washington County HRA	MN	231,444
Western Community Action	MN	62,354
Wings Family Supportive Services, Inc	MN	56,961
Young Women's Christian Association	MN	16,275
Young Women's Christian Association of St Paul MN	MN	80,585
Young Women's Christian Association of St Paul MN	MN	20,000
Zion Originated Outreach Ministry	MN	75,185
Benilde Hall	MO	51,350
Benilde Hall	MO	100,380
Catholic Charities of Kansas City-St. Joseph, Inc	MO	268,143
Catholic Charities of Kansas City-St. Joseph, Inc	MO	191,100
Catholic Charities of Kansas City-St. Joseph, Inc	MO	136,591
Catholic Charities of Kansas City-St. Joseph, Inc	MO	216,262
Catholic Charities of Kansas City-St. Joseph, Inc	MO	175,133
Catholic Charities of Kansas City-St. Joseph, Inc	MO	69,338
Catholic Family Services	MO	57,790
Church Army Inc	MO	68,906
City of Kansas City, Missouri	MO	313,824
City of Kansas City, Missouri	MO	48,300
City of Kansas City, Missouri	MO	24,856
City of Kansas City, Missouri	MO	36,131
City of Kansas City, Missouri	MO	125,890
City of Kansas City, Missouri	MO	114,450

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
City of Kansas City, Missouri	MO	199,399
City of Kansas City, Missouri	MO	32,935
City of Kansas City, Missouri	MO	133,891
City of St. Joseph	MO	44,924
City of St. Louis	MO	752,684
City of St. Louis	MO	241,010
City of St. Louis	MO	101,991
Columbia Housing Authority	MO	325,380
Community Caring Council	MO	186,389
Community Council of St. Charles County	MO	67,678
Community LINC	MO	110,058
Community Missions Corporation	MO	83,278
Community Missions Corporation	MO	187,278
Community Services League	MO	126,500
Covenant House Missouri	MO	261,450
Crider Health Center	MO	153,153
Crider Health Center 2	MO	35,112
Delta Area Economic Opportunity Corporation	MO	149,719
Delta Area Economic Opportunity Corporation	MO	116,657
Don Bosco Community Center	MO	81,505
Economic Security Corporation of Southwest Area	MO	37,426
Economic Security Corporation of Southwest Area	MO	64,088
Economic Security Corporation of Southwest Area	MO	68,603
Economic Security Corporation of Southwest Area	MO	38,376
Employment Connection	MO	176,705
Employment Connection	MO	350,457
F.A.I.T.H., Inc	MO	43,647
Family Counseling Center, Inc	MO	137,627
Family Counseling Center, Inc	MO	135,780
Family Counseling Center, Inc	MO	120,003
Family Self Help Center Inc dba Lafayette House	MO	63,000
High Hope Employment Services, Inc	MO	42,179
High Hope Employment Services, Inc	MO	74,033
Housing Authority of Kansas City Missouri	MO	110,376
Housing Authority of Kansas City Missouri	MO	118,260
Housing Authority of Springfield	MO	118,188
Humanitri	MO	200,586
Humanitri	MO	158,811
Humanitri	MO	326,479
Jasper County Public Housing Agency	MO	56,400
Mental Health America of the Heartland	MO	64,099
Mid America Assistance Coalition	MO	43,358
Missouri Association for Social Welfare	MO	110,794
Missouri Department of Mental Health	MO	373,488
Missouri Department of Mental Health	MO	235,440
Missouri Department of Mental Health	MO	115,044
Missouri Department of Mental Health	MO	147,492
Missouri Department of Mental Health	MO	687,048
Missouri Department of Mental Health	MO	74,448
Missouri Department of Mental Health	MO	417,024
Missouri Department of Mental Health	MO	477,348
Missouri Department of Mental Health	MO	327,420
Missouri Department of Mental Health	MO	124,356
Missouri Department of Mental Health	MO	372,240
Missouri Department of Mental Health	MO	106,968
Missouri Department of Mental Health	MO	128,532
Missouri Department of Mental Health	MO	213,972
Missouri Department of Mental Health	MO	139,356
Missouri Department of Mental Health	MO	91,332
Missouri Department of Mental Health	MO	164,244
Missouri Department of Mental Health	MO	178,368
Missouri Department of Mental Health	MO	917,496
Missouri Department of Mental Health	MO	275,940
Missouri Department of Mental Health	MO	340,800
Missouri Department of Mental Health	MO	144,696
Missouri Department of Mental Health	MO	1,462,560
Missouri Department of Mental Health	MO	1,522,500
Missouri Department of Mental Health	MO	237,240
Missouri Department of Mental Health	MO	931,200
Missouri Department of Mental Health	MO	126,960
Peter & Paul Community Services, Inc	MO	298,832
Pettis County Community Partnership	MO	118,207

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Phoenix Programs, Inc	MO	71,122
Phoenix Programs, Inc	MO	74,113
Places for People	MO	211,332
Preferred Family Healthcare	MO	105,663
Queen of Peace Center	MO	599,564
reStart, Inc	MO	206,817
reStart, Inc	MO	124,915
reStart, Inc	MO	226,306
Ripley County Family Resource Center	MO	53,570
Ripley County Family Resource Center	MO	109,360
Rose Brooks Center, Inc	MO	207,967
SAVE, Inc	MO	299,483
SAVE, Inc	MO	201,153
SEMO Christian Restoration Center	MO	108,389
SEMO Christian Restoration Center	MO	70,756
Shalom House	MO	239,053
Sheffield Place	MO	163,079
Sigma House of Springfield, Inc	MO	82,760
Society of St. Vincent de Paul Archdiocesan Council of St. Louis	MO	288,582
Society of St. Vincent de Paul Archdiocesan Council of St. Louis	MO	403,154
St. Louis Office for Developmental Disability Resources	MO	198,278
St. Louis Office for Developmental Disability Resources	MO	179,467
St. Louis Transitional Hope House, Inc	MO	766,669
St. Patrick Center	MO	304,722
St. Patrick Center	MO	528,764
St. Patrick Center	MO	435,301
Swope Health Services	MO	185,281
Synergy Services Inc	MO	275,000
The Kansas City Metropolitan Lutheran Ministry	MO	213,515
The Kitchen, Inc	MO	393,750
The Salvation Army	MO	236,698
The Salvation Army—Midland Division	MO	355,681
The Salvation Army—Midland Division	MO	26,655
The Salvation Army—Midland Division	MO	37,450
The Salvation Army—Midland Division	MO	148,882
The Salvation Army—Midland Division	MO	107,887
The Salvation Army—Midland Division	MO	80,000
The Salvation Army—Midland Division	MO	47,452
Truman Medical Center, Inc	MO	518,157
Young Women's Christian Associaltion of St. Joseph, Missouri	MO	57,391
YWCA Metro St. Louis	MO	76,597
AIDS Services Coalition	MS	132,605
Back Bay Mission	MS	92,160
Back Bay Mission	MS	66,735
Back Bay Mission	MS	38,175
Bolivar County Community Action Agency, Inc	MS	473,286
Bolivar County Community Action Agency, Inc	MS	176,201
Catholic Charities	MS	169,691
Catholic Charities Inc	MS	337,923
Forrest General Hospital	MS	262,500
Forrest General Hospital	MS	250,000
Grace House Inc	MS	108,712
Gulf Coast Women's Center for Nonviolence	MS	48,796
Gulf Coast Women's Center for Nonviolence	MS	38,788
HIS Foundation	MS	197,000
Jackson/Rankin, Madison Counties CoC	MS	118,650
Jackson/Rankin, Madison Counties CoC	MS	99,850
Lizzies House	MS	125,793
Mental Health Association of Mississippi	MS	27,328
Mental Health Association of Mississippi	MS	88,166
Mental Health Association of Mississippi	MS	61,997
Mental Health Association of Mississippi	MS	15,544
MS United to End Homelessness	MS	100,878
MS United to End Homelessness	MS	155,120
MS United to End Homelessness	MS	305,153
MS United to End Homelessness	MS	163,518
Multi-County Community Service Agency, Inc	MS	353,839
New Dimensions Development Foundation, Inc	MS	159,238
New Life for Women, Inc	MS	203,019
Open Doors Homeless Coalition	MS	45,648
Open Doors Homeless Coalition	MS	23,210
Recovery House, Inc	MS	110,321

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Recovery House, Inc	MS	213,960
South Mississippi AIDS Task Force, Inc	MS	129,046
Stewpot Community Services, Inc	MS	49,392
The Salvation Army	MS	199,999
The University of Southern Mississippi Institute for Disability Studies	MS	336,000
The University of Southern Mississippi Institute for Disability Studies	MS	182,082
District 7 Human Resources Development Council	MT	63,868
Florence Crittenton Home and Services	MT	124,546
God's Love, Inc	MT	143,305
Helena Housing Authority	MT	173,376
Housing Authority of Billings	MT	99,180
Human Resource Development Council of District IX, Inc	MT	20,000
Human Resources Council, District XII	MT	90,958
Missoula County	MT	100,201
Missoula County	MT	147,498
Missoula Housing Authority	MT	169,140
Missoula Housing Authority	MT	792,936
Montana Department of Commerce	MT	234,708
Mountain Home Montana, Inc	MT	76,798
Northwest Montana Human Resources, Inc	MT	35,769
Poverello Center Inc	MT	69,467
Public Housing Authority of Butte	MT	80,904
SAFE Harbor	MT	67,519
Samaritan House, Inc	MT	63,000
State of Montana	MT	23,053
State of Montana	MT	66,980
Supporters of Abuse Free Environments (SAFE), Inc	MT	34,000
The YWCA of Helena, Montana	MT	38,947
Tumbleweed Runaway Program Inc	MT	28,489
Alamance-Caswell Area Mental Health/Developmental Disabilites/Substance Abuse Authority	NC	213,648
Alcohol and Drug Services of Guilford, Inc	NC	34,996
As One Ministries, Inc	NC	56,322
As One Ministries, Inc	NC	63,840
As One Ministries, Inc	NC	70,427
Brunswick Family Assistance Agency, Inc	NC	42,356
Burlington Development Corporation	NC	74,639
Burlington Development Corporation	NC	74,215
Cape Fear Housing for Independent Living, Inc	NC	95,381
CenterPoint Human Services	NC	56,889
CenterPoint Human Services	NC	51,373
CenterPoint Human Services	NC	209,232
CenterPoint Human Services	NC	106,140
Christians United Outreach Center	NC	82,284
City of High Point	NC	77,352
City of Winston-Salem	NC	18,355
City of Winston-Salem	NC	26,413
City of Winston-Salem	NC	170,472
City of Winston-Salem	NC	56,889
City of Winston-Salem	NC	70,206
City of Winston-Salem	NC	17,670
City of Winston-Salem	NC	63,960
City of Winston-Salem	NC	43,975
City of Winston-Salem	NC	49,614
City of Winston-Salem	NC	172,140
City of Winston-Salem	NC	98,122
City of Winston-Salem	NC	47,545
City of Winston-Salem	NC	22,575
City of Winston-Salem	NC	14,663
City of Winston-Salem	NC	46,475
City of Winston-Salem	NC	38,376
City of Winston-Salem	NC	90,511
City of Winston-Salem	NC	118,188
City of Winston-Salem	NC	25,000
City of Winston-Salem	NC	56,829
Cleveland County Abuse Prevention Council	NC	69,204
Cleveland County Abuse Prevention Council	NC	7,152
Cleveland County Abuse Prevention Council	NC	37,158
Coastal Horizons Center, Inc	NC	80,619
Community Alternatives for Supportive Abodes	NC	217,113
Community Alternatives for Supportive Abodes	NC	50,176
Community Alternatives for Supportive Abodes	NC	21,677
Community Alternatives for Supportive Abodes	NC	118,600

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Community Alternatives for Supportive Abodes	NC	188,248
Community Alternatives for Supportive Abodes	NC	85,575
Community Link, Programs of Travelers Aid	NC	343,686
Community Link, Programs of Travelers Aid	NC	268,346
Community Link, Programs of Travelers Aid	NC	459,665
Crossroads Behavioral Healthcare	NC	38,468
Cumberland County, NC	NC	84,134
Cumberland County, NC	NC	49,231
Cumberland IHN	NC	120,588
Cumberland IHN	NC	262,736
Development Ventures Incorporated	NC	368,073
East Carolina Behavioral Health	NC	366,324
Eastpointe Human Services	NC	1,006,920
Family Service of the Piedmont, Inc	NC	70,218
First Fruit Ministries	NC	120,716
five county mental health authority	NC	130,884
five county mental health authority	NC	31,320
five county mental health authority	NC	70,392
five county mental health authority	NC	303,420
five county mental health authority	NC	231,672
Gaston County Interfaith Hospitality Network, Inc	NC	38,850
Gaston,Lincoln,Cleveland MH/DD/SA	NC	436,812
Genesis Home	NC	174,999
Genesis Home	NC	55,346
Good Shepherd Ministries of Wilmington, Inc	NC	45,482
Good Shepherd Ministries of Wilmington, Inc	NC	56,073
Graham Housing Authority	NC	55,872
Greensboro Housing Authority	NC	43,730
Greensboro Housing Authority	NC	427,536
Greensboro Housing Authority	NC	477,369
Greensboro Urban Ministry	NC	59,850
Haven House Inc	NC	52,330
Homeward Bound of Asheville, Inc	NC	45,629
Homeward Bound of Asheville, Inc	NC	22,339
Homeward Bound of Asheville, Inc	NC	147,886
Homeward Bound of Asheville, Inc	NC	22,251
Homeward Bound of Asheville, Inc	NC	35,000
Hope Haven Inc	NC	53,980
Hope Haven Inc	NC	383,500
Hope Haven Inc	NC	63,000
Hope Haven Inc	NC	52,867
Hospitality House of the Boone Area, Inc	NC	29,179
Hospitality House of the Boone Area, Inc	NC	31,181
Hospitality House of the Boone Area, Inc	NC	31,928
Housing Authority of the City of Asheville	NC	169,932
Housing Authority of the City of Asheville	NC	81,372
Housing Authority of the City of Greenville	NC	825,540
Housing Authority of the City of Wilmington/Hopewood	NC	134,928
Housing for New Hope, Inc	NC	21,761
Housing for New Hope, Inc	NC	24,150
Housing for New Hope, Inc	NC	106,001
Mary's House, Inc	NC	135,982
Mecklenburg County	NC	145,136
Mecklenburg County	NC	1,360,392
Mecklenburg County	NC	284,352
Mecklenburg County	NC	119,784
Mecklenburg County Area MH, DD, & SA Authority	NC	361,127
New River Service Authority	NC	69,517
Next Step Ministries, Inc	NC	37,800
North Carolina Housing Coalition	NC	75,249
North Carolina Housing Coalition	NC	588,668
Northwestern Housing Enterprises, Incorporated	NC	33,018
OASIS, Inc (Opposing Abuse with Service, Information and Shelter)	NC	29,294
OPC Mental Health, Developmental Disabilities and Substance Abuse Area Authority	NC	250,980
OPC Mental Health, Developmental Disabilities and Substance Abuse Area Authority	NC	8,340
OPC Mental Health, Developmental Disabilities and Substance Abuse Area Authority	NC	109,202
OPC Mental Health, Developmental Disabilities and Substance Abuse Area Authority	NC	33,360
OPC Mental Health, Developmental Disabilities and Substance Abuse Area Authority	NC	17,688
Open Door Ministries of High Point, Inc	NC	13,750
Open Door Ministries of High Point, Inc	NC	62,159
Open Door Ministries of High Point, Inc	NC	48,919
Passage Home, Inc	NC	205,752

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Passage Home, Inc	NC	192,134
Piedmont Behavioral Healthcare (PBH)	NC	783,360
Piedmont Behavioral Healthcare (PBH)	NC	174,624
Rockingham County Help For Homeless, Inc	NC	187,624
Salvation Army	NC	87,499
Salvation Army	NC	226,646
Sandhills Community Action Program, Inc	NC	6,312
Sandhills Community Action Program, Inc	NC	240,792
Sanford Hosuing Authority S+C 2011	NC	72,264
Smoky Mountain Center LME	NC	713,580
St. Peter's Homes, Inc	NC	262,311
St. Peter's Homes, Inc	NC	33,333
Surry Homeless and Affordable Housing Coalition	NC	60,091
The Arc of North Carolina Supportive Housing	NC	33,214
The Beacon Center	NC	189,360
The Greenville Community Shelters, Inc	NC	113,618
The Greenville Community Shelters, Inc	NC	72,177
The Housing Authority of The City of Durham	NC	88,236
The New Reidsville Housing Authority	NC	32,856
The New Reidsville Housing Authority	NC	78,420
The Salvation Army High Point	NC	19,274
The Salvation Army, a Georgia Corporation	NC	148,015
The Salvation Army, a Georgia Corporation	NC	80,057
The Salvation Army, a Georgia Corporation	NC	35,470
The Servant Center	NC	47,586
United Community Ministries	NC	88,200
United Community Ministries	NC	87,570
University of North Carolina at Chapel Hill	NC	36,225
University of North Carolina at Chapel Hill	NC	18,900
Urban Ministries of Durham	NC	62,345
Wake County Human Services	NC	23,904
Wake County Human Services	NC	1,142,904
Wake County Human Services	NC	220,238
Wake County Human Services	NC	209,220
WAMY Community Action, Inc	NC	35,567
Western Highlands, A Local Management Entity	NC	269,220
Western North Carolina Community Health Services, Inc	NC	260,360
Wilmington Housing Finance and Development/Driftwood	NC	62,333
Wilmington Interfaith Hospitality Network	NC	86,997
With Friends, Inc	NC	66,457
With Friends, Inc	NC	22,545
Youth Focus, Inc	NC	51,700
Abused Adult Resource Center	ND	78,819
Burleigh County Housing Authority	ND	168,168
Community Violence Intervention Center	ND	95,845
Fargo Housing and Redevelopment Authority	ND	85,800
Fargo Housing and Redevelopment Authority	ND	60,322
Fargo Housing and Redevelopment Authority	ND	212,496
Fargo Housing and Redevelopment Authority	ND	67,848
Fargo Housing and Redevelopment Authority	ND	150,000
Fraser, Ltd	ND	123,000
Grand Lodge of North Dakota, I.O.O.F.	ND	46,675
North Dakota Association for the Disabled	ND	34,184
North Dakota Coalition for Homeless People, Inc	ND	74,072
North Dakota Dept. of Commerce	ND	232,272
Prairie Harvest Mental Health	ND	84,999
Red River Valley Community Action	ND	45,202
Ruth Meiers Hospitality House	ND	39,999
Society of St. Vincent de Paul	ND	15,277
Women's Alliance, Inc DBA: Domestic Violence and Rape Crisis Center	ND	37,600
Young Women's Christian Association Minot ND	ND	36,103
YWCA Cass Clay	ND	80,504
YWCA Cass Clay	ND	75,948
YWCA Cass Clay	ND	134,277
Blue Valley Community Action, Inc	NE	200,502
Care Corps	NE	92,370
Care Corps	NE	122,067
Catholic Social Services	NE	115,148
Catholic Social Services	NE	95,658
CEDARS Youth Services	NE	130,707
CenterPointe	NE	191,642
CenterPointe	NE	93,145

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
CenterPointe	NE	191,797
CenterPointe	NE	446,251
Central Nebraska Community Services	NE	197,437
Central Nebraska Community Services	NE	150,000
Central Nebraska Community Services	NE	115,707
Cirrus House, Inc	NE	46,433
City of Omaha	NE	158,928
Community Action Partnership of Lancaster and Saunders Counties	NE	460,862
Community Action Partnership of Mid-Nebraska	NE	90,717
Community Action Partnership of Western Nebraska	NE	31,880
Community Action Partnership of Western Nebraska	NE	94,071
Heartland Family Service	NE	93,606
Heartland Family Service	NE	157,125
Heartland Family Service	NE	265,713
Heartland Family Service	NE	584,982
Heartland Family Service	NE	150,088
Hope of Glory Ministries, Inc	NE	76,822
Iowa Institute for Community Alliances	NE	121,537
Region V Systems	NE	214,537
St. Monica's	NE	140,456
The Christian Worship Center	NE	95,673
The Salvation Army	NE	130,453
The Salvation Army	NE	302,941
The Salvation Army	NE	58,020
The Salvation Army	NE	138,897
The Salvation Army	NE	146,694
University of Nebraska-Lincoln	NE	95,120
University of Nebraska-Lincoln	NE	75,437
Behavioral Health & Developmental Services of Strafford County, Inc	NH	85,865
Child and Family Services	NH	111,529
Community Council of Nashua, NH	NH	26,784
Families in Transition	NH	122,500
Families in Transition	NH	67,183
Families in Transition	NH	50,340
Families in Transition	NH	111,300
Families in Transition	NH	44,000
Families in Transition	NH	47,137
Families in Transition	NH	47,752
Greater Nashua Council on Alcoholism	NH	60,083
Harbor Homes, Inc	NH	13,121
Harbor Homes, Inc	NH	56,141
Harbor Homes, Inc	NH	50,000
Harbor Homes, Inc	NH	59,545
Harbor Homes, Inc	NH	873,170
Harbor Homes, Inc	NH	13,466
Harbor Homes, Inc	NH	171,308
Harbor Homes, Inc	NH	70,885
Harbor Homes, Inc	NH	104,440
Harbor Homes, Inc	NH	13,118
Helping Hands Outreach Center	NH	33,705
Marguerites Place Inc	NH	58,480
My Friend's Place	NH	54,239
Nashua Housing Authority	NH	31,752
Northern Human Services	NH	132,011
Southern New Hampshire Services, Inc	NH	32,191
Southern New Hampshire Services, Inc	NH	36,039
State of New Hampshire	NH	88,497
State of New Hampshire	NH	96,078
State of New Hampshire	NH	99,632
State of New Hampshire	NH	71,766
State of New Hampshire	NH	247,279
State of New Hampshire	NH	236,866
State of New Hampshire	NH	42,097
State of New Hampshire	NH	37,496
State of New Hampshire	NH	112,951
State of New Hampshire	NH	80,640
State of New Hampshire	NH	245,328
State of New Hampshire	NH	14,154
State of New Hampshire	NH	52,838
State of New Hampshire	NH	116,524
State of New Hampshire	NH	68,092
State of New Hampshire	NH	72,590

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
State of New Hampshire	NH	94,500
State of New Hampshire	NH	272,100
State of New Hampshire	NH	357,354
State of New Hampshire	NH	193,418
State of New Hampshire	NH	79,047
State of New Hampshire	NH	196,762
State of New Hampshire	NH	12,778
The Housing Partnership	NH	143,815
The Way Home	NH	47,734
The Way Home	NH	63,000
The Way Home	NH	100,757
The Way Home	NH	45,025
Tri County CAP, Inc	NH	188,568
180 Turning Lives Around, Inc	NJ	122,805
180 Turning Lives Around, Inc	NJ	142,530
A Major Step	NJ	138,365
A Major Step	NJ	250,474
AAH of Bergen County, Inc	NJ	98,437
AAH of Bergen County, Inc	NJ	78,925
AAH of Bergen County, Inc	NJ	88,322
Advance Housing, Inc	NJ	78,536
Advance Housing, Inc	NJ	330,750
Advance Housing, Inc	NJ	167,735
Advance Housing, Inc	NJ	358,255
Affordable Housing Alliance	NJ	43,923
Alternatives, Inc	NJ	63,170
Alternatives, Inc	NJ	98,478
Alternatives, Inc	NJ	15,557
Alternatives, Inc	NJ	101,278
Bergen County Community Action Partnership, Inc	NJ	93,712
Bergen County Community Action Partnership, Inc	NJ	63,702
Bergen County Community Action Partnership, Inc	NJ	92,748
Bergen County Housing Authority	NJ	111,384
Burlington County Community Action Program	NJ	14,172
Burlington County Community Action Program	NJ	10,667
Camden County Council On Economic Opportunity, Inc	NJ	173,389
Camden County Council On Economic Opportunity, Inc	NJ	124,926
Camden County Council On Economic Opportunity, Inc	NJ	134,043
Cape Counseling Services	NJ	182,311
Cape Counseling Services	NJ	27,738
Career Opportunity Development	NJ	51,442
Catholic Charities Diocese of Metuchen	NJ	233,047
Catholic Charities of the Archdiocese of Newark	NJ	248,664
Catholic Charities of the Archdiocese of Newark	NJ	160,000
Catholic Charities, Diocese of Trenton	NJ	24,860
Catholic Charities, Diocese of Trenton	NJ	69,218
Center For Family Services, Inc	NJ	65,214
Center For Family Services, Inc	NJ	35,437
Center For Family Services, Inc	NJ	18,130
Center For Family Services, Inc	NJ	33,864
Center For Family Services, Inc	NJ	30,935
Center For Family Services, Inc	NJ	67,217
Center For Family Services, Inc	NJ	31,250
City of East Orange	NJ	406,080
City of East Orange	NJ	190,740
City of Trenton Department of Human Services	NJ	798,377
City of Trenton Department of Human Services	NJ	115,928
City of Trenton Department of Human Services	NJ	14,815
City of Trenton Department of Human Services	NJ	94,368
City of Trenton Department of Human Services	NJ	49,464
City of Trenton Department of Human Services	NJ	181,368
City of Trenton Department of Human Services	NJ	9,720
City of Trenton Department of Human Services	NJ	67,174
City of Trenton Department of Human Services	NJ	128,268
City of Trenton Department of Human Services	NJ	129,073
City of Trenton Department of Human Services	NJ	303,552
City of Trenton Department of Human Services	NJ	115,096
City of Trenton Department of Human Services	NJ	240,312
City of Trenton Department of Human Services	NJ	54,960
City of Trenton Department of Human Services	NJ	164,424
City of Trenton Department of Human Services	NJ	69,862
City of Trenton Department of Human Services	NJ	25,296

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
City of Trenton Department of Human Services	NJ	7,613
Collaborative Support Programs of New Jersey PHA NJ880	NJ	69,888
Collaborative Support Programs of New Jersey PHA NJ880	NJ	97,524
Collaborative Support Programs of New Jersey PHA NJ880	NJ	27,864
Collaborative Support Programs of New Jersey PHA NJ880	NJ	676,800
Community Hope, Inc	NJ	60,236
Community Hope, Inc	NJ	244,981
Community Hope, Inc	NJ	44,667
Community Planning and Advocacy Council	NJ	526,455
Community Planning and Advocacy Council	NJ	9,372
Community Planning and Advocacy Council	NJ	162,000
Community Planning and Advocacy Council	NJ	131,356
Comprehensive Behavioral Healthcare Inc	NJ	110,376
County of Bergen Department of Human Services	NJ	93,068
County of Bergen Department of Human Services	NJ	85,900
County of Monmouth	NJ	195,048
County of Monmouth	NJ	51,012
County of Monmouth	NJ	226,939
County of Monmouth	NJ	382,176
County of Monmouth	NJ	183,000
County of Monmouth	NJ	271,284
County of Monmouth	NJ	301,500
County of Monmouth	NJ	86,664
Covenant House New Jersey	NJ	173,891
Covenant House New Jersey	NJ	94,500
Covenant House New Jersey	NJ	144,717
dackksgroup	NJ	41,335
Dooley House Inc	NJ	205,979
East Orange General Hosiptal	NJ	245,600
EASTER SEAL SOCIETY OF NEW JERSEY INC, THE	NJ	43,207
EASTER SEAL SOCIETY OF NEW JERSEY INC, THE	NJ	46,664
EASTER SEAL SOCIETY OF NEW JERSEY INC, THE	NJ	151,981
EASTER SEAL SOCIETY OF NEW JERSEY INC, THE	NJ	7,464
Edison Housing Authority	NJ	135,000
Edison Housing Authority	NJ	79,440
Elizabeth/Union County Continuum of Care	NJ	352,224
Elizabeth/Union County Continuum of Care	NJ	16,665
Elizabeth/Union County Continuum of Care	NJ	99,342
Elizabeth/Union County Continuum of Care	NJ	94,427
Elizabeth/Union County Continuum of Care	NJ	652,260
Elizabeth/Union County Continuum of Care	NJ	24,312
Elizabeth/Union County Continuum of Care	NJ	61,872
Elizabeth/Union County Continuum of Care	NJ	270,720
Elizabeth/Union County Continuum of Care	NJ	58,008
Elizabeth/Union County Continuum of Care	NJ	493,441
Elizabeth/Union County Continuum of Care	NJ	25,836
Elizabeth/Union County Continuum of Care	NJ	18,654
Elizabeth/Union County Continuum of Care	NJ	146,952
Elizabeth/Union County Continuum of Care	NJ	49,020
Elizabeth/Union County Continuum of Care	NJ	217,714
Elizabeth/Union County Continuum of Care	NJ	204,972
Elizabeth/Union County Continuum of Care	NJ	160,478
Elizabeth/Union County Continuum of Care	NJ	26,917
Elizabeth/Union County Continuum of Care	NJ	13,300
Elizabeth/Union County Continuum of Care	NJ	36,120
Elizabeth/Union County Continuum of Care	NJ	80,656
Elizabeth/Union County Continuum of Care	NJ	491,448
Elizabeth/Union County Continuum of Care	NJ	284,206
Essex County Division of Community Action	NJ	270,720
Family Service	NJ	42,000
HABcore, Inc	NJ	78,899
HABcore, Inc	NJ	172,473
Harmony House	NJ	142,354
Harmony House	NJ	142,919
HISPANIC MULTI PURPOSE SERVICE CENTER	NJ	41,902
Homeless Solutions Inc	NJ	396,965
Homeless Solutions Inc	NJ	64,299
Homeless Solutions Inc	NJ	219,397
Housing Authority of the City of Vineland	NJ	230,400
HOUSING AUTHORITY OF THE TOWNSHIP OF BERKELEY	NJ	120,600
HOUSING AUTHORITY OF THE TOWNSHIP OF BERKELEY	NJ	99,804
HOUSING AUTHORITY OF THE TOWNSHIP OF BERKELEY	NJ	89,031

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Integrity Inc	NJ	400,000
Interfaith Homeless Outreach Council	NJ	7,366
isaiah house	NJ	44,491
isaiah house	NJ	42,845
isaiah house	NJ	249,495
Jersey Battered Women's Service, Inc	NJ	198,137
Jersey City Episcopal Community Development Corporation (JCECDC)	NJ	391,797
Jersey City Episcopal Community Development Corporation (JCECDC)	NJ	420,000
Jersey City Episcopal Community Development Corporation (JCECDC)	NJ	222,581
Lakewood Housing Authority	NJ	12,915
Lets Celebrate Inc	NJ	83,794
Making It Possible to end Homelessness (MIPH)	NJ	35,000
Mental Health Association of Morris County, Inc	NJ	60,060
Middlesex County	NJ	169,039
Middlesex County	NJ	185,748
Middlesex County	NJ	397,328
New Jersey AIDS Services, Inc	NJ	77,688
Newark YMCA	NJ	821,100
NJ DEPARTMENT OF COMMUNITY AFFAIRS	NJ	34,200
NJ DEPARTMENT OF COMMUNITY AFFAIRS	NJ	200,220
NJ DEPARTMENT OF COMMUNITY AFFAIRS	NJ	94,560
NJ DEPARTMENT OF COMMUNITY AFFAIRS	NJ	155,664
NJ DEPARTMENT OF COMMUNITY AFFAIRS	NJ	40,368
NJ DEPARTMENT OF COMMUNITY AFFAIRS	NJ	40,608
NJ DEPARTMENT OF COMMUNITY AFFAIRS	NJ	57,000
NJ DEPARTMENT OF COMMUNITY AFFAIRS	NJ	274,152
NJ DEPARTMENT OF COMMUNITY AFFAIRS	NJ	150,612
NJ DEPARTMENT OF COMMUNITY AFFAIRS	NJ	135,360
NJ DEPARTMENT OF COMMUNITY AFFAIRS	NJ	80,736
NJ DEPARTMENT OF COMMUNITY AFFAIRS	NJ	267,144
NJ DEPARTMENT OF COMMUNITY AFFAIRS	NJ	812,160
NJ DEPARTMENT OF COMMUNITY AFFAIRS	NJ	175,968
NJ DEPARTMENT OF COMMUNITY AFFAIRS	NJ	1,036,260
NJ DEPARTMENT OF COMMUNITY AFFAIRS	NJ	146,484
NJ DEPARTMENT OF COMMUNITY AFFAIRS	NJ	69,451
NJ DEPARTMENT OF COMMUNITY AFFAIRS	NJ	86,304
NJ DEPARTMENT OF COMMUNITY AFFAIRS	NJ	30,888
NJ DEPARTMENT OF COMMUNITY AFFAIRS	NJ	175,968
NJ DEPARTMENT OF COMMUNITY AFFAIRS	NJ	284,016
NJ HMFA	NJ	3,000
NJ HMFA	NJ	1,998
NJ HMFA	NJ	17,000
NJ HMFA	NJ	3,000
NJ HMFA	NJ	2,000
NJ HMFA	NJ	2,560
NJ HMFA	NJ	2,457
NJ HMFA	NJ	22,667
NJ HMFA	NJ	25,000
NJ HMFA	NJ	2,001
NJ HMFA	NJ	40,655
NJ HMFA	NJ	2,667
NJ HMFA	NJ	85,667
NJ HMFA	NJ	69,000
NJ HMFA	NJ	56,727
NJ HMFA	NJ	45,028
NJ HMFA	NJ	19,970
NJ HMFA	NJ	149,999
NJ HMFA	NJ	25,000
North Hudson Community Action Corporation	NJ	404,148
ocean community economic action now, inc	NJ	40,718
ocean community economic action now, inc	NJ	41,697
ocean community economic action now, inc	NJ	38,500
ocean community economic action now, inc	NJ	305,373
ocean community economic action now, inc	NJ	81,957
Ocean's Harbor House	NJ	19,372
Passaic County Department of Human Services	NJ	47,736
Passaic County Department of Human Services	NJ	47,736
Passaic County Department of Human Services	NJ	121,824
Passaic County Department of Human Services	NJ	221,424
Passaic County Department of Human Services	NJ	1,192,497
Paterson Housing Authority	NJ	129,096
Paterson Housing Authority	NJ	132,504

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Positive Health care, Inc	NJ	176,283
Project H.O.P.E	NJ	55,795
Project Live, Inc	NJ	275,534
Saint Joseph's Home	NJ	558,534
Salem County Inter Agency Council of Human Services	NJ	140,560
Shelter Our Sisters	NJ	23,833
Shelter Our Sisters	NJ	16,382
Somerset Home for Temporarily Displaced Children	NJ	31,015
South Jersey Behavioral Health Resources, Inc	NJ	21,873
St. Philip's Ministry UMC	NJ	63,461
Strengthen Our Sisters	NJ	130,652
The Center in Asbury Park, Inc	NJ	184,819
The House of Faith, Inc	NJ	245,266
The Lester A. Drenk Behavioral Health Center Inc	NJ	264,023
The New Jersey Department of Veteran and Military Affairs	NJ	164,243
The Salvation Army, a New York Corporation	NJ	134,510
Transitional Housing Services, Inc	NJ	97,093
Triple C Housing	NJ	54,425
United Way of Hudson County	NJ	393,006
United Way of Hudson County	NJ	680,212
United Way of Hudson County	NJ	688,608
Vantage Health System, Inc	NJ	217,402
Vantage Health System, Inc	NJ	90,896
Vantage Health System, Inc	NJ	1,599,416
Vantage Health System, Inc	NJ	548,402
Vetgroup Inc	NJ	20,664
Volunteers of America Delaware Valley Inc	NJ	96,026
Volunteers of America Delaware Valley Inc	NJ	117,344
Volunteers of America Delaware Valley Inc	NJ	88,970
Volunteers of America Delaware Valley Inc	NJ	109,874
Volunteers of America Delaware Valley Inc	NJ	129,665
Volunteers of America Delaware Valley Inc	NJ	86,458
WomenRising	NJ	644,268
Albuquerque HealthCare for the Homeless, Inc	NM	135,267
Barrett Foundation, Inc	NM	23,780
Barrett Foundation, Inc	NM	97,447
Bernalillo County	NM	92,329
Casa Milagro	NM	82,250
Catholic Charities	NM	193,858
Catholic Charities	NM	241,153
Catholic Charities	NM	202,692
Catholic Charities	NM	51,371
Catholic Charities	NM	223,055
Catholic Charities of Gallup	NM	26,727
City of Albuquerque	NM	317,220
City of Albuquerque	NM	895,822
City of Albuquerque	NM	223,709
City of Albuquerque	NM	1,000,680
City of Las Cruces, New Mexico	NM	96,804
City of Las Cruces, New Mexico	NM	103,784
City of Santa Fe	NM	202,944
City of Santa Fe	NM	212,304
City of Santa Fe	NM	144,132
City of Santa Fe	NM	173,520
City of Santa Fe/Santa Fe Community Housing Trust	NM	565,140
City of Santa Fe/Santa Fe Community Housing Trust	NM	121,440
County of Sandoval	NM	197,592
Crossroads for Women	NM	191,940
Crossroads for Women	NM	112,834
Curry County	NM	129,864
DreamTree Project, Inc	NM	78,136
El Refugio, Inc	NM	66,150
Esperanza Shelter for Battered Families, Inc	NM	94,500
Goodwill Industries of New Mexico	NM	114,866
Haven House, Inc	NM	50,000
NewLife Homes, Inc	NM	233,049
S.A.F.E. House	NM	42,096
Samaritan House Inc	NM	96,164
San Juan County Partnership	NM	66,713
Santa Fe Civic Housing Authority	NM	366,360
Santa Fe Community Services, Inc	NM	54,747
Socorro County Housing Authority	NM	99,936

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
St. Elizabeth Shelter	NM	72,713
St. Elizabeth Shelter	NM	63,199
St. Martin's Hospitality Center	NM	115,500
Supportive Housing Coalition of New Mexico	NM	171,226
Supportive Housing Coalition of New Mexico	NM	26,775
Supportive Housing Coalition of New Mexico	NM	55,975
Transitional Living Services, Inc	NM	276,300
Transitional Living Services, Inc	NM	105,000
Valencia Shelter Services for Victims of Domestic Violence	NM	106,666
Village of Los Lunas, New Mexico	NM	158,496
Youth Shelters and Family Services	NM	141,725
Carson City Health & Human Services	NV	22,764
Churchill Council on Alcohol and Other Drugs	NV	16,726
Churchill County Social Services	NV	46,666
City of Reno, Nevada	NV	69,400
City of Reno, Nevada	NV	110,292
Douglas County	NV	133,449
Family Promise of Las Vegas	NV	282,989
Frontier Community Action Agency	NV	51,056
HELP Las Vegas Housing Corporation	NV	195,230
HELP of Southern Nevada	NV	338,743
HELP of Southern Nevada	NV	206,159
HopeLink	NV	162,056
HopeLink	NV	105,328
Las Vegas/Clark County project applicant	NV	495,000
Lutheran Social Services of Nevada	NV	104,556
Nevada Partnership for Homeless Youth	NV	221,854
Northern Nevada Adult Mental Health Services	NV	445,032
Northern Nevada Adult Mental Health Services	NV	75,600
Northern Nevada Community Housing Resource Board	NV	51,955
ReStart	NV	812,489
ReStart	NV	131,373
Rural Clinics Community Mental Health Centers	NV	226,488
Southern Nevada Children First	NV	237,546
Southern Nevada Mental Health Services	NV	412,553
Southern Nevada Mental Health Services	NV	1,547,748
St. Vincent HELP Inc	NV	257,702
The Salvation Army	NV	429,949
The Salvation Army Safe Haven	NV	323,451
United States Veterans Initiative	NV	662,933
United States Veterans Initiative	NV	164,509
United States Veterans Initiative	NV	116,015
United States Veterans Initiative	NV	120,556
Vitality Center	NV	84,164
Washoe County	NV	60,480
Washoe County	NV	60,480
Womens Development Center	NV	126,073
Womens Development Center	NV	119,285
Adirondack Vets House, Inc	NY	75,417
Albany Housing Authority	NY	209,112
Albany Housing Authority	NY	108,324
Albany Housing Authority	NY	42,780
Albany Housing Authority	NY	236,844
Albany Housing Authority	NY	227,424
Albany Housing Authority	NY	51,336
Albany Housing Authority	NY	270,384
Albany Housing Authority	NY	51,336
Albany Housing Authority	NY	147,852
Albany Housing Coalition, Inc	NY	63,502
Albany Housing Coalition, Inc	NY	43,155
Albany Housing Coalition, Inc	NY	29,970
Albany Housing Coalition, Inc	NY	21,000
Albany Housing Coalition, Inc	NY	38,251
Alcohol and Drug Dependency Services, Inc	NY	760,889
Altamont Program, Inc	NY	31,150
ANCHOR HOUSE, INC	NY	240,648
Argus Community, Inc	NY	430,101
Argus Community, Inc	NY	371,322
Argus Community, Inc	NY	370,278
Association to Benefit Children	NY	115,706
Auburn Housing Authority	NY	35,820
Bailey House Inc	NY	629,300

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Bailey House Inc	NY	166,666
Banana Kelly Community Improvement Assoc Inc	NY	386,525
Basics, Inc	NY	353,208
Bethesda House of Schenectady, Inc	NY	110,250
Bethesda House of Schenectady, Inc	NY	152,738
Bethesda House of Schenectady, Inc	NY	22,300
Bethesda House of Schenectady, Inc	NY	35,871
Bethesda House of Schenectady, Inc	NY	111,647
Bethesda House of Schenectady, Inc	NY	47,666
Bethesda House of Schenectady, Inc	NY	135,503
Binghamton Housing Authority	NY	141,600
Bowery Residents' Committee, Inc	NY	497,954
Bowery Residents' Committee, Inc	NY	511,358
Bowery Residents' Committee, Inc	NY	355,001
Bowery Residents' Committee, Inc	NY	368,496
Bowery Residents' Committee, Inc	NY	364,883
Bowery Residents' Committee, Inc	NY	318,891
Bowery Residents' Committee, Inc	NY	360,106
BronxWorks	NY	105,000
BronxWorks	NY	77,030
BronxWorks	NY	1,200,000
Brooklyn Bureau of Community Service	NY	474,924
Brooklyn Bureau of Community Service	NY	249,674
Capital Area Peer Services	NY	96,017
Catholic Charities Diocese of Rockville Centre	NY	155,595
Catholic Charities Diocese of Rockville Centre	NY	190,664
Catholic Charities Diocese of Rockville Centre	NY	174,584
Catholic Charities Diocese of Rockville Centre	NY	222,584
Catholic Charities Housing Office	NY	87,937
Catholic Charities of Chemung/Schuyler	NY	47,202
Catholic Charities of Chemung/Schuyler	NY	108,130
Catholic Charities of Chemung/Schuyler	NY	103,356
Catholic Charities of Chemung/Schuyler	NY	152,231
Catholic Charities of Chemung/Schuyler	NY	93,534
Catholic Charities of the Roman Catholic Diocese of Syracuse	NY	107,988
Catholic Charities of the Roman Catholic Diocese of Syracuse	NY	595,808
Catholic Charities of the Roman Catholic Diocese of Syracuse	NY	171,198
Catholic Charities of the Roman Catholic Diocese of Syracuse	NY	451,589
Catholic Charities of the Roman Catholic Diocese of Syracuse	NY	215,720
Catholic Charities of the Roman Catholic Diocese of Syracuse	NY	50,263
Catholic Charities of the Roman Catholic Diocese of Syracuse	NY	215,977
Catholic Charities of the Roman Catholic Diocese of Syracuse	NY	67,050
Catholic Family Center	NY	133,879
Catholic Family Center	NY	246,941
Cattaraugus Community Action, Inc	NY	94,314
Cayuga/Seneca Community Action Agency, Inc	NY	59,869
Cayuga/Seneca Community Action Agency, Inc	NY	35,289
Cayuga/Seneca Community Action Agency, Inc	NY	34,639
Cazenovia Recovery Systems	NY	210,980
CDCLI Housing Development Fund Corporation	NY	28,503
Central Nassau Guidance and Counseling Services, Inc	NY	257,300
Central Nassau Guidance and Counseling Services, Inc	NY	166,135
Central Nassau Guidance and Counseling Services, Inc	NY	214,894
Central Nassau Guidance and Counseling Services, Inc	NY	252,559
Central Nassau Guidance and Counseling Services, Inc	NY	154,730
Central Nassau Guidance and Counseling Services, Inc	NY	103,869
Central New York Services, Inc	NY	159,362
Central New York Services, Inc	NY	100,000
Central New York Services, Inc	NY	100,000
Central New York Services, Inc	NY	175,085
Central New York Services, Inc	NY	196,518
Central New York Services, Inc	NY	142,543
Central New York Services, Inc	NY	185,034
Central New York Services, Inc	NY	87,500
Central New York Services, Inc	NY	290,154
Chadwick Residence, Inc	NY	31,957
Chadwick Residence, Inc	NY	247,640
Chances and Changes, Inc	NY	119,461
Chautauqua Opportunities, Inc	NY	21,667
Circulo de la Hispanidad	NY	133,024
Circulo de la Hispanidad	NY	165,175
City of Mount Vernon	NY	143,031

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
City of Mount Vernon	NY	178,338
City of Mount Vernon	NY	71,736
City of Mount Vernon	NY	61,488
City of Mount Vernon	NY	94,104
City of Mount Vernon	NY	171,675
City of Mount Vernon	NY	114,156
City of Mount Vernon	NY	33,273
City of Mount Vernon	NY	37,800
City of Mount Vernon	NY	97,848
City of Mount Vernon	NY	30,450
City of Mount Vernon	NY	114,156
City of Mount Vernon	NY	49,749
City of Mount Vernon	NY	43,260
City of New York Acting by and through its Department of Housing Preservation and Development	NY	709,800
City of New York Acting by and through its Department of Housing Preservation and Development	NY	2,129,400
City of New York Acting by and through its Department of Housing Preservation and Development	NY	567,840
City of New York Acting by and through its Department of Housing Preservation and Development	NY	1,064,700
City of New York Acting by and through its Department of Housing Preservation and Development	NY	589,500
City of New York Acting by and through its Department of Housing Preservation and Development	NY	610,428
City of New York Acting by and through its Department of Housing Preservation and Development	NY	993,720
City of New York Acting by and through its Department of Housing Preservation and Development	NY	283,920
City of New York Acting by and through its Department of Housing Preservation and Development	NY	383,292
City of New York Acting by and through its Department of Housing Preservation and Development	NY	911,808
City of New York Acting by and through its Department of Housing Preservation and Development	NY	567,840
City of New York Acting by and through its Department of Housing Preservation and Development	NY	653,016
City of New York Acting by and through its Department of Housing Preservation and Development	NY	752,388
City of New York Acting by and through its Department of Housing Preservation and Development	NY	326,508
City of New York Acting by and through its Department of Housing Preservation and Development	NY	794,976
City of New York Acting by and through its Department of Housing Preservation and Development	NY	511,056
City of New York Acting by and through its Department of Housing Preservation and Development	NY	610,428
City of New York Acting by and through its Department of Housing Preservation and Development	NY	482,664
City of New York Acting by and through its Department of Housing Preservation and Development	NY	454,272
City of New York Acting by and through its Department of Housing Preservation and Development	NY	567,840
City of New York Acting by and through its Department of Housing Preservation and Development	NY	822,240
City of New York Acting by and through its Department of Housing Preservation and Development	NY	624,624
City of New York Acting by and through its Department of Housing Preservation and Development	NY	482,664
City of New York Acting by and through its Department of Housing Preservation and Development	NY	1,419,600
City of New York Acting by and through its Department of Housing Preservation and Development	NY	610,428
City of New York Acting by and through its Department of Housing Preservation and Development	NY	323,880
City of New York Acting by and through its Department of Housing Preservation and Development	NY	1,788,696
City of New York Acting by and through its Department of Housing Preservation and Development	NY	851,760
City of New York Acting by and through its Department of Housing Preservation and Development	NY	354,900
City of New York Acting by and through its Department of Housing Preservation and Development	NY	476,160
City of New York Acting by and through its Department of Housing Preservation and Development	NY	482,664
City of New York Acting by and through its Department of Housing Preservation and Development	NY	66,624
City of New York Acting by and through its Department of Housing Preservation and Development	NY	610,428
City of New York Acting by and through its Department of Housing Preservation and Development	NY	454,272
City of New York Acting by and through its Department of Housing Preservation and Development	NY	567,840
City of New York Acting by and through its Department of Housing Preservation and Development	NY	3,938,280
City of New York Acting by and through its Department of Housing Preservation and Development	NY	1,022,112
City of New York Acting by and through its Department of Housing Preservation and Development	NY	1,206,660
City of New York Acting by and through its Department of Housing Preservation and Development	NY	610,428
City of New York Acting by and through its Department of Housing Preservation and Development	NY	642,240
City of New York Acting by and through its Department of Housing Preservation and Development	NY	709,800
City of New York Acting by and through its Department of Housing Preservation and Development	NY	212,940
City of New York Acting by and through its Department of Housing Preservation and Development	NY	482,664
City of New York Acting by and through its Department of Housing Preservation and Development	NY	411,684
City of New York Acting by and through its Department of Housing Preservation and Development	NY	454,272
City of New York Acting by and through its Department of Housing Preservation and Development	NY	709,800
City of New York Acting by and through its Department of Housing Preservation and Development	NY	267,828
City of New York Acting by and through its Department of Housing Preservation and Development	NY	383,184
City of Saratoga Springs	NY	246,732
City of Schenectady	NY	123,600
City of Schenectady	NY	61,800
Coalition for the Homeless	NY	375,786
COLUMBA KAVANAGH HOUSE, INC	NY	388,163
COLUMBIA OPPORTUNITIES INCORPORATED	NY	2,145
COLUMBIA OPPORTUNITIES INCORPORATED	NY	9,697
COLUMBIA OPPORTUNITIES INCORPORATED	NY	14,967
Common Ground Community IV HDFC	NY	359,100
Common Ground Community IV HDFC	NY	141,382
Common Ground Community IV HDFC	NY	416,468

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Community Access, Inc	NY	404,974
Community Access, Inc	NY	240,318
Community Access, Inc	NY	224,210
Community Action For Human Services, Inc	NY	129,207
Community Action of Greene County,Inc	NY	14,897
Community Housing Innovations, Inc	NY	166,684
Community Housing Innovations, Inc	NY	52,968
Community Housing Innovations, Inc	NY	100,575
Community Housing Innovations, Inc	NY	52,148
Community Housing Innovations, Inc	NY	130,121
Community Housing Innovations, Inc	NY	86,110
Community Housing Innovations, Inc	NY	47,373
Community Housing Innovations, Inc	NY	168,638
Community Housing Innovations, Inc	NY	48,093
Community Housing Innovations, Inc	NY	69,328
Community Services for the Developmentally Disabled, Inc	NY	269,042
Community, Counseling, & Mediation	NY	232,181
Community, Counseling, & Mediation	NY	238,951
COMMUNITY__ACTION__FOR__HUMAN__SERVICES__INC.__CROTONA__PARK__WEST__PAIGE__APARTMENTS.	NY	436,241
Comunilife, Inc	NY	663,215
Comunilife, Inc	NY	635,623
Concern for Independent Living, Inc	NY	216,420
Corporation for AIDS Research, Education and Services, Inc	NY	25,000
Corporation for AIDS Research, Education and Services, Inc	NY	5,000
Corporation for AIDS Research, Education and Services, Inc	NY	26,250
Corporation for AIDS Research, Education and Services, Inc	NY	34,666
Corporation for AIDS Research, Education and Services, Inc	NY	16,666
Corporation for AIDS Research, Education and Services, Inc	NY	33,333
County of Dutchess	NY	132,828
County of Dutchess	NY	174,780
County of Dutchess	NY	86,796
County of Dutchess	NY	72,528
County of Dutchess	NY	84,216
County of Dutchess	NY	55,068
Covenant House New York/Under 21, Inc	NY	177,978
Covenant House New York/Under 21, Inc	NY	504,647
Covenant House New York/Under 21, Inc	NY	594,542
Covenant House New York/Under 21, Inc	NY	129,654
Covenant House New York/Under 21, Inc	NY	419,148
Covenant House New York/Under 21, Inc	NY	166,948
Covenant House New York/Under 21, Inc	NY	376,444
Crystal Run Village, Inc	NY	133,349
CUCS	NY	199,999
CUCS	NY	226,800
CUCS	NY	298,736
CUCS	NY	1,302,539
CUCS	NY	103,950
CUCS	NY	238,140
Damon House New York, Inc	NY	262,479
DePaul Community Services	NY	73,115
Domestic Violence and Rape Crisis Services of Saratoga County	NY	114,536
Domestic Violence and Rape Crisis Services of Saratoga County	NY	36,547
Domestic Violence and Rape Crisis Services of Saratoga County	NY	36,607
Domestic Violence and Rape Crisis Services of Saratoga County	NY	30,208
Dunkirk Housing Authority	NY	122,628
EAC	NY	107,139
East New York Urban Youth Corps	NY	96,756
Ecclesia Ministries of Newburgh, Inc	NY	62,954
El Regreso Foundation	NY	253,855
Emergency Housing Group, Inc	NY	186,148
Emergency Housing Group, Inc	NY	60,315
Equinox, Inc	NY	98,210
Equinox, Inc	NY	82,363
Equinox, Inc	NY	84,955
Equinox, Inc	NY	63,675
Erie County Department of Mental Health	NY	303,120
Erie County Department of Mental Health	NY	577,015
Erie County Department of Mental Health	NY	288,888
Erie County Department of Mental Health	NY	114,318
Erie County Department of Mental Health	NY	870,984
Erie County Department of Mental Health	NY	701,304

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Erie County Department of Mental Health	NY	208,456
Erie County Department of Mental Health	NY	216,425
Erie County Department of Mental Health	NY	500,771
Erie County Department of Mental Health	NY	153,000
Erie County Department of Mental Health	NY	154,523
Erie County Department of Mental Health	NY	243,625
ETC Housing Corp	NY	12,733
FACES NY	NY	184,553
FACES NY	NY	133,913
FACES NY 2011	NY	152,092
Family Nurturing Center of Central New York Inc	NY	19,250
Family Nurturing Center of Central New York Inc	NY	105,810
Family of Woodstock, Inc	NY	91,667
Family of Woodstock, Inc	NY	69,530
Family of Woodstock, Inc	NY	60,766
Family Residences and Essential Enterprises, Inc	NY	104,022
Family Residences and Essential Enterprises, Inc	NY	63,775
Family Service League, Inc	NY	92,344
Family Service League, Inc	NY	345,079
Federation Employment and Guidance Service, Inc	NY	558,906
Federation Employment and Guidance Service, Inc	NY	238,319
Federation Employment and Guidance Service, Inc	NY	582,961
Federation Employment and Guidance Service, Inc	NY	595,000
Federation Employment and Guidance Service, Inc	NY	676,767
Federation of Organizations for the New York State Mentally Disabled, Inc	NY	46,235
Federation of Organizations for the New York State Mentally Disabled, Inc	NY	45,268
Federation of Organizations for the New York State Mentally Disabled, Inc	NY	100,849
Foundation for Research on Sexually Transmitted Diseases	NY	871,533
Fountain House, Inc	NY	639,295
Franklin County Coc	NY	52,505
Gateway Community Industries, Inc	NY	91,069
Gateway Community Industries, Inc	NY	41,020
Gateway Community Industries, Inc	NY	70,350
Gateway Community Industries, Inc	NY	65,809
Gateway Community Industries, Inc	NY	45,120
Gateway Community Industries, Inc	NY	41,307
Geneva Housing Authority	NY	62,040
Geneva Housing Authority	NY	104,011
Geneva Housing Authority	NY	240,660
Gerard Place Housing Development Fund Company, Inc	NY	177,909
Glens Falls Housing Authority	NY	80,040
Glens Falls Housing Authority	NY	32,016
Glens Falls Housing Authority	NY	116,184
Goddard Riverside Community Center	NY	153,696
Goddard Riverside Community Center	NY	96,657
Goddard Riverside Community Center	NY	169,644
Goddard Riverside Community Center	NY	280,889
Good Shepherd Services—Chelsea Foyer	NY	414,000
Grace Church Community Center, Inc	NY	127,949
Grace Smith House, Inc	NY	18,385
Grace Smith House, Inc	NY	11,209
Greyston Health Services, Inc	NY	251,111
H.E.L.P. Equity Homes, Inc	NY	132,720
H.E.L.P. Equity Homes, Inc	NY	165,914
H.O.M.E.E. CLINIC, INC	NY	131,936
Hands Across Long Island, Inc	NY	56,800
Harlem United Community AIDS Center, Inc	NY	364,817
Harlem United Community AIDS Center, Inc	NY	227,834
HELP Social Service Corporation	NY	1,008,349
HELP Social Service Corporation	NY	791,172
HELP Suffolk Inc	NY	127,897
Heritage Health and Housing, Inc	NY	110,528
Heritage Health and Housing, Inc	NY	330,486
Heritage Health and Housing, Inc	NY	159,935
Heritage Health and Housing, Inc	NY	249,494
Hispanics United of Buffalo Inc	NY	246,661
Homeless Action Committee, Inc	NY	69,974
Homeless Action Committee, Inc	NY	79,747
Homeless Alliance of Western New York	NY	156,450
Homeless and Travelers Aid Society of the Capital District, Inc	NY	149,000
Homeless and Travelers Aid Society of the Capital District, Inc	NY	113,701
Homeless and Travelers Aid Society of the Capital District, Inc	NY	80,523

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Homeless and Travelers Aid Society of the Capital District, Inc	NY	186,957
Homeless and Travelers Aid Society of the Capital District, Inc	NY	111,104
HOPE Community Services, Inc	NY	233,799
Housing Plus	NY	231,676
Housing Plus	NY	156,549
Housing Plus	NY	313,584
Housing Council in the Monroe County Area Inc	NY	167,250
Housing Options Made Easy, Inc	NY	227,772
Housing Options Made Easy, Inc	NY	165,318
Housing Works, Inc	NY	469,535
Housing Works, Inc	NY	371,276
Housing Works, Inc	NY	333,635
Housing Works, Inc	NY	286,535
Hudson River Housing	NY	48,852
Hudson River Housing	NY	133,663
Hudson River Housing	NY	138,842
Hudson River Housing	NY	40,274
Hudson River Housing	NY	34,913
Human Services Coalition of Cayuga County Inc	NY	15,460
Independent Living, Inc	NY	129,885
INSTITUTE FOR COMMUNITY LIVING, INC	NY	240,060
INSTITUTE FOR COMMUNITY LIVING, INC	NY	126,395
INSTITUTE FOR COMMUNITY LIVING, INC	NY	377,444
INSTITUTE FOR COMMUNITY LIVING, INC	NY	109,319
INSTITUTE FOR COMMUNITY LIVING, INC	NY	141,627
INSTITUTE FOR COMMUNITY LIVING, INC	NY	230,945
INSTITUTE FOR COMMUNITY LIVING, INC	NY	26,496
INSTITUTE FOR COMMUNITY LIVING, INC	NY	126,394
INSTITUTE FOR COMMUNITY LIVING, INC	NY	315,787
INSTITUTE FOR COMMUNITY LIVING, INC	NY	179,281
INSTITUTE FOR COMMUNITY LIVING, INC	NY	672,657
Interfaith Nutrition Network	NY	34,959
Interfaith Partnership for the Homeless	NY	80,000
Interfaith Partnership for the Homeless	NY	111,105
Interfaith Partnership for the Homeless	NY	53,683
Jefferson County Department of Social Services	NY	284,376
Jefferson County Department of Social Services	NY	25,092
Jefferson County Department of Social Services	NY	250,920
Jefferson County Department of Social Services	NY	50,184
Jericho Project	NY	49,671
Jewish Board of Family and Children's Services, Inc	NY	415,395
Jewish Board of Family and Children's Services, Inc	NY	283,500
John Bosco House, Inc	NY	20,000
Joseph's House & Shelter, Inc	NY	129,500
Joseph's House & Shelter, Inc	NY	61,493
Joseph's House & Shelter, Inc	NY	55,491
Joseph's House & Shelter, Inc	NY	116,666
Joseph's House & Shelter, Inc	NY	70,000
Kenmore HDFC	NY	390,576
Lake Shore Behavioral Health	NY	573,225
Lakeview Mental Health	NY	84,091
Lantern Community Services	NY	630,000
Legal Aid Society of Northeastern New York, Inc	NY	33,183
Legal Aid Society of Northeastern New York, Inc	NY	35,595
Legal Aid Society of Northeastern New York, Inc	NY	30,120
Legal Assistance of Western New York, Inc	NY	33,600
Legal Assistance of Western New York, Inc	NY	47,250
Lenox Hill Neighborhood House	NY	285,998
Liberty Resources, Inc	NY	63,355
Long Island Coalition for the Homeless	NY	79,573
Long Island Coalition for the Homeless	NY	70,000
Long Island Coalition for the Homeless	NY	21,000
Long Island Coalition for the Homeless	NY	134,400
Lower Eastside Service Center, Inc	NY	492,100
Lower Eastside Service Center, Inc	NY	300,000
Lt. Col. Matt Urban Human Services Ctr of WNY	NY	1,677,863
Lutheran Social Services of New York	NY	210,000
Lutheran Social Services of New York	NY	397,950
Mental Health America of Dutchess County	NY	54,250
Mental Health Association in Jefferson County Inc	NY	76,600
Mental Health Association in Orange County, Inc	NY	244,472
Mental Health Association in Ulster County Inc	NY	58,209

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Mental Health Association of Nassau County	NY	205,475
Mental Health Association of Nassau County	NY	94,500
Mental Health Association of New York City, Inc	NY	584,272
Mental Health Association of New York City, Inc	NY	291,244
Mercy Haven Inc	NY	10,194
Metropolitan Council on Jewish Poverty	NY	99,942
Mohawk Opportunities, Inc	NY	125,347
Mohawk Opportunities, Inc	NY	72,612
Mohawk Opportunities, Inc	NY	56,355
MOMMAS Inc	NY	57,135
Monroe County	NY	51,030
Nassau County Coalition Against Domestic Violence	NY	105,202
Nassau County Coalition Against Domestic Violence	NY	122,356
Nassau County Coalition Against Domestic Violence	NY	170,957
Nassau County Coalition Against Domestic Violence	NY	136,603
Nassau County Housing & Homeless Services	NY	339,260
Nassau/Suffolk Law Services Committee, Inc	NY	69,616
Neighborhood Coalition for Shelter	NY	243,070
New York State Office of Alcoholism and Substance Abuse Sevices	NY	770,760
New York State Office of Alcoholism and Substance Abuse Sevices	NY	244,704
New York State Office of Alcoholism and Substance Abuse Sevices	NY	153,600
New York State Office of Alcoholism and Substance Abuse Sevices	NY	140,508
New York State Office of Alcoholism and Substance Abuse Sevices	NY	464,628
New York State Office of Alcoholism and Substance Abuse Sevices	NY	232,656
New York State Office of Alcoholism and Substance Abuse Sevices	NY	231,192
New York State Office of Alcoholism and Substance Abuse Sevices	NY	776,064
New York State Office of Alcoholism and Substance Abuse Sevices	NY	201,228
New York State Office of Alcoholism and Substance Abuse Sevices	NY	136,704
New York State Office of Alcoholism and Substance Abuse Sevices	NY	523,596
New York State Office of Alcoholism and Substance Abuse Sevices	NY	307,200
New York State Office of Alcoholism and Substance Abuse Sevices	NY	418,356
New York State Office of Alcoholism and Substance Abuse Sevices	NY	137,076
New York State Office of Alcoholism and Substance Abuse Sevices	NY	227,040
New York State Office of Alcoholism and Substance Abuse Sevices	NY	109,524
New York State Office of Alcoholism and Substance Abuse Sevices	NY	742,248
New York State Office of Alcoholism and Substance Abuse Sevices	NY	142,740
New York State Office of Alcoholism and Substance Abuse Sevices	NY	146,880
New York State Office of Alcoholism and Substance Abuse Sevices	NY	946,176
New York State Office of Alcoholism and Substance Abuse Sevices	NY	363,072
New York State Office of Alcoholism and Substance Abuse Sevices	NY	123,552
New York State Office of Alcoholism and Substance Abuse Sevices	NY	164,448
New York State Office of Alcoholism and Substance Abuse Sevices	NY	219,624
New York State Office of Alcoholism and Substance Abuse Sevices	NY	199,680
New York State Office of Alcoholism and Substance Abuse Sevices	NY	206,016
New York State Office of Alcoholism and Substance Abuse Sevices	NY	198,432
New York State Office of Alcoholism and Substance Abuse Sevices	NY	80,088
New York State Office of Alcoholism and Substance Abuse Sevices	NY	218,496
New York State Office of Alcoholism and Substance Abuse Sevices	NY	98,976
New York State Office of Alcoholism and Substance Abuse Sevices	NY	198,012
New York State Office of Alcoholism and Substance Abuse Sevices	NY	203,136
New York State Office of Alcoholism and Substance Abuse Sevices	NY	310,080
New York State Office of Alcoholism and Substance Abuse Sevices	NY	131,520
New York State Office of Alcoholism and Substance Abuse Sevices	NY	109,248
New York State Office of Alcoholism and Substance Abuse Sevices	NY	337,920
New York State Office of Alcoholism and Substance Abuse Sevices	NY	211,344
New York State Office of Alcoholism and Substance Abuse Sevices	NY	279,360
New York State Office of Alcoholism and Substance Abuse Sevices	NY	175,668
New York State Office of Alcoholism and Substance Abuse Sevices	NY	616,500
New York State Office of Alcoholism and Substance Abuse Sevices	NY	372,516
Newburgh Interfaith Emergency Housing Inc	NY	102,234
Niagara Fall/Niagara County Continuum of Care	NY	68,676
NY-511 Binghamton/Union Town/Broome, Otsego, Chenango Counties CoC	NY	82,000
NY-511 Binghamton/Union Town/Broome, Otsego, Chenango Counties CoC	NY	91,000
NY-511 Binghamton/Union Town/Broome, Otsego, Chenango Counties CoC	NY	143,732
NY-511 Binghamton/Union Town/Broome, Otsego, Chenango Counties CoC	NY	16,178
NY-600 CoC Registration 2009	NY	545,459
NY-600 CoC Registration 2009	NY	728,535
NYS Office of Mental Health	NY	401,280
NYS Office of Mental Health	NY	372,540
NYS Office of Mental Health	NY	345,324
NYS Office of Mental Health	NY	107,952
NYS Office of Mental Health	NY	91,668

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
NYS Office of Mental Health	NY	162,372
NYS Office of Mental Health	NY	376,356
NYS Office of Mental Health	NY	256,500
NYS Office of Mental Health	NY	40,368
NYS Office of Mental Health	NY	463,404
NYS Office of Mental Health	NY	306,036
NYS Office of Mental Health	NY	181,992
NYS Office of Mental Health	NY	517,776
NYS Office of Mental Health	NY	177,168
NYS Office of Mental Health	NY	310,884
NYS Office of Mental Health	NY	127,764
NYS Office of Mental Health	NY	102,600
NYS Office of Mental Health	NY	205,200
NYS Office of Mental Health	NY	114,120
NYS Office of Mental Health	NY	357,576
NYS Office of Mental Health	NY	184,536
NYS Office of Mental Health	NY	613,200
NYS Office of Mental Health	NY	158,388
NYS Office of Mental Health	NY	214,008
NYS Office of Mental Health	NY	98,520
Oneida County Department of Mental Health	NY	104,900
Oneida County Department of Mental Health	NY	14,927
Oneida County Department of Mental Health	NY	37,483
Oneida County Workforce Development	NY	39,900
Onondaga Case Management Services, Inc	NY	234,486
Options for Community Living, Inc	NY	86,706
Options for Community Living, Inc	NY	48,622
Options for Community Living, Inc	NY	49,804
Options for Community Living, Inc	NY	85,870
Options for Community Living, Inc	NY	80,563
Options for Community Living, Inc	NY	119,592
Options for Independence	NY	79,540
Options for Independence	NY	73,960
Orange County Department of Mental Health	NY	69,912
Orange County Department of Mental Health	NY	69,912
Orange County Department of Mental Health	NY	186,876
Palladia, Inc	NY	282,790
Palladia, Inc	NY	704,884
Palladia, Inc	NY	492,830
Palladia, Inc	NY	158,957
Palladia, Inc	NY	830,975
Palladia, Inc	NY	458,882
Palladia, Inc	NY	265,060
Palladia, Inc	NY	556,583
Palladia, Inc	NY	265,599
Palladia, Inc	NY	137,536
PathStone Corporation	NY	16,687
PathStone Corporation	NY	65,450
Pathways to Housing Inc	NY	274,156
Pathways to Housing Inc	NY	154,015
Pathways to Housing Inc	NY	584,268
Pathways to Housing Inc	NY	426,777
Pathways to Housing Inc	NY	527,647
PEOPLe, Inc	NY	82,152
Phase Piggy Back Inc	NY	305,947
Phase Piggy Back Inc	NY	137,838
Pibly Residential Programs, Inc	NY	463,234
Plattsburgh Housing Authority	NY	55,188
Plattsburgh Housing Authority	NY	110,376
POSTGRADUATE CENTER FOR MENTAL HEALTH	NY	472,677
Praxis Housing Initiatives	NY	800,633
Project Hospitality 385 Housing Development Fund Corporation	NY	477,034
Project Hospitality, Inc	NY	371,843
Project Renewal, Inc	NY	670,770
Project Renewal, Inc	NY	532,669
Project Renewal, Inc	NY	322,845
Project Renewal, Inc	NY	328,300
Project Renewal, Inc	NY	409,798
Project Renewal, Inc	NY	428,982
Project Renewal, Inc	NY	135,568
Recovery Houses of Rochester, Inc	NY	44,452
Regional Economic Community Action Program, Inc	NY	72,495

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Rehabilitation Support Services	NY	60,119
Rehabilitation Support Services	NY	66,381
Rehabilitation Support Services	NY	104,372
Rehabilitation Support Services, Inc	NY	69,865
Restoration Society, Inc	NY	200,281
Retreat, Inc	NY	95,592
Rochester Housing Authority	NY	149,400
Rochester Housing Authority	NY	470,880
Rochester Housing Authority	NY	721,284
Rochester Housing Authority	NY	185,700
Rochester Housing Authority	NY	2,254,272
Rochester Housing Authority	NY	445,824
Rochester Housing Authority	NY	89,808
Rochester Housing Authority	NY	207,540
Rochester Housing Authority	NY	875,172
Rockland County, New York	NY	215,610
Rockland County, New York	NY	110,310
Rockland County, New York	NY	445,796
Rockland County, New York	NY	74,000
Safe Harbors of the Hudson, Inc	NY	157,500
SAFE Inc of Schenectady	NY	48,267
Safe Space	NY	225,610
Samaritan Village, Inc	NY	342,709
Samaritan Village, Inc	NY	183,750
Saratoga County Rural Preservation Company	NY	43,417
Schenectady Community Action Program, Inc	NY	149,780
Schenectady Community Action Program, Inc	NY	165,905
Schenectady Community Action Program, Inc	NY	273,436
Schenectady Municipal Housing Authority	NY	451,788
Services for the UnderServed	NY	404,203
Services for the UnderServed	NY	74,812
Services for the UnderServed	NY	345,362
Services for the UnderServed	NY	588,490
Services for the UnderServed	NY	536,347
Services for the UnderServed	NY	210,728
Services for the UnderServed	NY	141,516
Sojourner House at PathStone, Inc	NY	135,640
Sojourner House at PathStone, Inc	NY	89,273
South Shore Association For Independent Living, Inc	NY	225,038
South Shore Association For Independent Living, Inc	NY	92,922
South Shore Association For Independent Living, Inc	NY	148,713
Southern Tier Environments for Living, Inc	NY	56,516
Spanish Action League of Onondaga County, Inc	NY	33,247
Spiritus Christi Prison Outreach, Inc	NY	80,000
Spiritus Christi Prison Outreach, Inc	NY	94,500
Spiritus Christi Prison Outreach, Inc	NY	46,444
Steuben Churchpeople Against Poverty, Inc	NY	68,137
Steuben Churchpeople Against Poverty, Inc	NY	136,945
Steuben County	NY	413,448
Suburban Housing F&H	NY	55,836
Suburban Housing H&P	NY	123,680
Suburban Housing P&W	NY	42,000
Suburban Housing W&H	NY	38,451
Suffolk County Department of Social Services	NY	175,104
Suffolk County United Veterans	NY	69,908
Sullivan County Continuum of Care	NY	13,079
Sullivan County Continuum of Care	NY	147,123
Sullivan County Continuum of Care	NY	39,896
Support Ministries, Inc	NY	91,705
Support Ministries, Inc	NY	112,137
Syracuse Brick House Inc	NY	187,426
Syracuse Brick House Inc	NY	95,899
Syracuse Brick House Inc	NY	221,092
Syracuse Brick House Inc	NY	83,988
Syracuse Brick House Inc	NY	111,286
Syracuse Brick House Inc	NY	272,450
Syracuse Brick House Inc	NY	95,252
Syracuse Brick House Inc	NY	182,292
Syracuse Brick House Inc	NY	105,256
Syracuse Housing Authority	NY	743,844
Syracuse Housing Authority	NY	1,806,360
Tempro Development Co. Inc	NY	142,215

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Tempro Development Co. Inc	NY	81,774
Tempro Development Co. Inc	NY	126,622
The Ali Forney Center	NY	527,857
The Ali Forney Center	NY	438,598
The Bridge, Inc	NY	115,431
The Bridge, Inc	NY	112,163
The Bridge, Inc	NY	224,339
The Bridge, Inc	NY	366,262
The Bridge, Inc	NY	304,581
The Bridge, Inc	NY	101,909
The Center For Youth Services, Inc	NY	126,871
The Center For Youth Services, Inc	NY	33,251
The Doe Fund, Inc	NY	1,951,512
The Doe Fund, Inc	NY	1,062,269
The Doe Fund, Inc	NY	348,447
The Fortune Society, Inc	NY	448,157
The Mental Health Association of Columbia-Greene Counties, Inc	NY	20,483
The Mental Health Association of Columbia-Greene Counties, Inc	NY	64,690
The Mental Health Association of Columbia-Greene Counties, Inc	NY	78,210
The Mental Health Association of Columbia-Greene Counties, Inc	NY	30,768
The Municipal Housing Authority for the City of Yonkers	NY	105,000
The Municipal Housing Authority for the City of Yonkers	NY	32,333
The Municipal Housing Authority for the City of Yonkers	NY	530,244
The Municipal Housing Authority for the City of Yonkers	NY	326,685
The Municipal Housing Authority for the City of Yonkers	NY	20,496
The Municipal Housing Authority for the City of Yonkers	NY	48,729
The Municipal Housing Authority for the City of Yonkers	NY	236,659
The Municipal Housing Authority for the City of Yonkers	NY	73,049
The Municipal Housing Authority for the City of Yonkers	NY	46,034
The Municipal Housing Authority for the City of Yonkers	NY	180,713
The Municipal Housing Authority for the City of Yonkers	NY	20,496
The Municipal Housing Authority for the City of Yonkers	NY	102,274
The Rescue Mission Alliance of Syracuse, NY	NY	100,000
The Salvation Army, a New York Corporation	NY	99,999
The Salvation Army, a New York Corporation	NY	115,448
The Salvation Army, a New York Corporation	NY	293,290
The Salvation Army, a New York Corporation	NY	249,270
The Salvation Army, a New York Corporation	NY	221,056
The Salvation Army, a New York Corporation	NY	51,427
The Salvation Army, a New York Corporation	NY	236,697
The Salvation Army, a New York Corporation	NY	163,244
The Salvation Army, a New York Corporation	NY	83,702
The Salvation Army, a New York Corporation	NY	52,789
The Unity Hospital of Rochester	NY	311,196
Tompkins Community Action	NY	84,713
Tompkins Community Action	NY	60,126
Transitional Living Services	NY	397,801
Transitional Services Association, Inc	NY	34,721
Transitional Services of New York for Long Island, Inc	NY	57,456
Troy Housing Authority	NY	86,520
Troy Housing Authority	NY	25,668
Troy Housing Authority	NY	98,928
Troy Housing Authority	NY	525,192
Troy Housing Authority	NY	55,620
Ulster County Department of Social Services	NY	202,716
Ulster County Department of Social Services	NY	358,116
United Bronx Parents, Inc	NY	419,528
United Veterans Beacon House, Inc	NY	136,099
Unity House of Troy, Inc	NY	183,170
Unity House of Troy, Inc	NY	61,454
Unity House of Troy, Inc	NY	812,961
University Consultation and Treatment Center, Inc	NY	244,998
Urban Justice Center	NY	109,686
Urban Justice Center	NY	142,711
Urban Pathways	NY	357,451
Urban Pathways	NY	160,886
Urban Pathways	NY	149,030
Urban Pathways	NY	174,673
Urban Resource Institute	NY	250,294
Veritas Therapeutic Community, Inc	NY	273,347
Veritas Therapeutic Community, Inc	NY	102,678
Veterans Outreach Center	NY	76,127

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
VIP Supportive Housing for Social Change	NY	324,920
Vocational Instruction Project Community Services, Inc	NY	278,854
Vocational Instruction Project Community Services, Inc	NY	90,016
Vocational Instruction Project Community Services, Inc	NY	227,666
Volunteers of America of Western New York, Inc	NY	205,000
WAIT House	NY	91,643
Warren Washington Association for Mental Health	NY	39,099
Warren Washington Association for Mental Health	NY	38,608
Warren Washington Association for Mental Health	NY	16,065
Wayne County Action Program, Inc	NY	22,256
Wayne County Action Program, Inc	NY	50,826
West Side Federation for Senior and Supportive Housing, Inc	NY	155,715
West Side Federation for Senior and Supportive Housing, Inc	NY	362,197
West Side Federation for Senior and Supportive Housing, Inc	NY	110,205
Westchester County Department of Community Mental Health	NY	473,952
Westchester County Department of Community Mental Health	NY	447,000
Westchester County Department of Community Mental Health	NY	983,508
Westchester County Department of Community Mental Health	NY	1,166,412
Westchester County Department of Community Mental Health	NY	572,124
Westchester County Department of Community Mental Health	NY	962,328
Westchester County Department of Community Mental Health	NY	679,680
Westchester County Department of Community Mental Health	NY	160,440
Westchester County Department of Community Mental Health	NY	448,092
Westchester County Department of Community Mental Health	NY	212,004
Westchester County Department of Community Mental Health	NY	229,860
Westchester County Department of Community Mental Health	NY	1,240,860
Westchester County Department of Social Services	NY	345,652
Westchester County Department of Social Services	NY	30,000
Westchester County Department of Social Services	NY	121,776
Westchester County Department of Social Services	NY	105,000
Westchester County Department of Social Services	NY	323,748
Westchester County Department of Social Services	NY	655,593
Westchester County Department of Social Services	NY	525,185
Westchester County Department of Social Services	NY	100,000
Westchester County Department of Social Services	NY	113,330
Westchester County Department of Social Services	NY	48,530
Westchester County Department of Social Services	NY	205,485
Weston United Community Renewal, Inc	NY	224,900
Wilson Commencement Park	NY	139,025
Women In Need, Inc	NY	327,681
Women In Need, Inc	NY	405,062
Women In Need, Inc	NY	325,270
Women In Need, Inc	NY	326,070
Women In Need, Inc	NY	363,711
Women In Need, Inc	NY	446,787
Women In Need, Inc	NY	265,059
Y.W.C.A. of the Mohawk Valley	NY	354,107
Y.W.C.A. of the Mohawk Valley	NY	161,836
YMCA of Greater New York	NY	570,504
ywca of binghamton/broome county	NY	99,074
ywca of binghamton/broome county	NY	107,081
ywca of binghamton/broome county	NY	152,077
YWCA of Rochester and monroe County	NY	123,781
YWCA of Schenectady	NY	211,271
YWCA of Syracuse & Onondaga County, Inc	NY	165,768
YWCA of the Tonawandas and Niagara Frontier, Inc	NY	31,271
YWCA of Troy-Cohoes Inc	NY	26,250
YWCA of Troy-Cohoes Inc	NY	76,958
YWCA of Western New York	NY	70,367
YWCA of Western New York	NY	166,700
300 Beds, Inc/Harbor House	OH	117,551
ACCESS, Inc	OH	118,711
AIDS Taskforce of Greater Cleveland	OH	75,655
AIDS Taskforce of Greater Cleveland	OH	111,330
Akron Metropolitan Housing Authority	OH	246,840
Akron Metropolitan Housing Authority	OH	73,488
Akron Metropolitan Housing Authority	OH	440,424
Akron Metropolitan Housing Authority	OH	200,064
Alcohol, Drug Addiction & Mental Health Services Board of Tuscarawas and Carroll Counties	OH	125,952
Allen Metropolitan Housing Authority	OH	182,520
Alliance for Children & Families	OH	126,786
Amethyst, Inc	OH	163,120

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Appleseed Community Mental Health Center, Inc	OH	67,549
Ashtabula County Mental Health and Recovery Services Board	OH	297,024
Athens Metropolitan Housing Authority	OH	235,332
Athens Metropolitan Housing Authority	OH	34,740
Aurora Project, Inc	OH	103,772
Battered Women's Shelter	OH	111,147
Battered Women's Shelter	OH	140,711
Beatitude House	OH	71,250
Beatitude House	OH	207,028
Beatitude House	OH	141,334
Beatitude House	OH	134,435
Bethany House Services, Inc	OH	316,538
Bethany House Services, Inc	OH	26,174
Caracole, Inc	OH	159,999
Catholic Charities Diocese of Toledo Inc	OH	217,505
Catholic Charities Diocese of Toledo Inc	OH	86,552
Catholic Charities Regional Agency	OH	17,850
Catholic Charities Regional Agency	OH	51,888
Center for Independent Living Options, Inc	OH	301,748
Center for Independent Living Options, Inc	OH	854,432
Center for Respite Care, Inc	OH	159,420
Cincinnati/Hamilton County CoC	OH	95,645
Cincinnati/Hamilton County CoC	OH	285,701
CincySmiles Foundation	OH	179,765
City of Cincinnati	OH	113,040
City of Cincinnati	OH	4,889,160
City of Cincinnati	OH	265,752
City of Dayton	OH	93,504
City of Dayton	OH	1,961,424
City of Dayton	OH	425,568
City of Springfield, Ohio	OH	31,296
City of Youngstown	OH	239,760
Cleveland Tenants Organization	OH	52,500
Cogswell Hall, Inc	OH	97,735
Coleman Professional Services	OH	31,521
Coleman Professional Services	OH	70,000
Coleman Professional Services	OH	70,927
Coleman Professional Services	OH	89,462
Columbiana County Mental Health Clinic dba The Counseling Center	OH	36,667
Columbiana Metropolitan Housing Authority	OH	29,040
Columbiana Metropolitan Housing Authority	OH	29,040
Columbiana Metropolitan Housing Authority	OH	215,088
Columbus Metropolitan Housing Authority	OH	1,331,892
Columbus Metropolitan Housing Authority	OH	120,900
Columbus Metropolitan Housing Authority	OH	697,608
Columbus Metropolitan Housing Authority	OH	1,231,980
Columbus Metropolitan Housing Authority	OH	746,040
Columbus Metropolitan Housing Authority	OH	94,800
Community Action Agency of Columbiana County, Inc	OH	95,730
Community Action Commission of Fayette County	OH	64,914
Community Action Partnership of the Greater Dayton Area	OH	56,371
Community AIDS Network	OH	65,799
Community Health Center	OH	135,108
Community Health Center	OH	73,165
Community Health Center	OH	116,475
Community Health Center	OH	119,713
Community Health Center	OH	29,049
Community Health Center	OH	175,711
Community Housing Network, Inc	OH	87,316
Community Housing Network, Inc	OH	236,416
Community Housing Network, Inc	OH	184,834
Community Housing Network, Inc	OH	656,422
Community Housing Network, Inc	OH	298,939
Community Housing Network, Inc	OH	83,283
Community Housing Network, Inc	OH	436,813
Community Housing Network, Inc	OH	245,103
Community Housing Network, Inc	OH	226,315
Community Housing Network, Inc	OH	97,293
Community Housing Network, Inc	OH	59,060
Community Housing Network, Inc	OH	35,233
Community Housing Network, Inc	OH	260,673
Community Services of Stark County, Inc	OH	133,333

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Community Shelter Board	OH	166,413
Community Support Services Inc	OH	162,385
Continue Life Inc	OH	212,973
Crisis Intervention and Recovery Center, Inc	OH	62,132
Cuyahoga County	OH	270,705
Cuyahoga County	OH	537,741
Cuyahoga County	OH	1,047,732
Cuyahoga County	OH	77,167
Cuyahoga County	OH	10,116,156
Cuyahoga County	OH	317,109
Cuyahoga County	OH	174,731
Cuyahoga County	OH	416,820
Cuyahoga Metropolitan Housing Authority	OH	386,373
Daybreak, Inc	OH	410,868
Daybreak, Inc	OH	191,774
emerald development & economic network	OH	572,959
emerald development & economic network	OH	703,431
emerald development & economic network	OH	27,276
emerald development & economic network	OH	806,702
emerald development & economic network	OH	555,615
emerald development & economic network	OH	468,367
Family & Community Services, Inc	OH	118,356
Family & Community Services, Inc	OH	184,701
Family & Community Services, Inc	OH	45,933
Family Abuse Shelter of Miami County, Inc	OH	42,000
Family Abuse Shelter of Miami County, Inc	OH	16,000
Family Outreach Community United Services	OH	271,820
Family Outreach Community United Services	OH	404,981
Family Outreach Community United Services	OH	308,076
Family Outreach Community United Services	OH	119,220
Family Recovery Center	OH	70,606
Family Violence Prevention Center of Greene County, Inc	OH	56,293
Family Violence Prevention Center of Greene County, Inc	OH	66,761
Freestore Foodbank Permanent Housing	OH	170,449
Freestore/Foodbank, Inc	OH	72,886
Freestore/Foodbank, Inc	OH	739,858
Geauga County Board of Mental Health & Recovery Services	OH	89,808
Greene Metropolitan Housing Authority	OH	141,660
H. M. Life Opportunity Services	OH	68,077
H. M. Life Opportunity Services	OH	179,584
H. M. Life Opportunity Services	OH	169,140
H. M. Life Opportunity Services	OH	48,218
Hitchcock Center For Women, Inc	OH	275,403
Hitchcock Center For Women, Inc	OH	236,841
Hocking Metropolitan Housing Authority	OH	210,816
Homefull	OH	174,394
Homefull	OH	254,000
Huckleberry House, Inc	OH	235,406
Humility of Mary	OH	76,624
Humility of Mary	OH	32,322
ICAN Inc	OH	48,134
ICAN Inc	OH	46,856
ICAN Inc	OH	190,357
ICAN Inc	OH	86,692
ICAN Inc	OH	77,350
Info Line, Inc	OH	159,796
Info Line, Inc	OH	95,778
Interfaith Hospitality Network of Springfield	OH	212,719
Ironton Lawrence County Area CAO, Inc	OH	104,200
Jefferson County Community Action Council	OH	138,432
Jefferson County Prevention and Recovery Board	OH	354,632
Jefferson County Prevention and Recovery Board	OH	229,764
JOSEPH HOUSE, INC	OH	107,660
JOSEPH HOUSE, INC	OH	77,049
Joseph's Home	OH	273,056
Knox Metropolitan Housing Authority	OH	133,500
Lake County Alcohol, Drug Addiction and Mental Health Services Board	OH	218,568
Lakewood Christian Service Center	OH	41,398
Legacy III, Inc	OH	75,920
Legacy III, Inc	OH	139,099
Legacy III, Inc	OH	134,904
Licking County Coalition for Housing	OH	588,371

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Licking Metropolitan Housing Authority	OH	312,936
Lighthouse Youth Services, Inc	OH	147,025
Lighthouse Youth Services, Inc	OH	409,122
Lighthouse Youth Services, Inc	OH	100,601
Lorain Metropolitan Housing Authority	OH	513,852
LUCAS METROPOLITAN HOUSING AUTHORITY	OH	151,380
Lutheran Metropolitan Ministry	OH	50,157
Maryhaven	OH	137,936
Maryhaven	OH	48,015
McKinley Hall, Inc	OH	40,615
Medina County Alcohol, Drug Addiction and Mental Health Board	OH	199,207
Medina Metropolitan Housing Authority	OH	348,600
Mental Health & Recovery Board of Union County	OH	60,580
Mental Health & Recovery Board of Union County	OH	73,361
Mental Health & Recovery Services Board of Lucas County	OH	241,752
Mental Health & Recovery Services Board of Lucas County	OH	393,486
Mental Health & Recovery Services Board of Lucas County	OH	96,660
Mental Health & Recovery Services Board of Lucas County	OH	96,660
Mental Health and Recovery Services Board of Stark County	OH	47,957
Mental Health and Recovery Services Board of Stark County	OH	105,437
Mental Health Services for Homeless Persons, Inc	OH	456,968
Mental Health Services for Homeless Persons, Inc	OH	264,099
Mental Health Services for Homeless Persons, Inc	OH	469,586
Mental Health Services for Homeless Persons, Inc	OH	39,032
Mental Health Services for Homeless Persons, Inc	OH	206,741
Mental Health Services for Homeless Persons, Inc	OH	1,634,897
Mental Health Services for Homeless Persons, Inc	OH	969,577
Mental Health Services for Homeless Persons, Inc	OH	446,546
Mental Health Services for Homeless Persons, Inc	OH	229,897
Mercy Manor	OH	101,718
Meridian Services, Inc	OH	124,640
Meridian Services, Inc	OH	35,945
Meridian Services, Inc	OH	80,876
Meridian Services, Inc	OH	136,786
Meridian Services, Inc	OH	113,300
Miami Valley Housing Opportunities, Inc	OH	50,364
Miami Valley Housing Opportunities, Inc	OH	127,105
Miami Valley Housing Opportunities, Inc	OH	116,914
Montgomery County Board of Commissioners	OH	137,898
National Church Residences	OH	415,400
National Church Residences	OH	42,292
National Church Residences	OH	250,092
Neighborhood Health Association, Inc	OH	52,979
Neighborhood Properties, Inc	OH	90,649
Neighborhood Properties, Inc	OH	180,088
Neighborhood Properties, Inc	OH	73,975
Neighborhood Properties, Inc	OH	108,889
Neighborhood Properties, Inc	OH	229,249
Neighborhood Properties, Inc	OH	239,499
Neighborhood Properties, Inc	OH	77,675
New Housing Ohio, Inc	OH	69,621
New Life Community	OH	55,643
New Sunrise Properties, Inc	OH	28,137
North Coast Community Homes, Inc	OH	33,468
North Coast Community Homes, Inc	OH	38,911
Ohio Department of Development	OH	212,536
Ohio Department of Development	OH	245,000
Ohio Multi-County Development Corporation	OH	408,893
Ohio Multi-County Development Corporation	OH	126,029
Ohio Multi-County Development Corporation	OH	78,185
Ohio Valley Goodwill Industries Rehabilitation Center, Inc	OH	172,001
Ohio Valley Goodwill Industries Rehabilitation Center, Inc	OH	285,595
Oriana House, Inc	OH	15,225
Over the Rhine Community Housing	OH	56,037
Pickaway County Community Action Organization, Inc	OH	123,145
PLACES Incorporated	OH	490,117
PLACES Incorporated	OH	325,372
PLACES Incorporated	OH	481,220
PLACES Incorporated	OH	71,081
PLACES Incorporated	OH	214,781
Portage Metropolitan Housing Authority	OH	183,720
Portage Metropolitan Housing Authority	OH	870,000

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Preble County Mental Health & Recovery Board	OH	171,240
Preparation for Adult Living (PAL) Mission	OH	66,666
Preparation for Adult Living (PAL) Mission	OH	109,301
Project Woman of Springfield and Clark County	OH	35,679
Project Woman of Springfield and Clark County	OH	236,911
Prospect House, Inc	OH	126,000
Residential Administrators, Inc	OH	102,721
Residential Administrators, Inc	OH	95,962
Shelterhouse Volunteer Group	OH	93,000
Shelterhouse Volunteer Group	OH	247,062
Shelterhouse Volunteer Group	OH	88,750
Southeast, Inc	OH	211,158
Southeast, Inc	OH	260,680
Springfield District Council of the St. Vincent de Paul Society	OH	23,040
Springfield Metropolitan Housing Authority	OH	106,188
St. Paul's Community Center	OH	183,816
St. Vincent de Paul Social Services, Inc	OH	109,410
St. Vincent de Paul Social Services, Inc	OH	106,910
St. Vincent de Paul Social Services, Inc	OH	181,200
Stark Metropolitan Housing Authority	OH	210,780
Stark Metropolitan Housing Authority	OH	423,660
Stark Metropolitan Housing Authority	OH	171,696
Summit County Children Services	OH	115,643
Talbert House	OH	165,000
TASC of Northwest Ohio, Inc	OH	92,830
TASC of Northwest Ohio, Inc	OH	212,595
Tender Mercies, Inc	OH	299,491
Tender Mercies, Inc	OH	58,630
The Center for Individual and Family Services	OH	56,066
The Mental Health, Drug and Alcohol Services Board	OH	40,348
The Salvation Army, a New York Corporation	OH	178,615
The Salvation Army, a New York Corporation	OH	666,627
The Salvation Army, a New York Corporation	OH	29,644
The Salvation Army, a New York Corporation	OH	526,797
Toledo Lucas HMIS	OH	88,915
Tom Geiger Guest House, Inc	OH	52,500
Transitional Housing, Inc	OH	122,528
Tri-County Board of Recovery & Mental Health Services	OH	34,908
Trumbull County Mental Health and Recovery Board	OH	97,767
Trumbull County Mental Health and Recovery Board	OH	221,556
Volunteers of America	OH	79,155
Volunteers of America	OH	246,967
Volunteers of America Northwest Ohio, Inc	OH	286,661
Volunteers of America Northwest Ohio, Inc	OH	291,955
Volunteers of America of Greater Ohio	OH	262,500
Volunteers of America of Greater Ohio	OH	357,325
Warren Metropolitan Housing Authority	OH	390,159
Warren Metropolitan Housing Authority	OH	234,360
Warren Metropolitan Housing Authority	OH	184,574
West Side Catholic Center	OH	120,901
West Side Catholic Center	OH	19,339
West Side Catholic Center	OH	127,829
West Side Catholic Center	OH	97,182
WSOS Community Action Commission, Inc	OH	592,775
WSOS Community Action Commission, Inc	OH	53,774
WSOS Community Action Commission, Inc	OH	293,822
WSOS Community Action Commission, Inc	OH	435,196
YMCA of Greater Cleveland	OH	905,203
YMCA of Greater Cleveland	OH	187,351
Young Women's Christian Association of Youngstown, Ohio	OH	55,728
Young Women's Christian Association of Youngstown, Ohio	OH	136,595
Young Women's Christian Association of Youngstown, Ohio	OH	89,353
Young Women's Christian Association of Youngstown, Ohio	OH	132,141
Young Women's Christian Association of Youngstown, Ohio	OH	105,248
Youngstown Area Goodwill Industries, Inc	OH	72,063
Youngstown City Health District	OH	52,083
Youngstown State University	OH	50,308
YWCA	OH	162,559
YWCA	OH	99,015
YWCA Dayton	OH	405,799
YWCA Dayton	OH	860,470
YWCA of Canton	OH	47,951

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
YWCA of Canton	OH	208,227
YWCA of Canton	OH	32,888
YWCA of Elyria	OH	120,932
YWCA of Elyria	OH	116,706
YWCA of Greater Cincinnati	OH	146,067
YWCA of Hamilton Ohio Inc	OH	119,320
Zanesville Metropolitan Housing Authority	OH	46,560
Central Oklahoma Community Action Agency	OK	34,075
Central Oklahoma Community Action Agency	OK	113,719
Central Oklahoma Community Action Agency	OK	34,571
Central Oklahoma Community Action Agency	OK	67,882
City of Oklahoma City	OK	240,815
City of Oklahoma City	OK	66,424
City of Oklahoma City	OK	73,001
City of Oklahoma City	OK	236,714
City of Oklahoma City	OK	185,762
City of Oklahoma City	OK	358,654
City of Oklahoma City	OK	89,872
City of Oklahoma City	OK	299,999
City of Oklahoma City	OK	33,456
City of Oklahoma City	OK	51,710
City of Oklahoma City	OK	16,728
City of Oklahoma City	OK	94,564
City of Oklahoma City	OK	124,999
City of Oklahoma City	OK	172,200
City of Oklahoma City	OK	162,500
City of Oklahoma City	OK	134,647
City of Oklahoma City	OK	183,563
Community Action Resource & Development, Inc	OK	13,718
Community Crisis Center, Inc	OK	50,129
Community Service Council—Projects	OK	123,113
Domestic Violence Intervention Services, Inc	OK	149,369
Domestic Violence Program of North Central Oklahoma, Inc	OK	70,613
East Main Place, Inc	OK	43,895
Food and Shelter for Friends	OK	51,337
Food and Shelter for Friends	OK	25,315
Freedom From Addiction Through Christ	OK	43,632
Housing Authority of the City of Lawton	OK	22,050
Housing Authority of the City of Lawton	OK	47,147
Housing Authority of the City of Norman	OK	80,640
Legal Aid Services of Oklahoma, Inc	OK	111,919
Mental Health Association in Tulsa, Inc	OK	252,008
Mental Health Association in Tulsa, Inc	OK	121,046
Mental Health Association in Tulsa, Inc	OK	310,633
Mental Health Association in Tulsa, Inc	OK	88,456
Mental Health Association in Tulsa, Inc	OK	222,768
Mental Health Association in Tulsa, Inc	OK	23,625
Norman Housing Authority	OK	68,880
Northeast Oklahoma COC	OK	253,995
Northeast Oklahoma Community Action Agency, Inc	OK	31,370
Northeast Oklahoma Community Action Agency, Inc	OK	26,708
northwest domestic crisis services 04	OK	118,544
Oklahoma Mental Health Council d/b/a Red Rock	OK	162,451
Progressive Independence, Inc	OK	37,392
Southern Territorial Headquarters of The Salvation Army, The	OK	110,431
Southern Territorial Headquarters of The Salvation Army, The	OK	336,679
State of Oklahoma	OK	179,016
State of Oklahoma	OK	48,216
Tulsa Day Center for the Homeless, Inc	OK	213,112
United Way of Ponca City, Inc	OK	44,765
Volunteers of America of Oklahoma, Inc	OK	103,663
Volunteers of America of Oklahoma, Inc	OK	125,481
Volunteers of America of Oklahoma, Inc	OK	211,941
Volunteers of America of Oklahoma, Inc	OK	77,914
Waynoka Mental Health Authority	OK	224,439
ACCESS, Inc	OR	10,901
Bradley-Angle House	OR	73,987
Cascadia BHC	OR	125,582
Cascadia BHC	OR	15,384
Cascadia BHC	OR	271,872
Cascadia BHC	OR	698,336
Central City Concern	OR	104,772

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Central City Concern	OR	200,083
Central City Concern	OR	223,014
Central City Concern	OR	236,968
Central City Concern	OR	160,602
Central Oregon Veterans Outreach	OR	25,506
City of Portland	OR	271,986
City of Portland	OR	241,074
Clackamas County Department of Health, Housing and Human Services	OR	29,977
Clackamas County Department of Health, Housing and Human Services	OR	64,057
Clackamas County Department of Health, Housing and Human Services	OR	36,193
Clackamas County Department of Health, Housing and Human Services	OR	184,229
Clackamas County Department of Health, Housing and Human Services	OR	114,200
Clackamas Women's Services	OR	81,290
Clatsop Community Action	OR	64,691
Clatsop Community Action	OR	17,951
Communities in Action	OR	116,951
Communities in Action	OR	41,820
Community Action Organization	OR	165,218
Community Action Program of East Central Oregon	OR	33,588
Community Action Program of East Central Oregon	OR	72,574
Community Action Team, Inc	OR	28,996
Community Action Team, Inc	OR	26,767
Community Action Team, Inc	OR	99,110
Community Action Team, Inc	OR	67,594
Community Connection of Northeast Oregon, Inc	OR	94,406
Community Outreach, Inc	OR	26,739
Community Services Consortium	OR	76,122
Community Works	OR	116,015
Eastern Oregon Alcoholism Foundation	OR	35,467
Give Them Wings, Inc	OR	49,259
Housing and Community Services Agency of Lane County	OR	424,956
Housing Authority of Clackamas County	OR	71,886
Housing Authority of Clackamas County	OR	327,528
Housing Authority of Portland	OR	1,914,768
Housing Authority of Portland	OR	476,244
Housing Authority of Portland	OR	263,952
Housing Authority of Portland	OR	463,944
Housing Authority of Portland	OR	503,388
Housing Authority of Portland	OR	408,420
Human Solutions, Inc	OR	51,905
Human Solutions, Inc	OR	372,973
Human Solutions, Inc	OR	361,691
Human Solutions, Inc	OR	104,928
JOIN	OR	179,800
Lane County	OR	174,549
Lane County	OR	96,260
Lane County	OR	131,705
Lane County	OR	323,346
Lane County	OR	30,835
Lane County	OR	527,903
Lincoln County Council on Alcohol and Drug Abuse, Inc	OR	43,311
Linn-Benton Housing Authority	OR	53,654
Linn-Benton Housing Authority	OR	66,578
Luke-Dorf, Inc	OR	166,293
Mid-Columbia Community Action Council Inc	OR	11,605
Mid-Columbia Community Action Council Inc	OR	58,248
Mid-Willamette Valley Community Action Agency	OR	83,572
Mid-Willamette Valley Community Action Agency	OR	306,901
Mid-Willamette Valley Community Action Agency	OR	30,394
Multnomah County	OR	12,635
Multnomah County	OR	278,736
Multnomah County	OR	142,142
Multnomah County	OR	45,801
Multnomah County	OR	462,083
Multnomah County	OR	1,150,995
Neighborhood House	OR	276,770
NeighborImpact Transitional Housing Program	OR	302,996
New Avenues for Youth	OR	71,190
Northwest Human Services, Inc	OR	235,025
Northwest Pilot Project, Inc	OR	122,879
Open Door Counseling Center	OR	38,095
Oregon Coast Community Action	OR	97,387

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Oregon Coast Community Action	OR	26,463
Oregon Coast Community Action	OR	82,535
Oregon Coast Community Action	OR	7,647
Oregon Coast Community Action	OR	14,580
Oregon Coast Community Action	OR	14,910
Oregon Coast Community Action	OR	22,025
Oregon Coast Community Action	OR	14,314
Oregon Department of Human Services	OR	17,496
Oregon Department of Human Services	OR	11,718
Oregon Housing and Community Services	OR	32,081
Portland Impact, Inc	OR	115,737
Rogue Valley Council of Governments	OR	132,297
Shangri-La Corporation	OR	33,323
Shangri-La Corporation	OR	37,800
Shangri-La Corporation	OR	153,860
St. Vincent de Paul Society of Lane County, Inc	OR	28,511
St. Vincent de Paul Society of Lane County, Inc	OR	88,470
St. Vincent de Paul Society of Lane County, Inc	OR	222,219
St. Vincent de Paul Society of Lane County, Inc	OR	249,736
St. Vincent de Paul Society of Lane County, Inc	OR	58,404
The Inn-Home for Boys	OR	244,192
The Inn-Home for Boys	OR	33,870
The Salvation Army	OR	39,375
The Salvation Army	OR	125,769
Tillamook Co. Community Action Resource Enterprises, Inc	OR	25,061
Transition Projects	OR	116,302
Transition Projects	OR	277,367
Transition Projects	OR	243,041
TSA Medford	OR	50,000
United Community Action Network	OR	42,525
United Community Action Network	OR	35,555
United Community Action Network	OR	35,487
United Community Action Network	OR	59,368
United Community Action Network	OR	80,425
Washington County Dept of Housing Services	OR	83,868
Washington County Dept of Housing Services	OR	14,496
Washington County Dept of Housing Services	OR	39,000
Washington County Dept of Housing Services	OR	31,027
Washington County Dept of Housing Services	OR	136,523
Washington County Dept of Housing Services	OR	119,465
Washington County Dept of Housing Services	OR	126,060
Washington County Dept of Housing Services	OR	1,058,256
Washington County Dept of Housing Services	OR	291,867
YCAP	OR	41,046
1260 Housing Development Corporation	PA	144,900
1260 Housing Development Corporation	PA	528,524
1260 Housing Development Corporation	PA	67,686
1260 Housing Development Corporation	PA	260,604
1260 Housing Development Corporation	PA	201,685
ACHIEVEability	PA	210,000
ACHIEVEability	PA	161,700
ACHIEVEability	PA	42,000
ActionAIDS	PA	178,750
ActionAIDS	PA	249,417
Adams County Housing Authority	PA	39,745
AIDS Care Group	PA	374,858
Allegheny County Department of Human Services	PA	127,844
Allegheny County Department of Human Services	PA	285,704
Allegheny County Department of Human Services	PA	284,525
Allegheny County Department of Human Services	PA	138,548
Allegheny County Department of Human Services	PA	152,566
Allegheny County Department of Human Services	PA	1,596,672
Allegheny County Department of Human Services	PA	149,370
Allegheny County Department of Human Services	PA	68,404
Allegheny County Department of Human Services	PA	304,500
Allegheny County Department of Human Services	PA	119,700
Allegheny County Department of Human Services	PA	606,630
Allegheny County Department of Human Services	PA	224,833
Allegheny County Department of Human Services	PA	228,989
Allegheny County Department of Human Services	PA	173,157
Allegheny County Department of Human Services	PA	193,696
Allegheny County Department of Human Services	PA	391,755

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Allegheny County Department of Human Services	PA	11,147
Allegheny County Department of Human Services	PA	175,455
Allegheny County Department of Human Services	PA	64,702
Allegheny County Department of Human Services	PA	196,461
Allegheny County Department of Human Services	PA	92,009
Allegheny County Department of Human Services	PA	39,454
Allegheny County Department of Human Services	PA	78,507
Allegheny County Department of Human Services	PA	112,356
Allegheny County Department of Human Services	PA	135,003
Allegheny County Department of Human Services	PA	99,378
Allegheny County Department of Human Services	PA	242,611
Allegheny County Department of Human Services	PA	133,992
Allegheny County Department of Human Services	PA	213,309
Allegheny County Department of Human Services	PA	164,146
Allegheny County Department of Human Services	PA	163,223
Allegheny County Department of Human Services	PA	208,827
Allegheny County Department of Human Services	PA	350,870
Allegheny County Department of Human Services	PA	113,814
Allegheny County Department of Human Services	PA	308,209
Allegheny County Department of Human Services	PA	105,875
Allegheny County Department of Human Services	PA	174,237
Allegheny County Department of Human Services	PA	87,995
Allegheny County Department of Human Services	PA	91,862
Allegheny County Department of Human Services	PA	171,552
Allegheny County Department of Human Services	PA	106,050
Allegheny County Department of Human Services	PA	155,429
Allegheny County Department of Human Services	PA	138,960
Allegheny County Department of Human Services	PA	122,165
Allegheny County Department of Human Services	PA	120,750
Allegheny County Department of Human Services	PA	311,949
Allegheny County Department of Human Services	PA	73,980
Allegheny County Department of Human Services	PA	315,837
Allegheny County Department of Human Services	PA	195,223
Allegheny County Department of Human Services	PA	107,841
Allegheny County Department of Human Services	PA	27,384
Allegheny County Department of Human Services	PA	215,526
Allegheny County Department of Human Services	PA	251,286
Allegheny County Department of Human Services	PA	1,398,600
Allegheny County Department of Human Services	PA	362,820
Allegheny County Department of Human Services	PA	230,186
Allegheny County Department of Human Services	PA	166,280
Allegheny County Department of Human Services	PA	251,514
Allegheny County Department of Human Services	PA	68,355
Allegheny County Department of Human Services	PA	55,556
Allegheny County Department of Human Services	PA	73,143
Allegheny County Department of Human Services	PA	64,315
Allegheny County Department of Human Services	PA	305,550
Allegheny County Department of Human Services	PA	145,873
Allegheny County Department of Human Services	PA	64,890
American Red Cross, The	PA	80,905
American Rescue Workers Inc	PA	116,793
Armstrong County Community Action Agency	PA	126,728
Armstrong County Community Action Agency	PA	121,082
Armstrong County Community Action Agency	PA	112,874
Asociacion Puertorriquenos en Marcha	PA	129,778
Asociacion Puertorriquenos en Marcha	PA	149,711
Bell Socialization Services	PA	354,632
Bell Socialization Services	PA	34,824
Berks Counseling Center, Inc	PA	306,180
Berks Counseling Center, Inc	PA	79,135
Berks Counseling Center, Inc	PA	39,660
Berks Counseling Center, Inc	PA	170,019
Berks Counseling Center, Inc	PA	133,745
Berks Counseling Center, Inc	PA	70,570
Berks Counseling Center, Inc	PA	99,960
Berks County Women in Crisis	PA	28,000
Bethesda Project	PA	160,900
Bethesda Project	PA	223,761
Blair County Community Action Program	PA	357,374
Blair County Community Action Program	PA	104,630
Borough of State College	PA	10,920
Bradford County Human Service Agency—County Office of Mental Health	PA	97,472

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Bucks County Housing Group, Inc	PA	160,407
Calcutta House, Inc	PA	115,943
Calcutta House, Inc	PA	75,455
Cameron and Elk Counties MH/MR Program	PA	67,732
CAPSEA, Inc	PA	93,581
Carson Valley Children's Aid	PA	353,396
Catherine McAuley Center	PA	113,700
Catherine McAuley Center	PA	138,399
Catholic Social Services	PA	88,200
Catholic Social Services	PA	120,749
Catholic Social Services	PA	87,780
Catholic Social Services	PA	60,245
Catholic Social Services	PA	160,101
Catholic Social Services	PA	102,229
Catholic Social Services	PA	202,085
Catholic Social Services of the Diocese of Scranton, Inc	PA	125,401
Catholic Social Services of the Diocese of Scranton, Inc	PA	125,924
Catholic Social Services of the Diocese of Scranton, Inc	PA	141,825
Catholic Social Services of the Diocese of Scranton, Inc	PA	104,499
Catholic Social Services of the Diocese of Scranton, Inc	PA	39,871
Catholic Youth Center	PA	318,101
Centre County Youth Service Bureau	PA	52,870
Chester County CoC	PA	100,000
Chester County CoC	PA	112,907
Chester County CoC	PA	17,304
Chester County CoC	PA	118,440
Chester County CoC	PA	106,380
Chester County CoC	PA	83,868
Chester County CoC	PA	305,220
Chester County CoC	PA	105,000
Chester County CoC	PA	56,736
Christian Churches United of the TriCounty Area	PA	311,280
City Mission—Living Stones, Inc	PA	133,417
City Mission—Living Stones, Inc	PA	108,581
City of Philadelphia Office of Supportive Housing	PA	706,512
City of Philadelphia Office of Supportive Housing	PA	116,328
City of Philadelphia Office of Supportive Housing	PA	73,799
City of Philadelphia Office of Supportive Housing	PA	811,320
City of Philadelphia Office of Supportive Housing	PA	99,272
City of Philadelphia Office of Supportive Housing	PA	485,150
City of Philadelphia Office of Supportive Housing	PA	106,380
City of Philadelphia Office of Supportive Housing	PA	377,580
City of Philadelphia Office of Supportive Housing	PA	430,200
City of Philadelphia Office of Supportive Housing	PA	315,094
City of Philadelphia Office of Supportive Housing	PA	129,192
City of Philadelphia Office of Supportive Housing	PA	133,224
City of Philadelphia Office of Supportive Housing	PA	81,146
City of Philadelphia Office of Supportive Housing	PA	78,604
City of Philadelphia Office of Supportive Housing	PA	316,980
City of Philadelphia Office of Supportive Housing	PA	166,812
City of Philadelphia Office of Supportive Housing	PA	147,924
City of Philadelphia Office of Supportive Housing	PA	182,136
City of Philadelphia Office of Supportive Housing	PA	295,740
City of Philadelphia Office of Supportive Housing	PA	14,184
City of Philadelphia Office of Supportive Housing	PA	215,760
City of Philadelphia Office of Supportive Housing	PA	189,120
City of Philadelphia Office of Supportive Housing	PA	63,828
City of Philadelphia Office of Supportive Housing	PA	85,104
City of Philadelphia Office of Supportive Housing	PA	953,940
City of Philadelphia Office of Supportive Housing	PA	431,520
City of Philadelphia Office of Supportive Housing	PA	221,550
City of Philadelphia Office of Supportive Housing	PA	872,400
City of Philadelphia Office of Supportive Housing	PA	107,880
City of Philadelphia Office of Supportive Housing	PA	28,368
City of Philadelphia Office of Supportive Housing	PA	451,500
City of Philadelphia Office of Supportive Housing	PA	448,968
City of Philadelphia Office of Supportive Housing	PA	736,651
City of Philadelphia Office of Supportive Housing	PA	380,604
City of Philadelphia Office of Supportive Housing	PA	70,920
City of Philadelphia Office of Supportive Housing	PA	312,936
Clearfield-Jefferson MH/MR Program	PA	88,237
Clinton County Housing Coalition, Inc	PA	168,048

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
COMHAR	PA	285,805
COMHAR	PA	509,646
Commission on Economic Opportunity	PA	203,236
Commission on Economic Opportunity	PA	164,485
Commission on Economic Opportunity	PA	110,224
Commission on Economic Opportunity	PA	222,632
Commission on Economic Opportunity	PA	260,818
Commission on Economic Opportunity	PA	171,124
Commission on Economic Opportunity	PA	187,682
Commission on Economic Opportunity	PA	80,255
Commission on Economic Opportunity	PA	179,869
Committee For Dignity and Fairness For the Homeless Housing Development, Inc	PA	30,569
Committee For Dignity and Fairness For the Homeless Housing Development, Inc	PA	212,306
Committee For Dignity and Fairness For the Homeless Housing Development, Inc	PA	122,253
Commonwealth of PA	PA	234,949
Community Action Agency of Delaware County, Inc	PA	438,961
Community Action Agency of Delaware County, Inc	PA	150,903
Community Action Agency of Delaware County, Inc	PA	340,865
Community Action Committee of the Lehigh Valley	PA	69,999
Community Action Partnership of Mercer County	PA	60,257
Community Action Partnership of Mercer County	PA	51,498
Community Action Program	PA	80,905
Community Action Southwest	PA	36,228
Community Action, Inc	PA	86,567
Community Action, Inc	PA	67,165
Community Alliance and Reinvestment Endeavor, Inc	PA	37,262
Community Basics, Inc	PA	116,443
Community Basics, Inc	PA	175,879
Community Housing Services	PA	116,539
Community Housing Services	PA	44,982
Community Housing Services	PA	113,761
Community Housing Services	PA	92,209
Community Services of Venango County, Inc	PA	54,268
Community, Youth and Women's Alliance, Inc (CYWA)	PA	44,593
Connect, Inc	PA	259,346
Connect, Inc	PA	121,579
Council on Chemical Abuse	PA	82,869
Council on Chemical Abuse	PA	106,824
Council on Chemical Abuse	PA	54,602
County of Bucks	PA	107,880
County of Bucks	PA	108,796
County of Butler	PA	83,975
County of Butler	PA	165,376
County of Cambria	PA	363,720
County of Franklin	PA	94,588
County of Franklin	PA	95,345
County of Montgomery, PA	PA	136,639
County of Washington	PA	145,812
County of Washington	PA	202,210
County of Washington	PA	169,128
County of Washington	PA	61,765
County of Washington	PA	93,816
County of Washington	PA	206,562
County of Washington	PA	165,950
County of Washington	PA	88,452
County of Washington	PA	225,654
County of York	PA	122,062
County of York	PA	74,712
Crawford County Coalition on Housing Needs, Inc	PA	40,759
Crawford County Commissioners	PA	160,680
Crawford County Mental Health Awareness Program, Inc	PA	91,783
Crawford County Mental Health Awareness Program, Inc	PA	25,216
Crawford County Mental Health Awareness Program, Inc	PA	37,648
Crawford County Mental Health Awareness Program, Inc	PA	121,800
Crisis Shelter of Lawrence County	PA	83,121
Dauphin County	PA	47,750
Dauphin County	PA	120,834
Delaware County Dept. of Human Services	PA	205,800
Delaware County Dept. of Human Services	PA	125,460
Delaware County Dept. of Human Services	PA	117,336
Delaware County Housing Authority	PA	212,388
Delaware County Housing Authority	PA	137,485

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Delaware County Housing Authority	PA	159,444
Delaware County Housing Authority	PA	136,133
Delaware County Housing Authority	PA	149,460
Delaware County Housing Authority	PA	131,004
Delaware County Housing Authority	PA	450,588
Domestic Violence Center of Chester County	PA	89,302
Domestic Violence Intervention of Lebanon County, Inc	PA	290,090
Domestic Violence Service Center, Inc	PA	57,015
Drueding Center	PA	1,081,414
DuBois Housing Authority	PA	333,588
Easy Does It, Inc	PA	31,040
Easy Does It, Inc	PA	338,270
Easy Does It, Inc	PA	65,333
EMDB dba New Bethany Ministries	PA	114,853
Episcopal Community Services	PA	647,203
Erie City & Erie County Project	PA	492,317
Erie City & Erie County Project	PA	341,712
Erie City & Erie County Project	PA	254,457
Erie City & Erie County Project	PA	177,297
Erie City & Erie County Project	PA	138,192
Erie City & Erie County Project	PA	365,400
Erie City & Erie County Project	PA	143,940
Erie City & Erie County Project	PA	196,200
Erie City & Erie County Project	PA	219,297
Family and Community Service of Delaware County	PA	108,069
Family Planning Council, Inc./Circle of Care	PA	127,661
Family Services of Montgomery County	PA	188,614
Fayette County Community Action Agency, Inc	PA	62,982
Fayette County Community Action Agency, Inc	PA	24,072
Fayette County Community Action Agency, Inc	PA	65,695
Fitzmaurice Community Services, Inc	PA	130,807
Fitzmaurice Community Services, Inc	PA	143,000
Futures Community Support Services	PA	35,882
Gaudenzia Concord Place	PA	138,601
Gaudenzia Foundation Inc	PA	55,385
Gaudenzia Inc	PA	65,953
Gaudenzia Inc	PA	233,175
Gaudenzia Inc	PA	68,040
Greene County Human Services	PA	134,315
Harbor Point Housing, Inc	PA	82,564
Hedwig House, Inc	PA	186,490
HELP Development Corporation	PA	487,622
Holcomb Associates, Inc	PA	116,999
Home Nursing AgencyCommunity Services	PA	210,216
Home Nursing AgencyCommunity Services	PA	17,090
HORIZON HOUSE REHABILITATION SERVICES INC	PA	347,215
HORIZON HOUSE REHABILITATION SERVICES INC	PA	801,713
HORIZON HOUSE REHABILITATION SERVICES INC	PA	351,217
HORIZON HOUSE REHABILITATION SERVICES INC	PA	96,201
HORIZON HOUSE REHABILITATION SERVICES INC	PA	644,582
HORIZON HOUSE REHABILITATION SERVICES INC	PA	228,199
HORIZON HOUSE REHABILITATION SERVICES INC	PA	226,223
Housing Authority of Centre County	PA	182,508
Housing Authority of Centre County	PA	68,736
Housing Authority of Monroe County	PA	155,100
Housing Authority of the City of Lancaster	PA	140,352
Housing Authority of the County of Butler	PA	141,750
Housing Authority of the County of Butler	PA	62,651
Housing Authority of the County of Butler	PA	52,447
Housing Authority of the County of Cumberland	PA	27,667
Housing Authority of the County of Cumberland	PA	63,555
Housing Authority of the County of Dauphin	PA	230,904
Housing Authority of the County of Dauphin	PA	107,640
Housing Authority of the County of Lebanon	PA	117,470
Housing Development Corporation of NEPA	PA	167,910
Housing Development Corporation of NEPA	PA	136,087
Housing Development Corporation of NEPA	PA	221,543
Housing Development Corporation of NEPA	PA	99,128
Housing Development Corporation of NEPA	PA	169,223
Housing Development Corporation of NEPA	PA	181,642
Housing Transitions, Inc	PA	71,098
Human Services Center	PA	60,195

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Huntingdon House Transitional Housing Program	PA	80,214
Impact Services Corporation	PA	624,728
Impact Services Corporation	PA	268,304
Indiana County Community Action Program, Inc	PA	82,842
Indiana County Community Action Program, Inc	PA	45,266
Keystone Opportunity Center	PA	44,989
Keystone Opportunity Center	PA	29,410
Lancaster County Mental Health, Mental Retardation and Early Intervention	PA	102,560
Lancaster County Mental Health, Mental Retardation and Early Intervention	PA	272,235
Lawrence County Social Services, Inc	PA	88,928
Lawrence County Social Services, Inc	PA	65,888
Lawrence County Social Services, Inc	PA	126,936
Lawrence County Social Services, Inc	PA	76,650
Lawrence County Social Services, Inc	PA	42,593
Lawrence County Social Services, Inc	PA	202,543
Lebanon County Community Action Partnership	PA	26,234
Lehigh County Conference of Churches	PA	203,542
Lehigh County Conference of Churches	PA	269,604
Lehigh County Conference of Churches	PA	168,716
Lehigh County Housing Authority	PA	217,920
Luzerne Intermediate Unit 18	PA	63,210
Maranatha	PA	261,796
Maranatha	PA	105,138
Maranatha	PA	177,234
Mechling-Shakley Veterans Center	PA	28,551
Mental Health Association of Southeastern Pennsylvania	PA	186,634
Mental Health Association of Southeastern Pennsylvania	PA	140,034
Mental Health Association of Southeastern Pennsylvania	PA	174,351
MERCER COUNTY HOUSING AUTHORITY	PA	81,780
Methodist Family Services of Philadelphia	PA	498,729
Methodist Family Services of Philadelphia	PA	250,354
Methodist Family Services of Philadelphia	PA	181,227
MidPenn Legal Services	PA	39,999
Montgomery County Community Action Development Commission (CADCOM)	PA	59,216
Montgomery County, PA, Dept. of BH/DD	PA	196,791
Montgomery County, PA, Dept. of BH/DD	PA	123,025
Montgomery County, PA, Dept. of BH/DD	PA	97,092
Montgomery County, PA, Dept. of BH/DD	PA	215,760
Montgomery County, PA, Dept. of BH/DD	PA	271,341
Neighborhood Services of Lancaster, inc	PA	360,689
Neighborhood Services of Lancaster, inc	PA	42,880
NHS Human Services of PA	PA	67,543
Northampton County Housing Authority	PA	105,408
Northern Cambria Community Development Corporation	PA	51,209
Northern Cambria Community Development Corporation	PA	63,414
Northern Cambria Community Development Corporation	PA	482,639
Northern Cambria Community Development Corporation	PA	131,843
Northern Cambria Community Development Corporation	PA	69,232
Northumberland County MH/MR	PA	78,131
Opportunity House	PA	42,827
Opportunity House	PA	84,000
Opportunity House	PA	30,654
Opportunity House	PA	58,997
Opportunity House	PA	102,504
overington house	PA	225,959
Penn Foundation, Inc	PA	66,272
Penndel Mental Health Center, Inc	PA	83,239
Penndel Mental Health Center, Inc	PA	72,904
People's Emergency Center	PA	78,995
People's Emergency Center	PA	496,362
People's Emergency Center	PA	241,082
People's Emergency Center	PA	34,815
People's Emergency Center	PA	14,584
People's Emergency Center	PA	103,670
People's Emergency Center	PA	369,810
People's Emergency Center	PA	53,384
People's Emergency Center	PA	98,188
Philadelphia Housing Authority	PA	70,920
Philadelphia Housing Authority	PA	255,312
Philadelphia Housing Authority	PA	42,552
Prince of Peace Center	PA	103,612
Project H.O.M.E	PA	773,964

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Project H.O.M.E	PA	124,922
Redevelopment Authority of the County of Lancaster	PA	68,977
Redevelopment Authority of the County of Lancaster	PA	50,307
Redevelopment Authority of the County of Lancaster	PA	116,154
Resources for Human Development, Inc	PA	486,335
Resources for Human Development, Inc	PA	225,435
Resources for Human Development, Inc	PA	166,378
Resources for Human Development, Inc	PA	326,308
Resources for Human Development, Inc	PA	257,887
Schuylkill Women in Crisis	PA	52,810
Schuylkill Women in Crisis	PA	33,328
Scranton Primary Health Care Center, Inc	PA	55,125
Shalom House	PA	78,938
St. Joseph's Center Mother Infant Program	PA	107,075
Supportive Services, Inc	PA	164,430
Supportive Services, Inc	PA	391,422
Supportive Services, Inc	PA	175,561
Tableland Services, Inc	PA	136,714
Tabor Community Services INC	PA	115,972
Tabor Community Services INC	PA	85,116
Tabor Community Services INC	PA	43,157
The Community Intervention Center of Lackawanna County	PA	101,500
The Community Intervention Center of Lackawanna County	PA	137,733
The Community Intervention Center of Lackawanna County	PA	154,166
THE DELTA COMMUNITY, INC	PA	84,067
The Housing Authority of the County of Beaver	PA	37,879
The Housing Authority of the County of Beaver	PA	204,822
The Lighthouse Foundation	PA	64,195
The Lighthouse Foundation	PA	39,274
The Lodge, Inc. of Pennsylvania	PA	258,061
The Lodge, Inc. of Pennsylvania	PA	161,860
The Philadelphia Veterans Multi-Service & Education Center	PA	301,698
THE PROGRAM for Women and Families, Inc	PA	110,408
The Salvation Army, a New York Corporation	PA	95,485
The Salvation Army, a New York Corporation	PA	183,193
The Salvation Army, a New York Corporation	PA	60,375
The Salvation Army, a New York Corporation	PA	203,440
The Salvation Army, a New York Corporation	PA	99,806
The Salvation Army, a New York Corporation	PA	159,570
The Salvation Army, a New York Corporation	PA	286,812
The Salvation Army, a New York Corporation	PA	207,198
The Salvation Army, a New York Corporation	PA	181,941
The Salvation Army, a New York Corporation	PA	278,869
The Salvation Army, a New York Corporation	PA	86,135
The Salvation Army, a New York Corporation	PA	70,024
Tioga County Housing Authority	PA	62,640
Travelers Aid Society of Philadelphia	PA	359,951
Travelers Aid Society of Philadelphia	PA	350,162
Travelers Aid Society of Philadelphia	PA	454,782
Travelers Aid Society of Philadelphia	PA	131,428
Travelers Aid Society of Philadelphia	PA	255,735
Turning Point Interfaith Mission	PA	113,111
Turning Point Interfaith Mission	PA	140,919
Turning Point Interfaith Mission	PA	204,154
Union-Snyder Community Action Agency	PA	113,506
United Christian Ministries	PA	90,403
United Christian Ministries	PA	87,959
United Neighborhood Centers of Northeastern Pennsylvania	PA	136,437
United Neighborhood Centers of Northeastern Pennsylvania	PA	59,556
United Neighborhood Centers of Northeastern Pennsylvania	PA	135,954
United Neighborhood Centers of Northeastern Pennsylvania	PA	216,269
United Neighborhood Centers of Northeastern Pennsylvania	PA	213,919
United Neighborhood Centers of Northeastern Pennsylvania	PA	169,913
Valley Housing Development Corporation	PA	215,964
Valley Housing Development Corporation	PA	120,626
Valley Housing Development Corporation	PA	131,770
Valley Youth House Committee, Inc	PA	468,880
Valley Youth House Committee, Inc	PA	236,273
Valley Youth House Committee, Inc	PA	371,604
Valley Youth House Committee, Inc	PA	497,322
Victim Outreach Intervention Center	PA	300,835
Victim Outreach Intervention Center	PA	87,178

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Volunteers of America	PA	291,572
Volunteers of America Delaware Valley Inc	PA	114,744
W.C. Atkinson Memorial Community Service Center, Inc	PA	15,925
Warren-Forest Counties Economic Opportunity Council	PA	61,675
Wesley House Community Corporation, Inc	PA	26,199
Westmoreland Community Action	PA	165,570
Westmoreland Community Action	PA	466,388
Westmoreland Community Action	PA	50,783
Westmoreland Community Action	PA	40,950
Women Against Abuse, Inc	PA	181,225
Women's Community Revitalization Project	PA	288,230
Women's Resource Center	PA	133,423
YMCA of Reading & Berks County	PA	98,568
YMCA of York and York County	PA	88,987
Young Women's Christian Association	PA	45,919
YWCA OF GREATER HARRISBURG	PA	58,729
YWCA OF GREATER HARRISBURG	PA	96,199
YWCA OF GREATER HARRISBURG	PA	78,071
YWCA of York	PA	148,050
YWCA/Liberty House	PA	227,244
Albergueelparaiso	PR	221,718
Albergueelparaiso	PR	283,970
Autonomous Municipality of Cidra	PR	243,129
Autonomous Municipality of Cidra	PR	80,136
Casa de Restauracion y Mas, Inc	PR	463,863
Casa de Restauracion y Mas, Inc	PR	139,933
CASA PROTEGIDA JULIA DE BURGOS, INC	PR	405,460
Centro Deambulantes Cristo Pobre, Inc	PR	188,188
Coalicion de Apoyo Continuo a Personas sin Hogar en San Juan	PR	100,000
Coalicion de Apoyo Continuo a Personas sin Hogar en San Juan	PR	516,705
Coalition of Guaynabo	PR	202,491
Coalition Pro-Homeless of the Eastern Area of Puerto Rico	PR	142,095
Corp. La Fondita de Jesus	PR	894,537
Corp. La Fondita de Jesus	PR	657,039
Corp. La Fondita de Jesus	PR	463,000
Corporacion Milagros del Amor	PR	201,122
Corporacion Milagros del Amor	PR	159,018
COSSMA, Inc	PR	148,137
COSSMA, Inc	PR	67,452
Estancia Corazon, Inc	PR	197,803
Estancia Corazon, Inc	PR	99,855
Estancia Corazon, Inc	PR	232,745
Estancia Corazon, Inc	PR	288,179
Fundacion de Desarrollo Comunal de P.R. Inc	PR	221,244
Fundacion de Desarrollo Comunal de P.R., Inc "FUNDESCO"	PR	135,477
FUNDESCO—HANDS FOR WORK	PR	154,795
Hogar del Buen Pastor, Inc	PR	111,630
Hogar del Buen Pastor, Inc	PR	237,609
Hogar Resurreccion, Inc	PR	207,650
INSTITUTO PRE-VOCACIONAL E INDUSTRIAL DE PUERTO RICO, INC	PR	149,964
Jayuya Municipality	PR	258,000
La Perla de Gran Precio	PR	118,738
La Perla de Gran Precio	PR	145,637
La Tierra Prometida, Inc	PR	267,578
Lucha Contra el SIDA, Inc	PR	77,086
Lucha Contra el SIDA, Inc	PR	180,963
Lucha Contra el SIDA, Inc	PR	575,880
MHAASA	PR	1,978,515
Municipality of Vega Alta	PR	91,276
Municipality of Aguas Buenas	PR	60,809
MUNICIPALITY OF AIBONITO	PR	291,564
Municipality of Coamo	PR	381,480
MUNICIPALITY OF ISABELA	PR	261,000
Municipality of San German	PR	81,144
Municipality of San Juan	PR	300,354
Municipality of San Juan	PR	298,510
Municipality of San Juan	PR	314,286
Municipality of San Juan	PR	474,120
Municipality of San Juan	PR	330,939
MUNICIPALITY OF VEGA BAJA	PR	153,417
MUNICIPALITY OF VEGA BAJA	PR	240,219
Municipio de Carolina	PR	308,569

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
MUNICIPIO DE HORMIGUEROS	PR	41,568
Municipio de Loiza	PR	77,160
Municipio de Naguabo	PR	63,180
MUNICIPIO DE NARANJITO	PR	88,816
PR Department of Housing	PR	599,400
PR Department of Housing	PR	486,360
Proyecto Amor Que Sana, Inc	PR	309,825
Proyecto Matria, Inc	PR	1,426,156
Shelter Plus Care Program Municipio de Cayey	PR	229,260
Silo Misión Cristiana, Inc	PR	203,761
Solo Por Hoy, Inc	PR	224,820
Family Resources Community Action	RI	32,428
newport county community mental health center	RI	8,204
Rhode Island Housing and Mortgage Finance Corporation	RI	178,087
Rhode Island Housing and Mortgage Finance Corporation	RI	95,250
Rhode Island Housing and Mortgage Finance Corporation	RI	637,951
Rhode Island Housing and Mortgage Finance Corporation	RI	1,059,852
Rhode Island Housing and Mortgage Finance Corporation	RI	26,517
Rhode Island Housing and Mortgage Finance Corporation	RI	11,248
Rhode Island Housing and Mortgage Finance Corporation	RI	37,474
Rhode Island Housing and Mortgage Finance Corporation	RI	23,605
Rhode Island Housing and Mortgage Finance Corporation	RI	149,797
Rhode Island Housing and Mortgage Finance Corporation	RI	232,131
Rhode Island Housing and Mortgage Finance Corporation	RI	47,482
Rhode Island Housing and Mortgage Finance Corporation	RI	63,813
Rhode Island Housing and Mortgage Finance Corporation	RI	253,752
Rhode Island Housing and Mortgage Finance Corporation	RI	161,879
Rhode Island Housing and Mortgage Finance Corporation	RI	32,800
Rhode Island Housing and Mortgage Finance Corporation	RI	82,625
Rhode Island Housing and Mortgage Finance Corporation	RI	190,474
Rhode Island Housing and Mortgage Finance Corporation	RI	90,029
Rhode Island Housing and Mortgage Finance Corporation	RI	64,692
Rhode Island Housing and Mortgage Finance Corporation	RI	57,424
Rhode Island Housing and Mortgage Finance Corporation	RI	126,393
Rhode Island Housing and Mortgage Finance Corporation	RI	55,000
Rhode Island Housing and Mortgage Finance Corporation	RI	32,340
Rhode Island Housing and Mortgage Finance Corporation	RI	107,716
Rhode Island Housing and Mortgage Finance Corporation	RI	120,220
Rhode Island Housing and Mortgage Finance Corporation	RI	22,880
Rhode Island Housing and Mortgage Finance Corporation	RI	88,334
Rhode Island Housing and Mortgage Finance Corporation	RI	67,916
Rhode Island Housing and Mortgage Finance Corporation	RI	26,705
Rhode Island Housing and Mortgage Finance Corporation	RI	60,897
Rhode Island Housing and Mortgage Finance Corporation	RI	117,959
Rhode Island Housing and Mortgage Finance Corporation	RI	32,456
Rhode Island Housing and Mortgage Finance Corporation	RI	24,712
Rhode Island Housing and Mortgage Finance Corporation	RI	17,864
Rhode Island Housing and Mortgage Finance Corporation	RI	71,332
Rhode Island Housing and Mortgage Finance Corporation	RI	93,779
Rhode Island Housing and Mortgage Finance Corporation	RI	166,666
Rhode Island Housing and Mortgage Finance Corporation	RI	30,924
Rhode Island Housing and Mortgage Finance Corporation	RI	78,000
Rhode Island Housing and Mortgage Finance Corporation	RI	45,299
Rhode Island Housing and Mortgage Finance Corporation	RI	125,517
Rhode Island Housing and Mortgage Finance Corporation	RI	639,684
Rhode Island Housing and Mortgage Finance Corporation	RI	129,639
The Providence Center	RI	41,133
Washington Square Services Corporation	RI	103,217
Any Length Recovery	SC	78,746
Charleston County Human Services Commission	SC	75,913
Crisis Ministries	SC	71,598
Crisis Ministries	SC	77,752
Crisis Ministries	SC	442,143
Crisis Ministries	SC	50,000
Crisis Ministries	SC	113,506
Crisis Ministries	SC	101,136
Crisis Ministries	SC	73,336
Eastern Carolina Homelessness Organization	SC	126,360
Family Services Inc	SC	143,072
Florence Crittenton Programs of South Carolina	SC	49,946
Greenville Area Interfaith Hospitality Network	SC	21,775
Growing Home Southeast	SC	26,250

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Healing Properties, Inc	SC	79,046
Home Alliance Inc	SC	98,650
Home Alliance Inc	SC	23,332
Home Alliance Inc	SC	40,000
Home Alliance Inc	SC	68,606
Homes of Hope, Inc	SC	55,866
MEG's House Shelter for Abused Women and Children	SC	159,563
MEG's House Shelter for Abused Women and Children	SC	160,089
MEG's House Shelter for Abused Women and Children	SC	223,358
Mental Health America of Aiken County	SC	120,398
Myrtle Beach Housing Authority	SC	215,064
Pee Dee Community Actions Agency—TH	SC	179,098
Pee Dee Community Actions Agency (Dillon)	SC	46,552
Pee Dee Community Actions Agency (Dillon)	SC	154,478
Project Care, Inc	SC	327,233
Richland County	SC	40,000
Richland County	SC	80,544
Sistercare Inc	SC	279,410
South Carolina Department of Mental Health	SC	218,640
South Carolina Department of Mental Health	SC	69,168
South Carolina Department of Mental Health	SC	229,080
South Carolina Department of Mental Health	SC	487,500
South Carolina Department of Mental Health	SC	235,632
Street Reach Ministries	SC	117,921
Sunbelt Human Advancement Resources, Inc (SHARE)	SC	721,300
The ACCESS Network, Inc	SC	202,585
The ACCESS Network, Inc	SC	52,090
The ACCESS Network, Inc	SC	100,076
The Butterfly Foundation	SC	159,564
The Butterfly Foundation	SC	327,271
The Housing Authority of the City of Columbia, SC	SC	208,656
The Housing Authority of the City of Columbia, SC	SC	68,996
The Housing Authority of the City of Columbia, SC	SC	144,825
The Housing Authority of the City of Columbia, SC	SC	338,612
The Samaritan House of Orangeburg, Inc	SC	101,812
Trinity Housing Corporation	SC	80,316
United Way of Kershaw County	SC	83,100
Upstate Homeless Coalition of South Carolina	SC	158,818
Upstate Homeless Coalition of South Carolina	SC	110,000
Upstate Homeless Coalition of South Carolina	SC	133,875
Upstate Homeless Coalition of South Carolina	SC	642,151
Upstate Homeless Coalition of South Carolina	SC	184,305
Upstate Homeless Coalition of South Carolina	SC	160,164
Wateree Community Actions, Inc	SC	122,550
Williamsburg Enterprise Community Commission	SC	128,041
Behavior Management Systems	SD	67,248
Cornerstone Rescue Mission	SD	73,704
Lewis & Clark Behavioral Health Services, Inc	SD	126,978
Lutheran Social Services of South Dakota	SD	102,381
Lutheran Social Services of South Dakota	SD	87,836
Pennington County Housing and Redevelopment Commission	SD	160,560
SD HMIS 2011	SD	40,443
Sioux Falls Housing & Redevelopment Commission	SD	278,940
Sioux Falls Housing & Redevelopment Commission	SD	149,700
South Dakota Statewide CoC	SD	162,277
South Dakota Statewide CoC	SD	319,373
Volunteers of America, Dakotas	SD	62,172
AGAPE Child & Family Services, Inc	TN	245,477
AGAPE Child & Family Services, Inc	TN	193,040
Alpha Omega Veterans Services, Inc	TN	93,424
Alpha Omega Veterans Services, Inc	TN	165,900
Alpha Omega Veterans Services, Inc	TN	142,158
Alpha Omega Veterans Services, Inc	TN	106,888
Aphesis House	TN	61,389
Appalachian Regional coalition on Homelessness	TN	112,578
ASafeHarborHome, Inc	TN	85,646
Beech Bluff United Pentecostal Church	TN	72,775
Behavioral Health Initiatives, Inc	TN	78,750
Buffalo Valley, Inc	TN	71,375
Buffalo Valley, Inc	TN	49,575
Buffalo Valley, Inc	TN	72,836
Buffalo Valley, Inc	TN	73,047

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Buffalo Valley, Inc	TN	445,651
Buffalo Valley, Inc	TN	444,151
Buffalo Valley, Inc	TN	131,539
Buffalo Valley, Inc	TN	228,444
Buffalo Valley, Inc	TN	24,850
Campus for Human Development	TN	31,500
Campus for Human Development	TN	132,370
Carey Counseling Center, Inc	TN	61,595
Carey Counseling Center, Inc	TN	17,150
Carey Counseling Center, Inc	TN	25,107
Case Management Inc	TN	13,537
Case Management Inc	TN	87,173
Catholic Charities	TN	135,899
Catholic Charities of East Tennessee, Inc	TN	116,698
Catholic Charities of East TN	TN	84,180
Catholic Charities, Inc	TN	490,963
Catholic Charities, Inc	TN	454,894
Catholic Charities, Inc	TN	296,565
Chattanooga Church Ministries, Inc	TN	94,827
Chattanooga Church Ministries, Inc	TN	105,874
Chattanooga Church Ministries, Inc	TN	90,873
Chattanooga Homeless Coalition	TN	93,000
Chattanooga Homeless Coalition	TN	100,558
Chattanooga Homeless Coalition	TN	34,240
Chattanooga Housing Authority	TN	218,556
Chattanooga Room in the Inn	TN	45,648
Child & Family Tennessee	TN	268,697
City of Chattanooga	TN	176,520
City of Chattanooga	TN	31,980
City of Clarksville	TN	105,660
City of Memphis, Tennessee	TN	300,960
City of Memphis, Tennessee	TN	185,760
City of Memphis, Tennessee	TN	124,704
Cocaine & Alcohol Awareness Program, Inc	TN	168,748
Community Alliance for the Homeless	TN	100,170
Community Alliance for the Homeless	TN	37,572
Community Alliance for the Homeless	TN	46,514
Community Health of East Tennessee	TN	184,281
Comprehensive Counseling Network	TN	217,500
Cumberland Regional Development Corp.	TN	88,338
Cumberland Regional Development Corp.	TN	57,580
Damascus Road, Inc	TN	36,408
Damascus Road, Inc	TN	65,352
Damascus Road, Inc	TN	36,426
Damascus Road, Inc	TN	49,257
Domestic Violence Program Inc	TN	12,423
Domestic Violence Program Inc	TN	30,766
Door of Hope, Inc	TN	158,237
Fairview Housing Management Corp	TN	117,759
Fayette Cares, Inc	TN	38,369
Fortwood Center, Inc	TN	79,852
GAP Community Development Resources, Inc	TN	134,637
Genesis House, Inc	TN	64,161
Greenhouse Ministries	TN	39,183
Hardeman County Government	TN	50,832
Hardin County Government	TN	104,700
Helen Ross McNabb Center	TN	61,209
Henry County, Tennessee	TN	281,424
Homeless Law Project	TN	22,011
Hope House Maury County Center Against Domestic Violence	TN	74,212
HOPE Ministries	TN	31,091
Housing Opportunities and People Enterprises, Inc	TN	19,202
Interfaith Hospitality Network of Greater Johnson City	TN	81,608
Jackson Area Council on Alcoholism and Drug Dependency	TN	63,408
Jackson Housing Authority	TN	116,688
Kingsport Housing & Redevelopment Authority	TN	42,732
Kingsport Housing & Redevelopment Authority	TN	503,880
Kingsport Housing & Redevelopment Authority	TN	41,004
Kingsport Housing & Redevelopment Authority	TN	41,613
Kingsport Housing & Redevelopment Authority	TN	65,761
Knoxville HMIS	TN	132,282
Knoxville-Knox County Community Action Committee	TN	104,580

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Knoxville-Knox County Community Action Committee	TN	139,050
Knoxville-Knox County Community Action Committee	TN	90,096
Legal Aid of East TN	TN	16,870
Life of Victory International Christian Ministries	TN	26,304
Marshall County	TN	16,416
Matthew 25	TN	37,041
Memphis Family Shelter	TN	197,886
Mending Hearts	TN	40,008
Metropolitan Development & Housing Agency	TN	1,570,152
Metropolitan Development & Housing Agency	TN	58,161
Metropolitan Development & Housing Agency	TN	54,852
Metropolitan Development & Housing Agency	TN	41,508
Metropolitan Development & Housing Agency	TN	76,404
Metropolitan Inter-Faith Association	TN	497,674
Metropolitan Inter-Faith Association	TN	145,621
Morristown/Tennessee Valley CoC	TN	71,384
Morristown/Tennessee Valley CoC	TN	99,300
Morristown/Tennessee Valley CoC	TN	197,748
Murfreesboro Housing Authority	TN	15,718
Murfreesboro Housing Authority	TN	333,816
Murfreesboro Housing Authority	TN	27,360
North Memphis Community Development Corporation	TN	446,653
Operation Stand Down Nashville, Inc	TN	50,000
Park Center	TN	124,080
Partnership for Families, Children and Adults	TN	27,978
Positively Living	TN	70,204
Professional Care Services, Inc	TN	9,000
Pump Springs Baptist Church	TN	186,614
Quinco Community Mental Health Centers	TN	68,595
Renewal House, Inc	TN	60,443
Robertson County	TN	30,372
Safe Haven Family Shelter	TN	148,118
Safe Haven Family Shelter	TN	56,910
Second Chance Ministry	TN	18,637
Shelby County Government	TN	228,782
SOUTHEAST TENNESSEE HUMAN RESOURCE AGENCY	TN	286,452
SOUTHEAST TENNESSEE HUMAN RESOURCE AGENCY	TN	549,435
SOUTHEAST TENNESSEE HUMAN RESOURCE AGENCY	TN	213,120
T.A.M.B. of Jackson, Inc	TN	29,172
T.A.M.B. of Jackson, Inc	TN	39,549
Tennessee Homeless Solutions	TN	45,017
Tennessee Homeless Solutions	TN	55,956
The Council for Alcohol and Drug Abuse Services, Inc	TN	211,254
The Journey Home	TN	7,798
The Journey Home	TN	48,301
The Mary Parrish Center	TN	34,330
The Next Door, Inc	TN	117,400
The Salvation Army	TN	229,565
The Salvation Army	TN	207,648
The Salvation Army	TN	385,192
The Salvation Army, a Georgia Corporation	TN	70,099
Town of Crossville Housing Authority	TN	29,340
Town of Crossville Housing Authority	TN	88,716
Town of Crossville Housing Authority	TN	221,520
Town of Crossville Housing Authority	TN	68,472
Town of Crossville Housing Authority	TN	72,960
Urban Housing Solutions	TN	262,784
Urban Housing Solutions	TN	119,000
Urban Housing Solutions	TN	229,830
Volunteer Behavioral Health Care System	TN	80,000
Volunteer Ministry Center	TN	50,000
Welcome Home Ministries	TN	47,951
Wo/Men's Resource and Rape Assistance Program	TN	72,976
YWCA of Nashville and Middle Tennessee	TN	173,769
Abilene Hope Haven, Inc	TX	68,013
ACH Child and Family Services	TX	113,922
AIDS Foundation Houston, Inc	TX	409,192
AIDS Foundation Houston, Inc	TX	519,072
AIDS Foundation Houston, Inc	TX	963,357
AIDS Foundation Houston, Inc	TX	613,230
AIDS Foundation Houston, Inc	TX	396,314
AIDS Services of Dallas	TX	574,389

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Alamo Area Resource	TX	222,062
Alternative Building Concepts Group	TX	56,883
Alternative Building Concepts Group	TX	384,720
Arlington Life Shelter	TX	83,686
Arlington Life Shelter	TX	63,471
Austin Travis County MHMR Center	TX	28,893
Austin Travis County MHMR Center	TX	40,000
Austin Travis County MHMR Center	TX	78,533
Austin Travis County MHMR Center	TX	348,007
Bay Area Homeless Services	TX	234,005
Bay Area Turning Point, Inc	TX	107,210
Brighter Tomorrows	TX	176,876
Bryan/College Station/Brazos Valley TCM	TX	32,332
Bryan/College Station/Brazos Valley TCM	TX	61,363
Bryan/College Station/Brazos Valley TCM	TX	165,991
Buckner Children and Family Services, Inc	TX	35,016
Career and Recovery Resources, Inc	TX	117,110
Caritas of Austin	TX	196,492
Caritas of Austin	TX	303,712
Caritas of Austin	TX	414,451
Caritas of Austin	TX	198,885
Catholic Charities of the Archdiocese Galveston-Houston	TX	183,655
Center Against Family Violence	TX	82,929
Central Texas Youth Services Bureau	TX	84,728
Centro San Vicente	TX	139,998
Change HAPPENS!	TX	88,293
Change HAPPENS!	TX	120,750
City of Amarillo	TX	206,564
City of Amarillo	TX	356,676
City of Beaumont	TX	123,972
City of Corpus Christi Project	TX	181,142
City of Corpus Christi Project	TX	122,673
City of Corpus Christi Project	TX	160,255
City of Corpus Christi Project	TX	134,971
City of Corpus Christi Project	TX	142,720
City of Corpus Christi Project	TX	142,569
City of Corpus Christi Project	TX	128,394
CITY OF DALLAS	TX	154,027
CITY OF DALLAS	TX	86,280
CITY OF DALLAS	TX	257,606
CITY OF DALLAS	TX	458,760
CITY OF DALLAS	TX	880,680
CITY OF DALLAS	TX	374,016
CITY OF DALLAS	TX	701,906
City of Longview	TX	287,112
City of Waco	TX	29,088
City of Waco	TX	89,040
City of Waco	TX	63,709
CitySquare (formerly Central Dallas Ministries)	TX	504,983
CitySquare (formerly Central Dallas Ministries)	TX	610,110
CitySquare (formerly Central Dallas Ministries)	TX	185,117
Coalition for the Homeless of Houston/Harris County	TX	167,709
Coalition for the Homeless of Houston/Harris County	TX	185,480
Collin County Mental Health Mental Retardation Center	TX	169,445
Community Enrichment Center, Inc	TX	222,846
Community Partnership for the Homeless DBA Green Doors	TX	65,985
Compassion Ministries of Waco, Inc	TX	161,275
Cross Culture Experiences	TX	181,996
Dallas County	TX	242,532
Dallas Housing Authority	TX	146,676
Dental Healh Programs, Inc dba Community Dental Care	TX	146,632
Denton County Mental Health Mental Retardation Center	TX	264,318
El Paso Coalition for the Homeless	TX	107,902
El Paso Coalition for the Homeless	TX	26,250
El Paso MHMR	TX	176,761
El Paso MHMR	TX	203,982
Families In Crisis, Inc	TX	923,202
Family Abuse Center, Inc	TX	81,656
Family Gateway, Inc	TX	198,018
Family Gateway, Inc	TX	150,701
Family Gateway, Inc	TX	42,438
Family Services of Southeast Texas, Inc	TX	150,977

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Fort Bend County Women's Center	TX	668,360
Fort Bend County Women's Center	TX	394,932
Front Steps	TX	94,668
Front Steps	TX	60,174
Front Steps	TX	198,885
Grayson County Juvenile Alternatives, Inc dba North Texas Youth Connection	TX	675,865
Harmony House, Inc	TX	133,571
Harmony House, Inc	TX	358,470
Harmony House, Inc	TX	315,443
Harris County Community Services Department	TX	2,401,080
Harris County Community Services Department	TX	593,352
Harris County Community Services Department	TX	750,240
Harris County Community Services Department	TX	125,040
Harris County Community Services Department	TX	37,056
Harris County Community Services Department	TX	473,172
Harris County Community Services Department	TX	187,380
Harris County Community Services Department	TX	293,460
Harris County Community Services Department	TX	83,376
Harvest Life Foundation	TX	196,407
Health Services of North Texas, Inc	TX	243,812
HELP Development Corporation	TX	439,456
Homeward bound Homeless Coalition	TX	612,831
Homeward bound Homeless Coalition	TX	91,925
HOPE, Inc	TX	67,333
HOPE, Inc	TX	33,873
Hopes Door	TX	161,710
Hopes Door	TX	69,345
Housing Authority of the City of Arlington	TX	154,692
Housing Authority of the City of Arlington	TX	54,744
Housing Authority of the City of Arlington	TX	262,378
Housing Authority of the City of Austin	TX	183,888
Housing Authority of the City of Austin	TX	370,776
Housing Authority of the City of El Paso	TX	100,620
Housing Authority of the City of Fort Worth	TX	1,946,352
Housing Authority of the City of Fort Worth	TX	2,237,604
Housing Authority of the City of Fort Worth	TX	76,572
Housing Authority of Travis County	TX	561,996
Housing Authority of Travis County	TX	203,376
Housing Crisis Center	TX	532,944
Housing Crisis Center	TX	194,271
Housing Crisis Center	TX	106,200
Housing Crisis Center	TX	334,321
Housing Crisis Center	TX	188,196
Houston Area Community Services, Inc	TX	985,654
Houston Area Community Services, Inc	TX	665,647
Houston Area Community Services, Inc	TX	1,400,076
Houston Area Community Services, Inc	TX	646,747
Houston Area Women's Center	TX	79,194
Houston Area Women's Center	TX	291,402
Houston Area Women's Center	TX	610,858
Interfaith Housing Coalition	TX	348,885
International AIDS Empowerment	TX	43,898
Irving, Texas	TX	98,484
La Posada Home, Inc	TX	89,026
La Posada Home, Inc	TX	53,544
Legal Aid of NorthWest Texas	TX	142,932
Legal Aid of NorthWest Texas	TX	53,941
LifeNet Community Behavioral Healthcare	TX	1,318,381
Mental Health and Mental Retardation Authority of Harris County	TX	350,446
Mental Heath and Mental Retardation of Tarrant County	TX	295,780
Metro Dallas Homeless Alliance	TX	169,395
Metrocare Services	TX	280,240
Metrocare Services	TX	413,004
Metrocare Services	TX	792,229
MHMR of Tarrant County—Addiction Services	TX	67,435
Mid-Coast Family Services	TX	164,345
Montgomery County Emergency Assistance	TX	27,331
Montgomery County Emergency Assistance	TX	101,753
Montgomery County Homeless Coalition	TX	47,050
Montrose Counseling Center, Inc	TX	105,259
Neighborhood Development Corp	TX	148,604
New Beginning Center	TX	192,928

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Nexus Recovery Center, Inc	TX	853,102
Northwest Assistance Ministries	TX	501,892
Northwest Assistance Ministries	TX	300,730
Opportunity Center for the Homeless	TX	161,091
Opportunity Center for the Homeless	TX	171,919
Opportunity Center for the Homeless	TX	78,721
Opportunity Center for the Homeless	TX	132,870
Opportunity Center for the Homeless	TX	115,135
Opportunity Center for the Homeless	TX	108,551
Opportunity Center for the Homeless	TX	250,734
Perpetual Help Home	TX	33,111
Perpetual Help Home	TX	92,983
Port Cities Rescue Mission Ministries	TX	175,037
Presbyterian Night Shelter	TX	225,040
Presbyterian Night Shelter	TX	181,077
Presbyterian Night Shelter	TX	712,008
Promise House Inc	TX	269,737
Promise House Inc	TX	220,986
Rainbow Days, Inc	TX	257,237
Recovery Resource Council	TX	234,831
Recovery Resource Council	TX	169,404
Rescue Mission of El Paso, Inc	TX	46,895
Sabine Valley Center	TX	124,226
Sabine Valley Center	TX	123,480
San Antonio Housing Authority	TX	639,168
San Antonio Metropolitan Ministries Inc	TX	583,218
San Antonio Metropolitan Ministries Inc	TX	358,268
San Antonio Metropolitan Ministries Inc	TX	104,596
San Antonio/Bexar County Projects	TX	216,048
San Antonio/Bexar County Projects	TX	392,021
San Antonio/Bexar County Projects	TX	194,864
San Antonio/Bexar County Projects	TX	268,738
San Antonio/Bexar County Projects	TX	387,273
San Antonio/Bexar County Projects	TX	429,597
San Antonio/Bexar County Projects	TX	136,335
San Antonio/Bexar County Projects	TX	79,199
San Antonio/Bexar County Projects	TX	364,296
San Antonio/Bexar County Projects	TX	93,954
San Antonio/Bexar County Projects	TX	244,566
San Antonio/Bexar County Projects	TX	614,811
San Antonio/Bexar County Projects	TX	138,909
San Antonio/Bexar County Projects	TX	171,729
San Antonio/Bexar County Projects	TX	210,000
San Antonio/Bexar County Projects	TX	352,562
San Antonio/Bexar County Projects	TX	385,718
San Antonio/Bexar County Projects	TX	25,211
San Antonio/Bexar County Projects	TX	91,974
San Antonio/Bexar County Projects	TX	131,250
Santa Maria Hostel, Inc	TX	487,280
SEARCH	TX	96,520
SEARCH	TX	330,673
Shared Housing Center	TX	93,390
Shared Housing Center	TX	530,239
Shelter Agencies For Families in East Texas, Inc	TX	480,924
Some Other Place, Inc	TX	111,888
Southeast Texas Regional Planning Commission	TX	23,008
Southern Territorial Headquarters of The Salvation Army, The	TX	1,000,000
Southern Territorial Headquarters of The Salvation Army, The	TX	349,188
Star of Hope Mission	TX	1,041,806
Star of Hope Mission	TX	207,406
Stop Turning Entering Prison Inc	TX	174,888
Stragent Foundation	TX	153,962
Tarrant County	TX	21,815
Tarrant County	TX	322,293
Tarrant County	TX	145,435
Tarrant County	TX	24,237
Tarrant County	TX	166,404
Tarrant County	TX	97,293
Tarrant County	TX	50,680
Tarrant County	TX	103,445
Tarrant County	TX	1,063,427
Tarrant County	TX	212,663

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Tarrant County	TX	356,805
Tarrant County	TX	106,864
Tarrant County	TX	85,617
Tarrant County	TX	108,491
Tarrant County	TX	124,665
Tarrant County	TX	340,320
Tarrant County Homeless Coalition	TX	276,849
Temenos Community Development Center	TX	633,666
Texas ReEntry Services	TX	104,482
Texas RioGrande Legal Aid, Inc	TX	124,908
The Bridge Over Troubled Waters, Inc	TX	932,248
The Children's Center, Inc	TX	160,000
The Children's Center, Inc	TX	85,285
The Children's Center, Inc	TX	192,237
The Family Place	TX	981,236
The Gulf Coast Center	TX	216,499
The Gulf Coast Center	TX	120,271
The Gulf Coast Center	TX	525,537
The Gulf Coast Center	TX	60,942
The Salvation Army—Galveston	TX	457,676
The Salvation Army—Galveston	TX	276,595
The Salvation Army a Georgia Corporation	TX	390,671
The Salvation Army, a Georgia Corporation	TX	137,777
The Salvation Army, A Georgia Corporation	TX	538,081
The Women's Home	TX	126,717
Travis County Domestic Violence and Sexual Assault Survival Center, d/b/a SafePlace	TX	613,002
United States Veterans Initiative	TX	489,977
United States Veterans Initiative	TX	110,441
Vogel Alcove	TX	166,441
Volunteers of America Texas, Inc	TX	212,069
Wellsprings Village, Inc	TX	77,293
Wheeler Avenue 5 C's	TX	160,656
Williamson-Burnet County Opportunities, Inc	TX	284,382
Women Opting for More Affordable Housing Now, Inc (WOMAN, Inc.)	TX	104,168
Youth and Family Alliance dba LifeWorks	TX	212,969
YWCA El Paso Del Norte Region	TX	229,728
YWCA El Paso Del Norte Region	TX	270,616
Bear River Association of Governments	UT	49,564
Catholic Community Services of Utah	UT	91,787
Cedar City Housing Authority	UT	13,912
Center for Women and Children in Crisis	UT	16,252
Center for Women and Children in Crisis	UT	51,692
Community Action Services	UT	228,653
Community Action Services	UT	34,926
Davis Behavioral Health	UT	104,036
DCCAV-Safe Harbor Transitional Housing	UT	61,075
Family Connection Center	UT	171,149
Family Support Center	UT	32,844
Family Support Center	UT	67,698
Family Support Center	UT	13,003
Four Corners Community Behavioral Health, Inc	UT	134,191
Golden Spike Rehab	UT	35,056
Housing Authority of Salt Lake City	UT	37,152
Housing Authority of Salt Lake City	UT	342,576
Housing Authority of Salt Lake City	UT	169,920
Housing Authority of the County of Salt Lake	UT	127,008
Housing Authority of the County of Salt Lake	UT	77,040
Housing Authority of the County of Salt Lake	UT	772,728
Housing Authority of the County of Salt Lake	UT	212,760
Housing Authority of Utah County	UT	14,040
Housing Authority of Utah County	UT	262,656
Housing Authority of Utah County	UT	14,040
Iron County Care and Share	UT	35,071
Mountainlands Community Housing Trust	UT	124,913
Ogden Housing Authority	UT	184,920
Papilion House, Inc	UT	35,056
Papilion House, Inc	UT	18,313
Provo City Housing Authority	UT	21,379
Provo City Housing Authority	UT	252,720
Salt Lake County Continuum of Care	UT	95,104
Salt Lake County Continuum of Care	UT	128,047
Southwest Behavioral Health Center	UT	27,182

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Southwest Behavioral Health Center	UT	146,638
The Erin Kimball Memorial Foundation, Inc	UT	75,091
The Road Home	UT	394,940
The Road Home	UT	15,000
The Road Home	UT	603,628
The Road Home	UT	555,506
The Road Home	UT	111,209
The Road Home	UT	25,495
The Road Home	UT	36,850
Utah Department of Community and Culture	UT	28,464
Utah Department of Community and Culture	UT	44,181
Utah Department of Community and Culture	UT	29,899
Utah Department of Community and Culture	UT	25,675
Utah Department of Community and Culture	UT	33,043
Utah Department of Community and Culture	UT	156,389
Utah Department of Community and Culture	UT	50,741
Valley Mental Health, Inc	UT	52,545
Volunteers of America, Utah	UT	99,750
Volunteers of America, Utah	UT	106,753
Volunteers of America, Utah	UT	155,774
Volunteers of America, Utah	UT	118,696
West Valley City Housing Authority	UT	192,600
Young Womens Christian Assn of Salt Lake City	UT	155,989
Your Community Connection	UT	67,023
AIDS Services Group	VA	60,004
Alexandria Community Services Board	VA	54,608
Alexandria Community Services Board	VA	131,643
Alexandria Community Services Board	VA	29,812
Alexandria Community Services Board	VA	98,150
Arlington Alexandria Coalition for the Homeless	VA	222,324
Arlington County Government	VA	102,963
Arlington County Government	VA	341,064
Arlington Street People's Assistance Network, INC	VA	166,058
Arlington Street People's Assistance Network, INC	VA	93,294
Arlington Street People's Assistance Network, INC	VA	211,446
Arlington Street People's Assistance Network, INC	VA	45,375
Arlington-Alexandria Coalition for the Homeless	VA	143,238
Avalon: A Center for Women and Children	VA	64,454
Barrett Haven Inc	VA	144,913
CANDII, Inc	VA	128,694
CANDII, Inc	VA	272,097
CANDII, Inc	VA	348,123
Chesapeake Community Services Board	VA	12,768
Christian Relief Services Charities, Inc	VA	120,676
Christian Relief Services Charities, Inc	VA	135,673
Christian Relief Services Charities, Inc	VA	80,713
Christian Relief Services Charities, Inc	VA	76,220
Christian Relief Services of Virginia, Inc	VA	216,780
Christian Relief Services of Virginia, Inc	VA	291,788
City of Lynchburg	VA	81,288
City of Portsmouth, Department of Behavioral Healthcare Services	VA	457,188
City of Portsmouth, Department of Behavioral Healthcare Services	VA	69,013
City of Richmond Department of Social Services	VA	60,480
City of Richmond, Department of Social Services	VA	964,092
Community Alternatives Management Group	VA	111,014
Community Alternatives Management Group	VA	366,954
Community Alternatives Management Group	VA	79,049
Council of Community Services	VA	17,457
Council of Community Services	VA	80,232
County of Loudoun	VA	64,386
County of Loudoun	VA	106,429
Danville Redevelopment and Housing Authority	VA	67,200
DHCD-BOS	VA	26,250
DHCD-BOS	VA	60,855
Emergency Shelter, Inc	VA	544,806
Emergency Shelter, Inc	VA	99,960
Emergency Shelter, Inc	VA	199,500
FACETS	VA	152,945
Fairfax County Department of Family Services	VA	453,346
Fairfax County Department of Family Services	VA	431,580
Fairfax County Department of Housing and Community Development	VA	241,176
Fairfax County Department of Housing and Community Development	VA	527,040

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Fairfax County Department of Housing and Community Development	VA	472,824
Fairfax County Department of Housing and Community Development	VA	341,064
Fairfax-Falls Church Community Services Board	VA	254,652
ForKids, inc	VA	103,804
ForKids, inc	VA	367,081
ForKids, inc	VA	192,050
ForKids, inc	VA	125,708
George Washington Regional Commission	VA	59,305
Hampton-Newport News Community Services Board	VA	119,422
Hampton-Newport News Community Services Board	VA	57,446
Hampton-Newport News Community Services Board	VA	287,796
Harrisonburg/Rockingham County 2011 CoC	VA	42,000
Helping Overcome Poverty's Existence, Inc	VA	83,818
Hilliard House	VA	262,917
Homestretch Inc	VA	150,727
Homeward	VA	26,745
Homeward	VA	15,802
Homeward	VA	22,819
Judeo-Christian Outreach Center	VA	56,247
Kurdish Human Rights Watch, Inc. (KHRW)	VA	438,973
LINK of Hampton Roads, Inc	VA	256,582
LINK of Hampton Roads, Inc	VA	80,359
LINK of Hampton Roads, Inc	VA	323,934
Lynchburg Community Action Group, Inc	VA	44,665
Lynchburg Neighborhood Development Foundation	VA	64,748
Micah Ecumenical Ministries	VA	31,632
Micah Ecumenical Ministries	VA	27,848
Miriam's House, Inc	VA	21,357
Miriam's House, Inc	VA	87,252
New Hope Housing, Inc	VA	221,122
New Hope Housing, Inc	VA	245,541
New Hope Housing, Inc	VA	58,850
New Hope Housing, Inc	VA	24,040
New Hope Housing, Inc	VA	121,850
New Hope Housing, Inc	VA	45,301
Newport News Redevelopment and Housing Authority	VA	102,144
Norfolk Community Services Board	VA	613,848
Norfolk Community Services Board	VA	130,641
Northwestern Community Services	VA	61,299
Northwestern Community Services	VA	259,824
NOVACO Inc	VA	111,492
OasisCommission of Social Ministryof Portsmouth/Chesapeake	VA	250,069
Our House Families	VA	109,798
Pathway Homes, Inc	VA	153,386
Pathway Homes, Inc	VA	314,906
Pathway Homes, Inc	VA	157,788
Pathway Homes, Inc	VA	153,657
People Incorporated of Virginia	VA	24,751
Portsmouth Area Resources Coalition, Inc	VA	53,550
Portsmouth Area Resources Coalition, Inc	VA	122,421
Portsmouth Area Resources Coalition, Inc	VA	45,123
Portsmouth Area Resources Coalition, Inc	VA	104,832
Portsmouth Christian Outreach Ministries	VA	79,309
Portsmouth Volunteers for the Homeless	VA	55,650
Prince William County CoC	VA	91,900
Prince William County CoC	VA	36,230
Prince William County CoC	VA	126,463
Prince William County CoC	VA	141,156
Prince William County CoC	VA	143,585
Prince William County CoC	VA	134,032
Prince William County CoC	VA	7,094
PRS, Inc	VA	168,450
Rappahannock Refuge, Inc. T/A Hope House	VA	57,918
Region Ten CSB	VA	135,720
Region Ten CSB	VA	146,160
Roanoke City/Salem Continuum of Care	VA	177,924
Roanoke City/Salem Continuum of Care	VA	137,669
Rush Lifetime Homes, Inc	VA	51,100
Saint Columba Ecumenical Ministries	VA	130,179
Samaritan House	VA	36,887
Samaritan House	VA	109,848
Sheltered Homes of Alexandria	VA	89,288

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Sheltered Homes of Alexandria	VA	77,748
South River Development Corporation	VA	39,933
St. Joseph's Villa	VA	272,000
The Daily Planet, Inc	VA	90,300
The Daily Planet, Inc	VA	208,171
The Planning Council	VA	54,090
The Planning Council	VA	50,533
The Salvation Army, a Georgia Corporation	VA	94,505
The Salvation Army, Tidewater Area Command	VA	55,207
The Salvation Army, Tidewater Area Command	VA	282,604
Thurman Brisben Homeless Shelter, Inc	VA	36,804
Total Action Against Poverty	VA	264,316
Total Action Against Poverty	VA	26,074
Transitions Family Violence Services	VA	137,852
Trust House	VA	56,551
United Community Ministries, Inc	VA	138,216
Urban League of Greater Richmond	VA	70,350
Virginia Beach Community Development Corporation	VA	4,620
Virginia Beach Community Development Corporation	VA	75,084
Virginia Beach Community Development Corporation	VA	371,406
Virginia Supportive Housing	VA	316,763
Virginia Supportive Housing	VA	276,180
Virginia Supportive Housing	VA	330,739
Virginia Supportive Housing	VA	48,466
Virginia Supportive Housing	VA	39,860
Virginia Supportive Housing	VA	94,470
Virginia Supportive Housing	VA	67,007
Virginia Supportive Housing	VA	322,022
Virginia Supportive Housing	VA	25,000
Virginia Supportive Housing	VA	69,237
Waynesboro Redevelopment and Housing Authority	VA	40,054
Winchester/Shenandoah, Frederick, Warren Counties Project Applicant	VA	59,201
YWCA of South Hampton Roads	VA	38,516
YWCA of South Hampton Roads	VA	96,882
Methodist Training & Outreach Center, Inc	VI	168,352
Addison County Community Action Group	VT	145,045
Brattleboro Housing Authority	VT	199,728
Burlington Housing Authority	VT	72,132
Burlington Housing Authority	VT	72,132
Burlington Housing Authority	VT	109,260
Burlington Housing Authority	VT	76,536
Champlain Valley Office of Economic Opportunity	VT	222,440
HowardCenter	VT	181,146
HowardCenter	VT	200,402
Vermont State Housing Authority	VT	55,939
Vermont State Housing Authority	VT	71,642
Vermont State Housing Authority	VT	69,904
Vermont State Housing Authority	VT	126,720
Vermont State Housing Authority	VT	55,524
Vermont State Housing Authority	VT	38,535
Vermont State Housing Authority	VT	148,815
Vermont State Housing Authority	VT	30,000
Vermont State Housing Authority	VT	62,733
Vermont State Housing Authority	VT	37,247
Vermont State Housing Authority	VT	90,455
Vermont State Housing Authority	VT	122,136
Vermont State Housing Authority	VT	1,499,196
Vermont State Housing Authority	VT	8,427
Archdiocesan Housing Authority	WA	105,422
Archdiocesan Housing Authority	WA	197,739
Auburn Youth Resources	WA	123,286
Bellingham Housing Authority	WA	222,552
Bellingham Housing Authority	WA	865,788
Benton & Franklin Counties Department of Human Services	WA	97,692
Benton Franklin Community Action Committee	WA	180,369
Benton Franklin Community Action Committee	WA	74,472
Benton Franklin Community Action Committee	WA	125,704
Benton Franklin Community Action Committee	WA	128,308
Blue Mountain Action Council	WA	142,724
Building Changes	WA	387,191
Catholic Community Services of Western Washington	WA	110,000
Catholic Community Services of Western Washington	WA	201,576

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Child Care Resources	WA	529,095
City of Bremerton	WA	40,368
City of Bremerton	WA	112,500
City of Bremerton	WA	50,952
City of Seattle Human Services Department	WA	168,153
City of Seattle Human Services Department	WA	470,753
City of Seattle Human Services Department	WA	79,906
City of Seattle Human Services Department	WA	320,463
City of Seattle Human Services Department	WA	294,978
City of Seattle Human Services Department	WA	470,754
City of Seattle Human Services Department	WA	57,278
City of Seattle Human Services Department	WA	105,000
City of Seattle Human Services Department	WA	696,732
City of Seattle Human Services Department	WA	545,049
City of Seattle Human Services Department	WA	121,545
City of Seattle Human Services Department	WA	507,350
City of Seattle Human Services Department	WA	25,422
City of Seattle Human Services Department	WA	181,306
City of Seattle Human Services Department	WA	838,688
City of Seattle Human Services Department	WA	80,012
City of Seattle Human Services Department	WA	492,048
City of Seattle Human Services Department	WA	586,377
City of Seattle Human Services Department	WA	279,551
City of Seattle Human Services Department	WA	139,650
City of Seattle Human Services Department	WA	27,395
City of Seattle Human Services Department	WA	1,129,355
City of Seattle Human Services Department	WA	462,500
City of Seattle Human Services Department	WA	326,054
City of Seattle Human Services Department	WA	183,540
City of Seattle Human Services Department	WA	548,598
City of Seattle Human Services Department	WA	114,450
City of Seattle Human Services Department	WA	443,471
City of Seattle Human Services Department	WA	81,370
City of Seattle Human Services Department	WA	116,397
City of Seattle Human Services Department	WA	517,251
City of Seattle Human Services Department	WA	30,000
City of Spokane	WA	88,698
City of Spokane	WA	111,989
City of Spokane	WA	106,003
City of Spokane	WA	131,649
City of Spokane	WA	394,236
City of Spokane	WA	118,908
City of Spokane	WA	14,917
City of Spokane	WA	89,932
City of Spokane	WA	67,164
City of Spokane	WA	77,175
City of Spokane	WA	38,215
City of Spokane	WA	154,128
City of Spokane	WA	85,723
City of Spokane	WA	51,424
City of Spokane	WA	27,739
City of Spokane	WA	68,635
City of Spokane	WA	42,621
City of Spokane	WA	280,581
City of Spokane	WA	187,365
City of Spokane	WA	106,082
City of Spokane	WA	27,799
City of Spokane	WA	169,687
City of Spokane	WA	44,028
City of Spokane	WA	86,880
City of Spokane	WA	56,251
City of Spokane	WA	167,591
City of Spokane	WA	38,802
City of Spokane	WA	116,892
Columbia Gorge Housing Authority	WA	36,828
Columbia River Mental Health Services	WA	52,909
Columbia River Mental Health Services	WA	123,064
Community Action Center	WA	19,152
Community Psychiatric Clinic	WA	75,171
Community Psychiatric Clinic	WA	348,156
Community Services Northwest	WA	91,700
Community Youth Services	WA	151,516

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Compass Health	WA	57,259
Compass Health	WA	41,393
Compass Health	WA	34,600
Compass Housing Alliance	WA	26,284
Council for the Homeless	WA	72,697
Development Association of Goodwill Baptist Church	WA	28,596
Development Association of Goodwill Baptist Church	WA	56,642
El Centro de la Raza	WA	17,603
Friends of Youth	WA	123,062
HopeSource	WA	46,346
Housing Authority City of Kelso	WA	90,468
Housing Authority of Island County	WA	37,848
Housing Authority of Snohomish County	WA	2,733,912
Housing Authority of the City of Bremerton	WA	136,450
Housing Authority of Thurston County	WA	133,921
Housing Hope	WA	80,315
Housing Hope	WA	29,828
Joint City of Republic-Ferry County Housing Authority	WA	36,316
Kent Youth and Family Services	WA	38,134
King County Department of Community and Human Services	WA	624,566
King County Department of Community and Human Services—Community Services Division	WA	63,258
King County Department of Community and Human Services—Community Services Division	WA	876,480
King County Department of Community and Human Services—Community Services Division	WA	251,744
King County Department of Community and Human Services—Community Services Division	WA	5,157,696
King County Department of Community and Human Services—Community Services Division	WA	99,739
King County Department of Community and Human Services—Community Services Division	WA	140,085
King County Department of Community and Human Services—Community Services Division	WA	363,168
King County Department of Community and Human Services—Community Services Division	WA	74,613
King County Department of Community and Human Services—Community Services Division	WA	303,975
King County Department of Community and Human Services—Community Services Division	WA	121,939
Lewis County	WA	108,814
Low Income Housing Institute	WA	31,500
Low Income Housing Institute	WA	36,141
Low Income Housing Institute	WA	398,285
Low Income Housing Institute	WA	56,085
Lower Columbia CAP	WA	30,219
Mason County Shelter	WA	98,299
Multi-Service Center	WA	26,724
Next Step Housing	WA	46,835
Northwest Youth Services	WA	261,785
Okanogan Behavioral HealthCare	WA	52,637
Olympic Community Action Programs	WA	135,599
Opportunity Council	WA	140,868
Opportunity Council	WA	218,879
Opportunity Council	WA	47,174
Opportunity Council	WA	84,130
Peninsula Housing Authority	WA	132,854
Seattle Housing Authority	WA	9,896
Second Step Housing	WA	164,101
Second Step Housing	WA	92,365
Second Step Housing	WA	25,526
Serenity House of Clallam County	WA	78,481
Serenity House of Clallam County	WA	142,951
Serenity House of Clallam County	WA	138,769
Share	WA	61,267
Share	WA	83,229
Share	WA	25,896
Share	WA	34,429
Skagit County Community Action	WA	50,054
Snohomish County	WA	161,634
Snohomish County	WA	109,270
Snohomish County	WA	180,671
Snohomish County	WA	164,820
Snohomish County	WA	23,609
Snohomish County	WA	124,476
Snohomish County	WA	43,636
Snohomish County	WA	58,203
Snohomish County	WA	70,369
Snohomish County	WA	87,585
Snohomish County	WA	75,435
Snohomish County	WA	81,523
Snohomish County	WA	175,513

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Snohomish County	WA	101,356
Snohomish County	WA	163,659
Snohomish County	WA	60,349
Snohomish County	WA	35,931
Solid Ground of Washington	WA	158,620
Spokane Neighborhood Action Programs	WA	134,839
Spokane Neighborhood Action Programs	WA	133,448
Sun Community Service	WA	36,013
Tacoma Housing Authority	WA	57,480
The Family Support Center of South Sound	WA	54,810
The Salvation Army—Hickman House	WA	77,838
The Salvation Army William Booth Center	WA	253,988
Triumph Treatment Services	WA	158,792
United Indians of All Tribes Foundation	WA	343,565
Vancouver Housing Authority	WA	135,696
Vietnam Veterans Leadership Program	WA	23,579
WA—503 Tacoma/Lakewood/Pierce County CoC	WA	45,150
WA—503 Tacoma/Lakewood/Pierce County CoC	WA	59,885
WA—503 Tacoma/Lakewood/Pierce County CoC	WA	167,339
WA—503 Tacoma/Lakewood/Pierce County CoC	WA	143,477
WA—503 Tacoma/Lakewood/Pierce County CoC	WA	34,701
WA—503 Tacoma/Lakewood/Pierce County CoC	WA	29,512
WA—503 Tacoma/Lakewood/Pierce County CoC	WA	162,335
WA—503 Tacoma/Lakewood/Pierce County CoC	WA	348,601
WA—503 Tacoma/Lakewood/Pierce County CoC	WA	66,539
WA—503 Tacoma/Lakewood/Pierce County CoC	WA	89,527
WA—503 Tacoma/Lakewood/Pierce County CoC	WA	34,106
WA—503 Tacoma/Lakewood/Pierce County CoC	WA	136,799
WA—503 Tacoma/Lakewood/Pierce County CoC	WA	542,485
WA—503 Tacoma/Lakewood/Pierce County CoC	WA	111,377
WA—503 Tacoma/Lakewood/Pierce County CoC	WA	173,616
WA—503 Tacoma/Lakewood/Pierce County CoC	WA	130,878
WA—503 Tacoma/Lakewood/Pierce County CoC	WA	32,444
WA—503 Tacoma/Lakewood/Pierce County CoC	WA	24,741
WA—503 Tacoma/Lakewood/Pierce County CoC	WA	89,040
WA—503 Tacoma/Lakewood/Pierce County CoC	WA	375,341
WA—503 Tacoma/Lakewood/Pierce County CoC	WA	165,201
WA—503 Tacoma/Lakewood/Pierce County CoC	WA	24,324
WA—503 Tacoma/Lakewood/Pierce County CoC	WA	36,902
WA—503 Tacoma/Lakewood/Pierce County CoC	WA	94,031
Walla Walla County	WA	66,101
Washington Gorge Action Programs	WA	109,986
Washington State Department of Commerce	WA	143,082
Womens Resource Center	WA	210,000
Womens Resource Center	WA	38,758
Yakima County	WA	10,815
Yakima County	WA	48,188
Yakima County	WA	69,191
Yakima County	WA	62,670
Yakima County	WA	43,109
Yakima County	WA	10,568
Yakima County	WA	30,306
YouthCare	WA	105,602
YouthCare	WA	151,856
YWCA of Kitsap County	WA	24,938
YWCA of Seattle-King County-Snohomish County	WA	29,683
YWCA of Seattle-King County-Snohomish County	WA	103,619
YWCA of Seattle-King County-Snohomish County	WA	167,867
YWCA of Seattle-King County-Snohomish County	WA	42,540
YWCA of Seattle-King County-Snohomish County	WA	85,614
YWCA of Seattle-King County-Snohomish County	WA	57,319
YWCA of Seattle-King County-Snohomish County	WA	78,878
YWCA of Seattle-King County-Snohomish County	WA	72,245
ADVOCAP, Inc	WI	110,216
ADVOCAP, Inc	WI	158,583
ADVOCAP, Inc	WI	197,658
CAP Services, Inc	WI	105,025
Catherine Marian Housing, Inc	WI	55,053
Center for Veterans Issues, Ltd	WI	132,021
Center for Veterans Issues, Ltd	WI	972,205
Center for Veterans Issues, Ltd	WI	415,911
Center for Veterans Issues, Ltd	WI	94,831

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Center for Veterans Issues, Ltd	WI	170,568
Central Wisconsin Community Action Council, Inc	WI	262,322
City of Appleton	WI	177,763
City of Appleton	WI	51,513
Community Action Coalition for South Central Wisconsin, Inc	WI	127,223
Community Action Coalition for South Central Wisconsin, Inc	WI	226,190
Community Action Coalition for South Central Wisconsin, Inc	WI	165,020
Community Action Inc of Rock and Walworth Counties	WI	517,583
Community Advocates, Inc	WI	403,631
Community Advocates, Inc	WI	428,544
Community Advocates, Inc	WI	693,053
Community Advocates, Inc	WI	120,514
Community Advocates, Inc	WI	318,388
Community Development Partners, Inc	WI	97,815
Community Development Partners, Inc	WI	126,721
Couleecap, Inc	WI	254,126
Couleecap, Inc	WI	366,316
Dane County, WI	WI	789,780
Family Services of Northeast Wisconsin	WI	159,800
Forward Service Corporation	WI	402,991
Grace Place Salvation Army	WI	241,495
Guest House of Milwaukee, Inc	WI	837,503
Guest House of Milwaukee, Inc	WI	235,625
Guest House of Milwaukee, Inc	WI	180,454
Guest House of Milwaukee, Inc	WI	196,230
Health Care for the Homeless of Milwaukee, Inc	WI	255,068
Health Care for the Homeless of Milwaukee, Inc	WI	450,454
Hebron House of Hospitality, Inc	WI	167,071
Hebron House of Hospitality, Inc	WI	116,535
Homeless Assistance Leadership Organization, Inc	WI	118,448
Homeless Assistance Leadership Organization, Inc	WI	304,934
Homeless Assistance Leadership Organization, Inc	WI	114,428
Homeless Assistance Leadership Organization, Inc	WI	152,028
Hope House of Milwaukee, Inc	WI	30,679
Hope House of Milwaukee, Inc	WI	65,514
Hope House of Milwaukee, Inc	WI	579,715
HOPES Center of Racine, Inc	WI	51,969
Housing Initiatives Inc	WI	11,659
Kenosha Human Development Services Inc	WI	126,651
Kenosha Human Development Services Inc	WI	141,095
Lakeshore CAP, Inc	WI	117,663
Legal Action of WI, Inc	WI	80,536
Legal Action of Wisconsin	WI	111,300
Legal Action of Wisconsin, Inc	WI	16,000
Meta House, Inc	WI	130,385
Meta House, Inc	WI	328,031
Meta House, Inc	WI	121,092
Milwaukee County of	WI	2,696,916
Milwaukee County of	WI	419,979
My Home Your Home, Inc	WI	183,547
NEWCAP, Inc	WI	184,347
North Central Community Action Program, Inc	WI	177,165
Northwest Wisconsin Community Services Agency Inc	WI	113,670
Northwest Wisconsin Community Services Agency Inc	WI	92,612
Porchlight, Inc	WI	62,194
Porchlight, Inc	WI	344,766
Porchlight, Inc	WI	50,768
Porchlight, Inc	WI	111,373
Porchlight, Inc	WI	61,820
Porchlight, Inc	WI	162,742
Racine Vocational Ministry	WI	28,941
Richard's Place	WI	112,555
Richard's Place	WI	144,841
SAFE Haven of Racine, Inc	WI	16,963
St. Aemilian-Lakeside, Inc	WI	167,828
St. Catherine Residence, Inc	WI	144,379
Starting Points, Inc	WI	117,400
Starting Points, Inc	WI	182,179
Starting Points, Inc	WI	509,525
State of Wisconsin	WI	238,908
State of Wisconsin	WI	364,486
SWCAP	WI	203,834

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Applicant name	State	Award amount
Tellurian UCAN, Inc	WI	64,575
Tellurian UCAN, Inc	WI	155,106
Tellurian UCAN, Inc	WI	66,415
Tellurian UCAN, Inc	WI	249,165
The Road Home Dane County	WI	54,995
The Road Home Dane County	WI	82,426
The Salvation Army	WI	152,129
The Salvation Army	WI	229,270
The Salvation Army	WI	42,500
The Salvation Army	WI	38,193
The Salvation Army	WI	31,473
WALKER'S POINT YOUTH AND FAMILY CENTER	WI	195,781
Walworth County Housing Authority	WI	69,486
West Central Wisconsin Community Action Agency, Inc	WI	434,523
Western Dairyland EOC, Inc	WI	264,926
Women and Children's Horizons Inc	WI	220,566
Women's Resource Center of Racine, Inc	WI	19,066
YWCA Greater Milwaukee	WI	116,549
YWCA of Madison, Inc	WI	375,095
YWCA of the Coulee Region	WI	73,322
Cabell-Huntington Coalition for the Homeless Projects	WV	92,378
Cabell-Huntington Coalition for the Homeless Projects	WV	211,811
Cabell-Huntington Coalition for the Homeless Projects	WV	130,846
Caritas House, Inc	WV	131,157
Charleston Housing—Kanawha Housing	WV	120,240
Charleston Housing—Kanawha Housing	WV	120,240
City of Charleston	WV	99,144
Clarksburg Housing Authority	WV	160,776
Community Action of South Eastern WV	WV	52,710
Community Networks, Inc	WV	241,380
Community Networks, Inc	WV	76,756
Covenant House	WV	109,500
Greenbrier County Housing Authority	WV	67,716
Greenbrier County Housing Authority	WV	51,983
Housing Authority of Mingo County	WV	81,220
Huntington WV Housing Authority	WV	59,880
Huntington WV Housing Authority	WV	37,495
Huntington WV Housing Authority	WV	38,274
Huntington WV Housing Authority	WV	329,376
Huntington WV Housing Authority	WV	23,952
Huntington WV Housing Authority	WV	59,880
Huntington WV Housing Authority	WV	322,260
Huntington WV Housing Authority	WV	91,560
Huntington WV Housing Authority	WV	29,940
Huntington WV Housing Authority	WV	378,720
Kanawha Valley Collective, Inc	WV	50,000
Kanawha Valley Collective, Inc	WV	13,999
Mid-Ohio Valley Fellowship Home, Inc	WV	9,838
North Central WV Community Action Association, Inc	WV	55,653
North Central WV Community Action Association, Inc	WV	55,582
Opportunity House, Inc	WV	50,281
Parkersburg Housing Authority	WV	143,400
Prestera Center for Mental Health Services	WV	137,466
Religious Coalition for Community Renewal	WV	72,513
Roark-Sullivan Lifeway Center	WV	250,071
Southwestern Community Action Council	WV	71,637
Stop Abusive Family Environments, Inc	WV	135,799
Telamon Corporation	WV	138,457
Telamon Corporation	WV	158,036
Telamon Corporation	WV	70,209
Telamon Corporation	WV	155,011
West Virginia Coalition to End Homelessness—Balance of State	WV	384,835
Westbrook Health Services, Inc	WV	42,174
Westbrook Health Services, Inc	WV	32,628
Westbrook Health Services, Inc	WV	139,194
Wheeling/Weirton Area CoC	WV	135,796
Wheeling/Weirton Area CoC	WV	250,272
Wheeling/Weirton Area CoC	WV	26,536
Wheeling/Weirton Area CoC	WV	11,200
Worthington Mental Health Services, Inc	WV	46,857
Young Women's Christian Association of Charleston, WV	WV	44,691
Young Women's Christian Association of Charleston, WV	WV	29,858

CONTINUUM OF CARE PROGRAM GRANT AWARDS FROM FY2011 NOTICE OF FUNDING AVAILABILITY—Continued

Applicant name	State	Award amount
Young Women's Christian Association of Charleston, WV	WV	62,697
YWCA of Charleston-Sojourner's Education/Job Readiness Center	WV	174,126
Community Action Partnership of Natrona County	WY	113,175
Council of Community Services	WY	61,016
Self Help Center Inc	WY	97,660
Wyoming Community Network	WY	66,666
Total		1,674,959,117

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